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IMPACT ASSESSMENT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

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{SWD(2017) 469 final} - {SWD(2017) 470 final}

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ANNEX 11: BACKGROUND INFORMATION ON OBJECTIVE 1 – REINFORCING MARKET SURVEILLANCE COOPERATION PROCEDURES

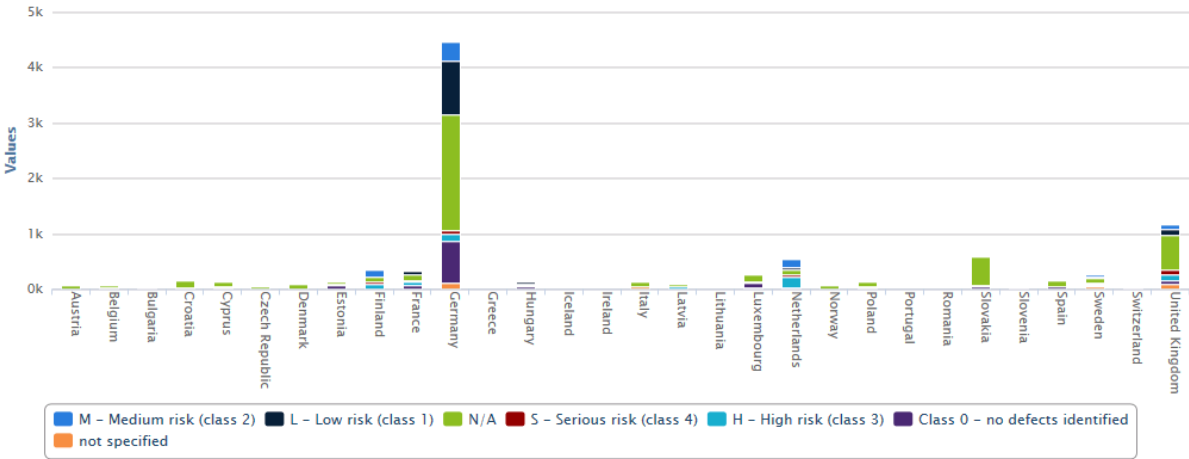
1. COORDINATION OF ENFORCEMENT OF PRODUCT LEGISLATION WITHIN THE EU (BASELINE)

The current section provides a short recollection of main legal, technical, administrative and financial tools currently available to optimise **cross-border cooperation and work sharing** among authorities.

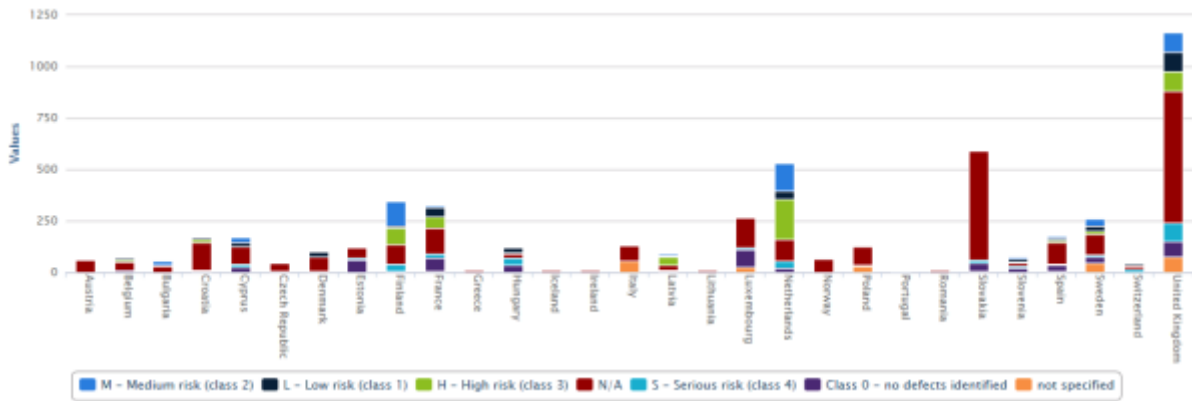
1.1. ICSMS

ICSMS (Information and Communication System for Market Surveillance) is the database for information concerning product compliance (ICSMS) referred to in Article 23 of Regulation (EC) No 765/2008. The Commission carries out continuous activities to facilitate the take up of the ICSMS system among authorities by means of trainings, the development of user guides and discussion in regular experts' groups meetings. More than 7 000 products are encoded in the system every year. In 2015 the database contained information on around 70 000 products and more than 250 000 files stored (i.e.: test lab reports, DoC, pictures, etc.). The Commission also examined the possibility of a convergence between ICSMS and RAPEX (see below).

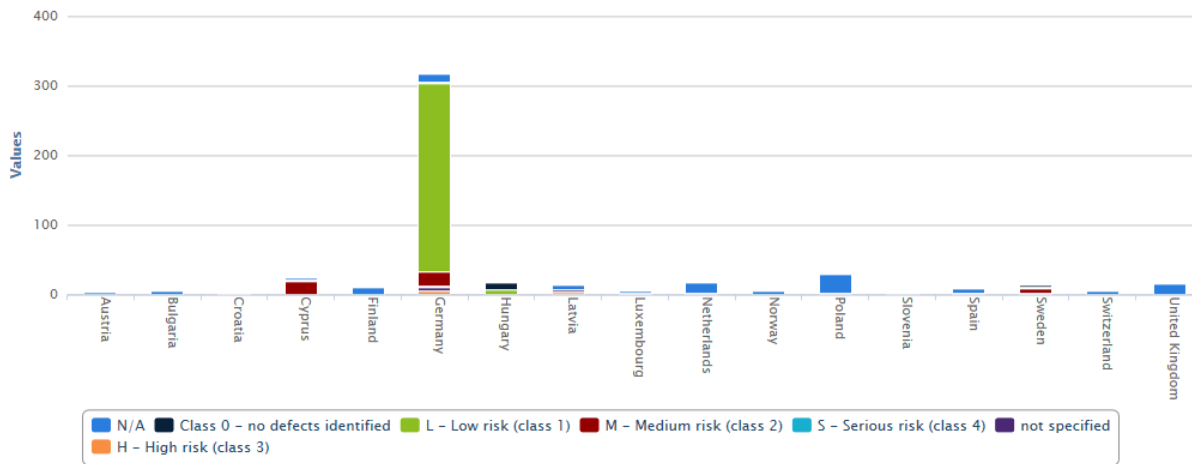
However, Member States use the system to different degrees, as shown in the diagrams below which show the numbers of product information input to the ICSMS system during 2016. Clearly the system is not used very well by many market surveillance authorities and some are not using the system at all. Even within member states, such as the UK and Germany, there is a great variance between different market surveillance authorities on their use of the system.



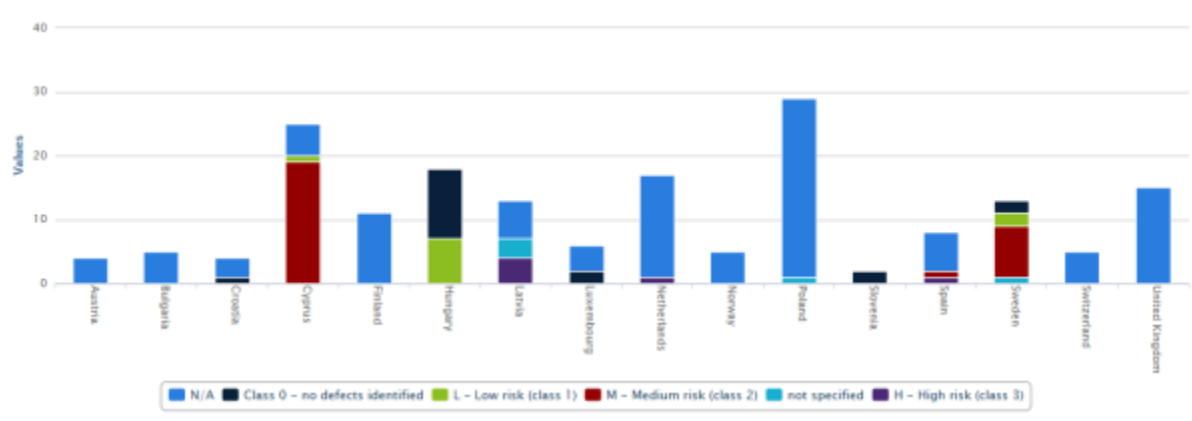
Use of ICSMS by all EU/EEA Member States in 2016 (2 with no entries)



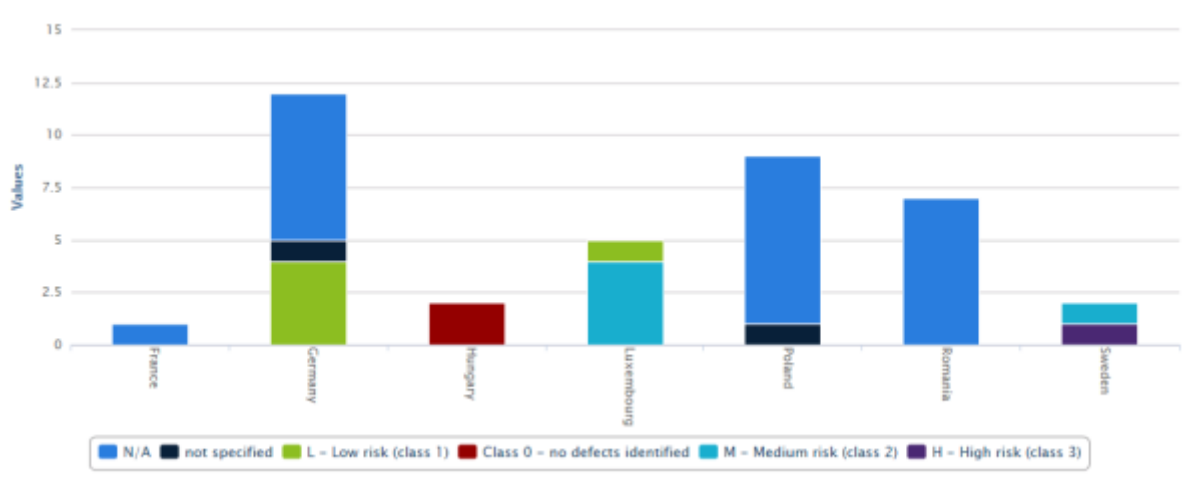
Use of ICSMS by EU/EEA Member States excluding Germany in 2016



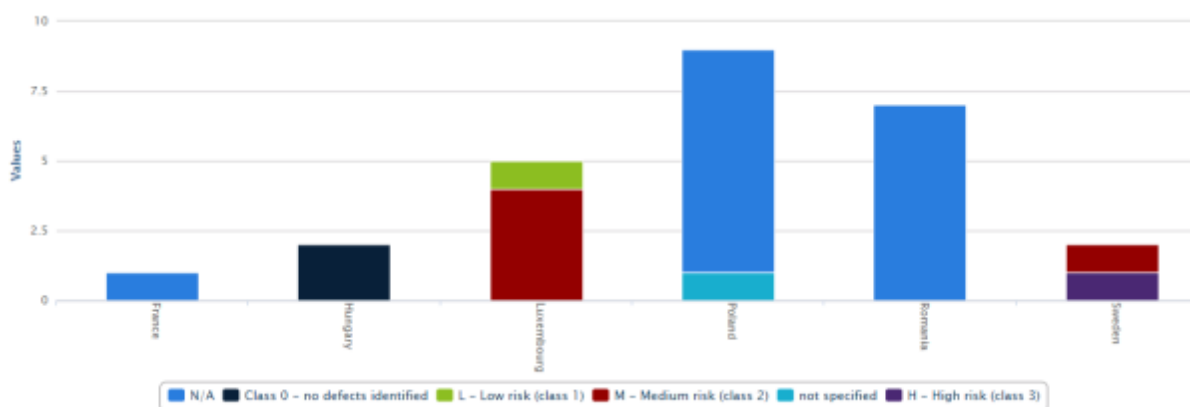
Use of ICSMS for EMC 2004 by all EU/EEA Member States in 2016 (15 with no entries)



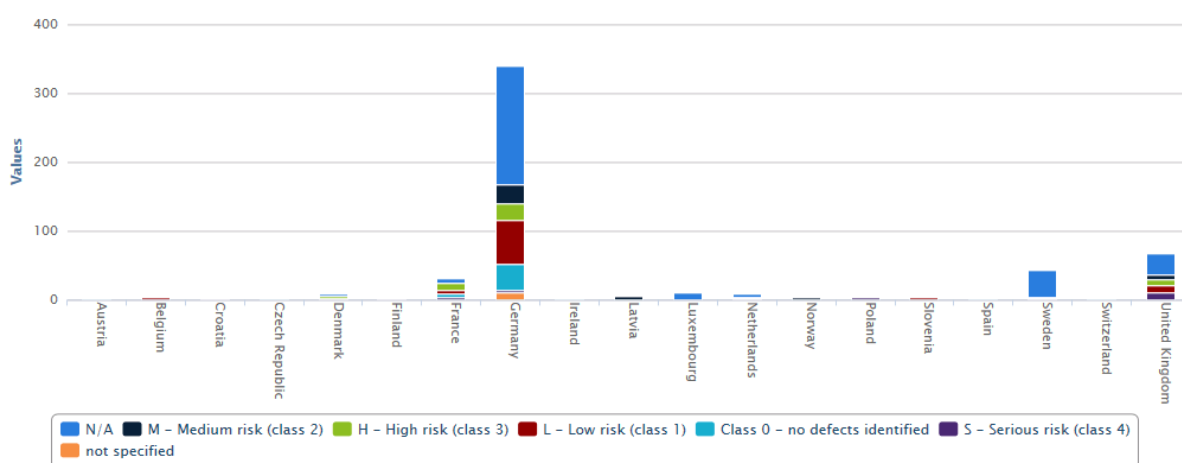
Use of ICSMS for EMC 2004 by EU/EEA Member States excluding Germany in 2016



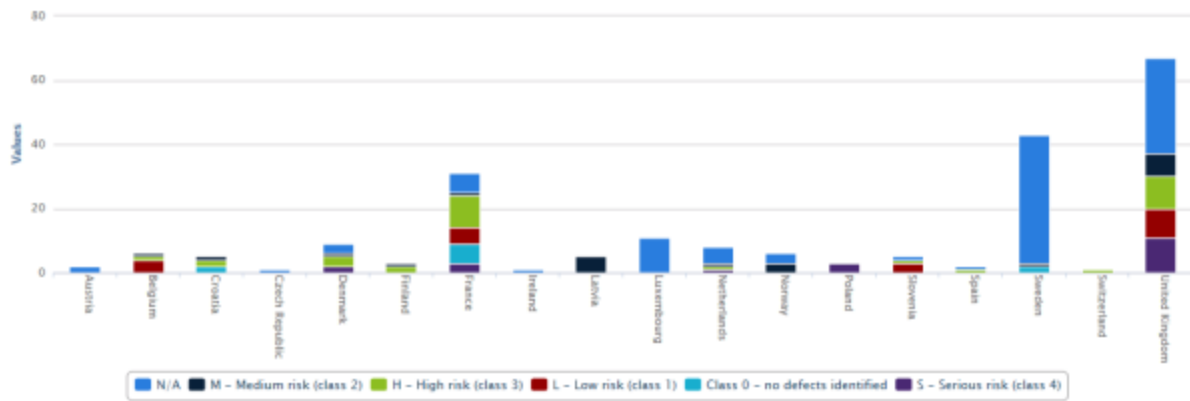
Use of ICSMS for EMC 2014 by all EU/EEA Member States in 2016 (25 with no entries)



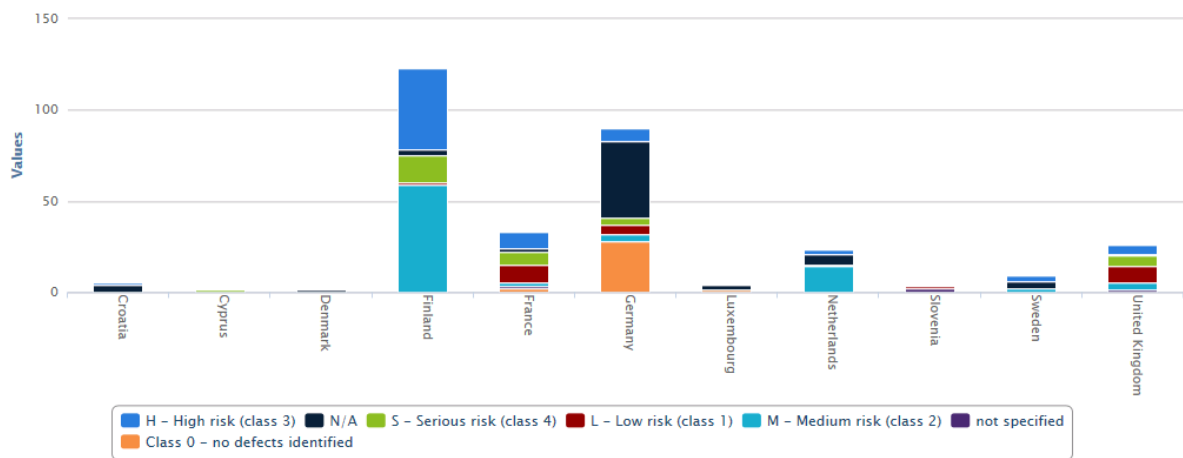
Use of ICSMS for EMC 2014 by EU/EEA Member States excluding Germany in 2016



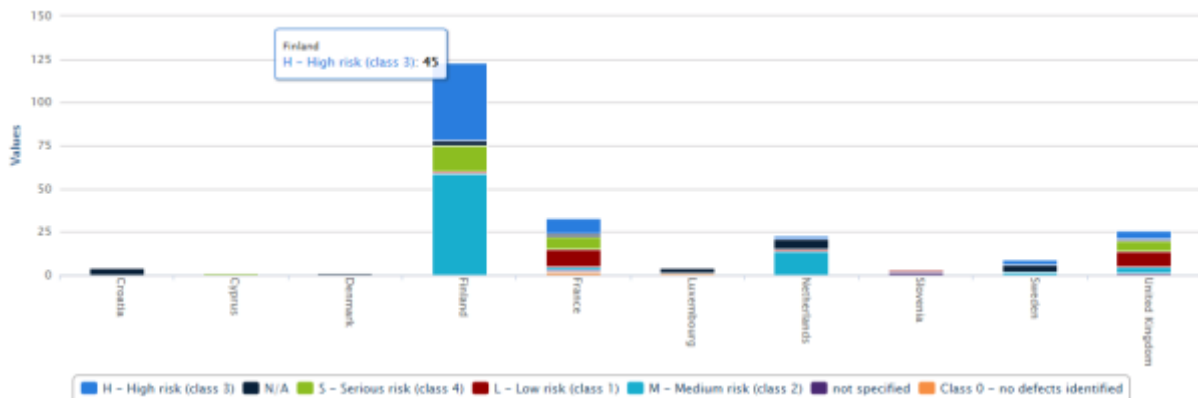
Use of ICSMS for Machinery by all EU/EEA Member States in 2016 (13 with no entries)



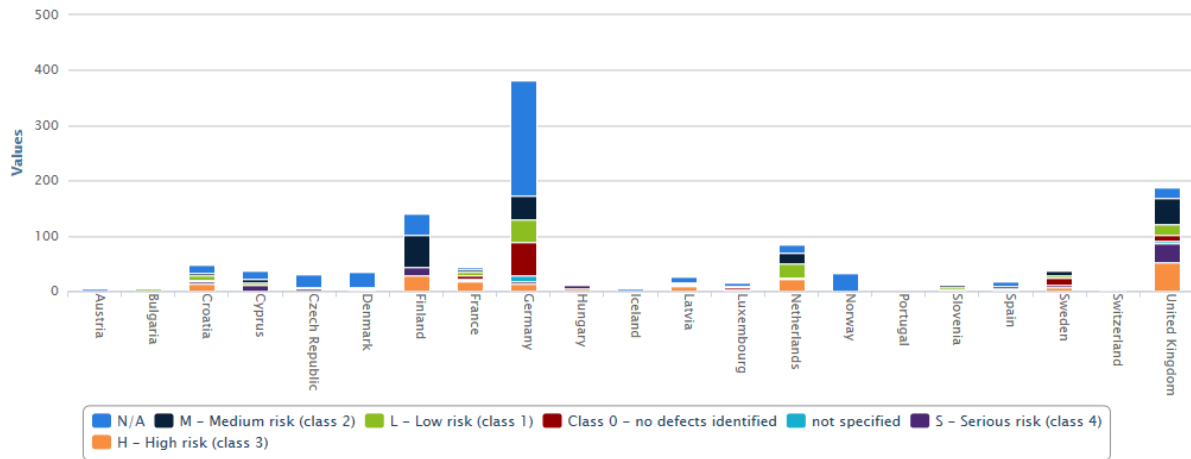
Use of ICSMS for Machinery by EU/EEA Member States excluding Germany in 2016



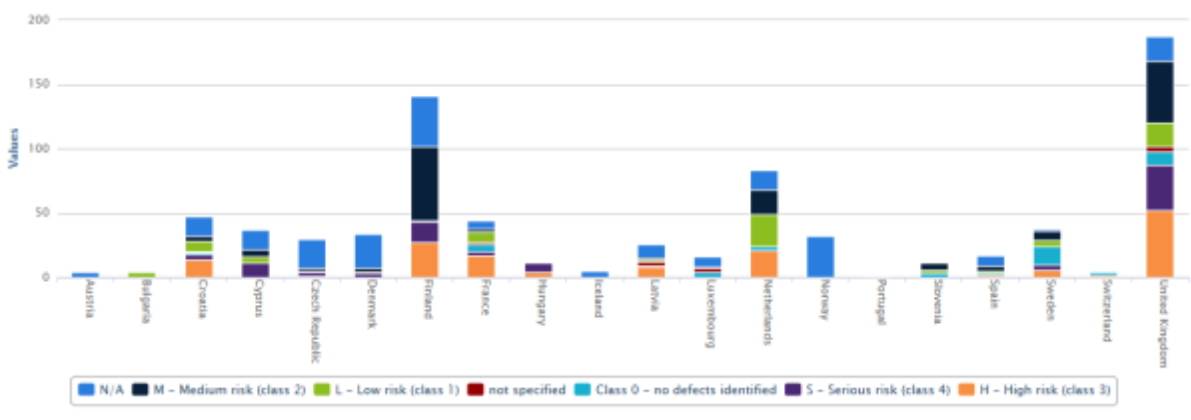
Use of ICSMS for LVD 2014 by all EU/EEA Member States in 2016 (21 with no entries)



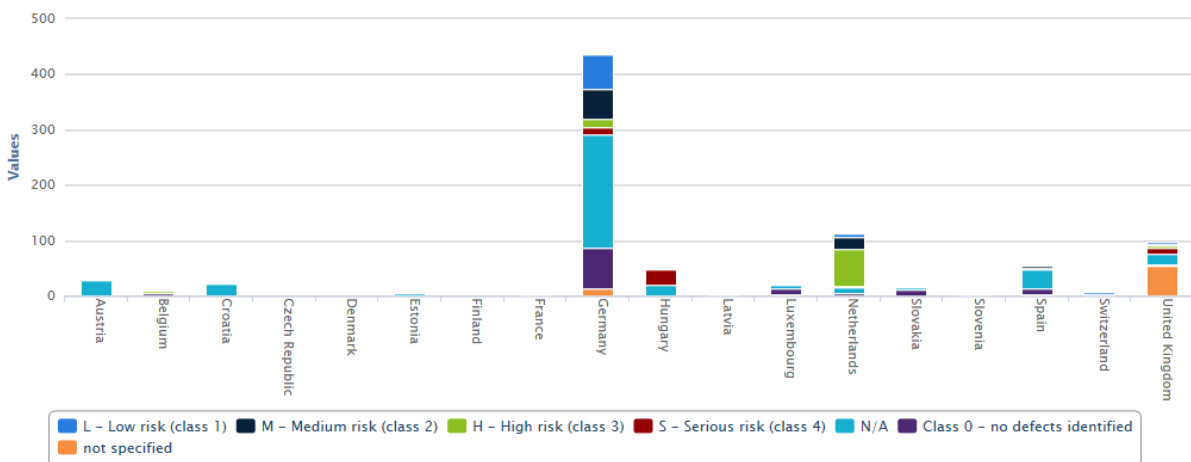
Use of ICSMS for LVD 2014 by EU/EEA Member States excluding Germany in 2016



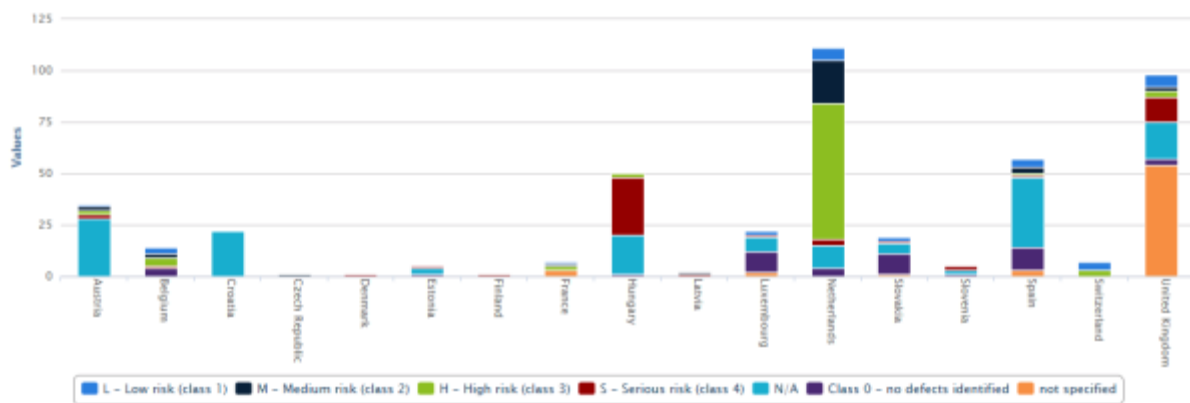
Use of ICSMS for LVD 2006 by all EU/EEA Member States in 2016 (11 with no entries)



Use of ICSMS for LVD 2006 by EU/EEA Member States excluding Germany in 2016



Use of ICSMS for GPSD by all EU/EEA Member States in 2016 (14 with no entries)



Use of ICSMS for GPSD by EU/EEA Member States excluding Germany in 2016

1.2. Official notification of measures to other Member States

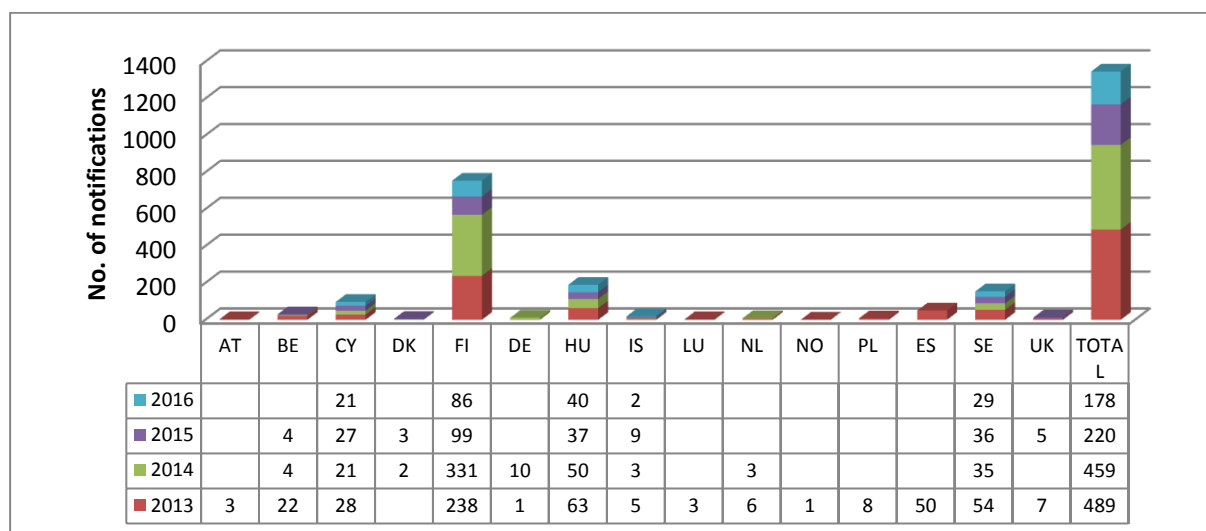
EU product legislation set out an obligation for Member States' competent authorities to communicate to the other Member States restrictive measures taken against non-compliant products. Furthermore, receiving Member States then have an obligation to 'follow up' on those notifications, i.e. adopt in turn appropriate measures in respect of their national territory. In many cases they also have the possibility to object to the measures notified and in this case the Commission will assess whether it was justified¹. Recent guidance discussed at expert's working group level clarifies principles for cooperation based on the existing legal framework². It also stresses the importance of this transmission mechanism to make sure that in relation to products available in various countries non-compliance found by a single authority could turn into effective corrective action across the whole Single Market.

However, with the exception of few sectors (notably low voltage equipment) only few notifications of restrictive measures are actually officially sent by national market surveillance authorities. Furthermore, even in these 'best case scenarios' sectors many Member States do not actually notify any measures and the number of notifications is decreasing overtime, as illustrated by the following figure.

1 The possibility of objections is set out in sector-specific legislation aligned to the reference provisions of Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

2 Guidance on cross-border cooperation among EU market surveillance authorities (<http://ec.europa.eu/DocsRoom/documents/17108/attachments/1/translations>).

Figure 11-1: State of play of notifications of measures addressing non-compliant products under the Low Voltage Directive



In May 2016 the Commission included in ICSMS an IT tool to allow the simultaneous notification of restrictive measures adopted by a national authority to all Member States, which should facilitate the actual use of the notification mechanism by those Member States. Nevertheless, considering the level of take up of ICSMS and other difficulties faced by authorities, this IT improvement will not be sufficient to address the problem of low notifications.

Finally, there is no official information on the degree of follow-up to the notifications received by authorities. However, this is expected to be rather low.

In case of products presenting a serious risk a notification in the RAPEX Rapid Alert System is also required³. Since 2004, more than 20 000 measures taken against dangerous products have been raised in the Rapid Alert System.⁴ During the 2010-2015 period Member States' authorities transmitted between 1 800 and 2 500 notifications per year. However the rate of response to each notification remains relatively small as for instance in 2015 each Member State reacted on average to 3% of notifications received.

Table 11-1: Notifications and reactions in RAPEX Rapid Alert System in 2015⁵

Country	Notifications		Reactions	
	Number	Percentage	Number	Percentage
Austria	17	0.82%	53	1.93%
Belgium	6	0.29%	29	1.06%
Bulgaria	151	7.25%	92	3.35%

3 Articles 20 and 22 of Regulation (EC) No 765/2008.

4 Source: RAPEX statistics and reports:

http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/index_en.htm

5 The figures reported represent an approximation as they disregard the fact that some of the reactions sent by Member States in 2015 relate to notifications filed in 2014 and vice versa some 2015 notifications received reactions in 2016.

Country	Notifications		Reactions	
	Number	Percentage	Number	Percentage
Croatia	7	0.34%	138	5.03%
Cyprus	117	5.62%	17	0.62%
Czech Republic	109	5.24%	18	0.66%
Denmark	27	1.30%	209	7.61%
Estonia	21	1.01%	32	1.17%
Finland	52	2.50%	179	6.52%
France	135	6.48%	105	3.83%
Germany	208	9.99%	85	3.10%
Greece	14	0.67%	108	3.93%
Hungary	238	11.43%	56	2.04%
Iceland	14	0.67%	26	0.95%
Ireland	5	0.24%	106	3.86%
Italy	56	2.69%	24	0.87%
Latvia	60	2.88%	15	0.55%
Liechtenstein	0	0.00%	0	0.00%
Lithuania	74	3.55%	25	0.91%
Luxembourg	9	0.43%	11	0.40%
Malta	25	1.20%	30	1.09%
Netherlands	62	2.98%	203	7.40%
Norway	15	0.72%	186	6.78%
Poland	19	0.91%	3	0.11%
Portugal	42	2.02%	153	5.57%
Romania	25	1.20%	10	0.36%
Slovakia	74	3.55%	89	3.24%
Slovenia	21	1.01%	132	4.81%
Spain	239	11.48%	319	11.62%
Sweden	78	3.75%	181	6.59%

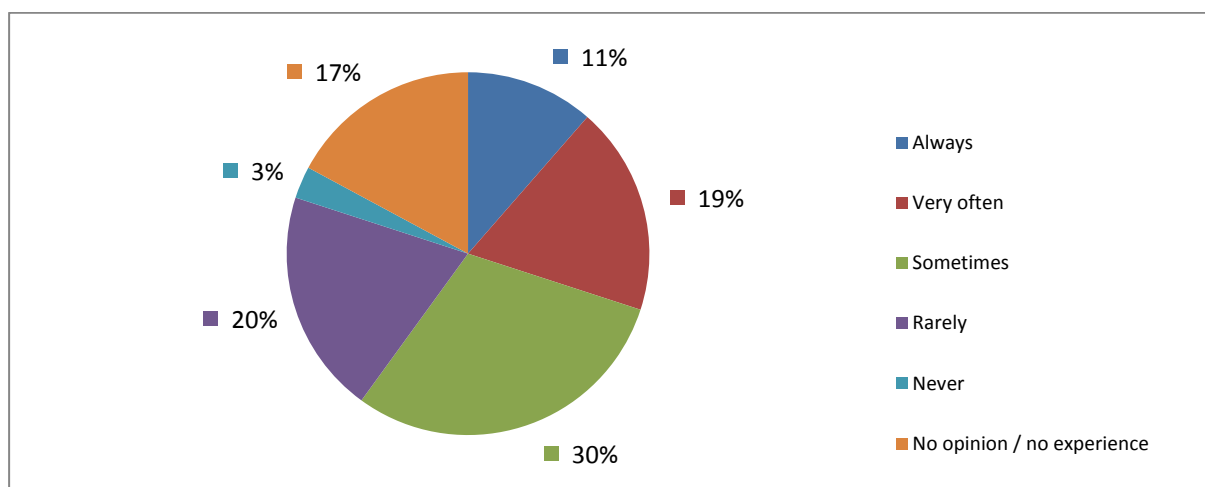
Country	Notifications		Reactions	
	Number	Percentage	Number	Percentage
United Kingdom	162	7.78%	111	4.04%
Average	67	3%	89	3%
Total	2082	100,00%	2745	100,00%

Source: Rapid Alert System 2015 results

http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/index_en.htm

While progress was achieved in the legal framework and the actual practice concerning the notification of measures among authorities, there is a feeling that a more systematic follow up of measures notified by other Member States should be achieved. When asked how often authorities measure to restrict the marketing of products are adopted following the exchange of information a good 30% of authorities responding to the consultation still replied this happens 'rarely' or 'never' or declared 'no experience' (see figure 11-2).

Figure 11-2: In your experience or knowledge in the relevant product category(-ies) how often do national authorities restrict the marketing of a product following the exchange of information about measures adopted by another authority in the EU against the same product?



1.3. Mutual assistance between Member States' authorities

The current legal framework⁶ makes possible mutual assistance among authorities in different Member States to supply each other with information or documentation and to carry out appropriate investigations or any other measure. The relevant provision does not provide any detail on the procedure (e.g. the means to be used, the language, the time to reply, etc.) to be followed to request and grant such assistance. Some guidance was recently developed on the applicable principles².

6 Article 24 of Regulation (EC) No 765/2008.

Although no structured information on requests for mutual assistance exists, informal feedback from national authorities experts involved in Administrative Cooperation Groups—see following section – indicate this happens only occasionally. Authorities able to produce figures mentioned in general less than 10 cases per year. An exception seems to be represented by the sector of medical devices where specific procedures have been gradually established and on average several⁷ requests of mutual assistance are made annually. In the majority of cases, information on the use of the mutual assistance principle confirms a general tendency among authorities to focus their action exclusively on correcting non-compliance in the national territory.

According to information in their 2010-2013 reports on market surveillance⁸, the practice of collaborating in inspections initiated by a specific Member States is virtually non-existent in most sectors. In the areas of cosmetics, machinery, electrical, electronic and radio equipment it is not completely absent but definitely still at an embryonic stage.

1.4. Administrative Cooperation Groups (AdCos)

In many sectors, cooperation between national administrations takes place in working groups set up under the Union harmonisation legislation. Discussions mainly focus on interpretation issues, but questions related to market surveillance and administrative cooperation are also dealt with.

The Expert Group on Internal Market for Products (IMP-MSG) deals with general policy questions related to the implementation and enforcement of Union harmonisation legislation at 'horizontal' level, i.e. without addressing issues arising in the particular sectors.

Cooperation between national administrations competent for carrying out market surveillance in specific sectors takes place by means of the so-called Administrative Cooperation groups (AdCos)⁹. It concerns a number of sectors.¹⁰ AdCos participants discuss several issues related to the market surveillance, elaborate common guidance documents and sometimes carry out joint enforcement actions. An overview of the most recent concrete outcomes of common discussion can be found on the AdCo webpage hosted by the European Commission.¹¹

Since 2013 the Commission provides logistical and financial support to the organisation of the groups' meetings. According to the feedback received from AdCo Chairs this support has proven beneficial to increase and stabilise the rate of participation of national authorities in the meetings. However not all Member states participate in administrative cooperation. During the 2014-2016 period for most AdCos (ATEX, CPR, EMC, LVD, MACHINE, PPE, PYROTECH, RCD, TOYS, WELMEC) about two thirds of Member States did take part in meetings (with a peak of 80% participation rate for the radio equipment group); however in others (GAD, LIFT, PED) only about 50% Member States participated in the meetings and in

7 The figure of 200 requests was mentioned during a meeting with national authorities.

8 See figures in Annex 9 Section 5.

9 https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en

10 Measuring instruments and non-automatic weighing instruments (WELMEC), low voltage equipment (LVD ADCO), Eco-Design ADCO Group, electromagnetic compatibility (EMC administrative cooperation), civil explosives (CIVEX), machinery, noise emissions by outdoor equipment (NOISE), medical devices (Vigilance Working Group and COEN – Compliance and Enforcement Group), construction products (CPR), PEMSAC (The Platform of European Market Surveillance Authorities for Cosmetics), Toy-ADCO (The Administrative Cooperation Group of toys), recreational craft (RCD), personal protective equipment (PPE), equipment for use in explosive atmospheres (ATEX), Radio and Telecommunications Terminal Equipment (RED), Cableways (CABLE), Energy Labelling and Eco-design (ENERLAB/ECOD), Gas Appliances (GAD), Lifts (LIFT), Marine Equipment (MED), Pressure equipment sector (PED/SVPD), Pyrotechnics (PYROTEC), Chemicals (REACH), Restriction of the use of certain hazardous substances (ROHS), Transportable Pressure Equipment (TPED), Labelling of tyres.

11 <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail&groupID=2798>

the case of CABLE, NOISE and TPED only about 30-40% of Member States were involved. Details on Member States participation are illustrated in Table 11-2. Furthermore, according to the feedback received by AdCo Chairs many representatives of the Member States participating in the meetings do not get actively involved in common discussions and activities.

As regards the chemical sector a role analogous to that of the AdCos is played by the Forum of the ECHA authority (<https://echa.europa.eu/about-us/who-we-are/enforcement-forum>). In this case the Forum is a body of ECHA and some ECHA fulfil the role of secretariat for the Forum. The participation of Member States in the meetings of the Forum is very high (90%).

Table 11-2: Data on participation in AdCos meetings

AdCo	2014				2015				2016 (1 st semester)			
	Partici- pants	Represented countries			Partici- pants	Represented countries			Partici- pants	Represented countries		
		MSs	Other	Total		MS s	Other	Total		MSs	Other	Total
ATEX	35	15	3	18	33	17	3	20	33	21	2	23
	33	17	3	20	33	17	2	19	33	14	2	16
CABLE	23	12	3	15	21	10	2	12	26	12	3	15
CIVEX	no data for 2014				30	20	1	21	October/November			
COEN	no data for 2014				no data for 2015				no data for 2016			
CPR	31	20	2	22	43	21	4	25	36	15	4	19
	46	23	3	26	44	25	2	27				
EMC	38	20	4	24	37	21	5	26	40	18	4	27
	36	19	4	23	34	22	4	26				
ENERLAB / ECOD	no data for 2014				32	22	1	23	43	21	1	22
	no data for 2014				34	18	3	21				
GAD	18	14	0	14	15	8	2	10	19	12	2	14
	14	11	0	11	16	11	2	13				
LIFT	25	12	3	15	24	14	3	17	25	17	2	19
	21	14	2	16								
LVD	31	15	4	19	32	20	4	24	36	17	4	21
	33	19	3	22	34	22	3	25				
	31	18	4	22								
MACHINE	32	17	3	20	33	20	3	23	38	20	4	24
	33	15	3	18	30	19	3	22				

NOISE	22	10	2	12	23	9	2	11	Meeting October 2016			
PED	22	13	3	16	25	15	4	19	24	15	4	19
	25	18	3	21	15	11	1	12				
PPE	44	21	4	25	39	19	4	23	39	20	5	25
	37	19	4	23	40	21	4	25				
PYROTEC	30	14	0	14	34	17	0	17	32	19	1	20
	30	15	0	15	34	19	0	19				
RCD	35	17	2	19	22	15	2	17	31	19	2	21
	33	16	3	19	30	19	1	20				
RED	23	12	2	14	41	25	4	28	41	23	2	25
	40	24	2	26	41	22	4	26	40	25	2	27
	39	19	4	23								
	44	22	3	25								
TOYS	no data for 2014				37	18	5	23	32	15	4	19
	no data for 2014				40	25	3	28				
TPED	12	9	0	9	23	12	1	13	21	8	3	11
	13	5	1	6								
WELMEC	no data for 2014				31	21	1	22	33	19	4	23
	no data for 2014				36	19	4	23				

As regards the development of common market surveillance projects, the following table summarises the joint actions carried out or launched within different AdCos during the 2013-2016 period and number of countries participating in the action

Table 11-3: Joint actions organised within AdCos and number of Member States (MS) participating¹²

AdCo ¹⁰	2013	2014	2015	2016
ATEX				
CABLE				
CIVEX				
COEN			Information and instructions on reprocessible products (12 MS)	Clinical data (7-8) Harmonising inspections (7-8 MS)
CPR	2012-2013: EPS (10 MS)	Smoke alarms (10 MS)	Windows (7 MS)	

¹² Most joint actions are indicated under the year during which they were launched, although projects lasted two or more years.

ECOD / ENERLAB / ROHS	ECOD: Lighting and chain lighting (10 MS) ROHS: Toys (8 MS) and Kitchen appliances (10 MS)	ROHS: Cheap products (10 MS)	ROHS: Cables/USB/others (6 MS)	ECOD: Defeat devices (4 MS) ENERLAB: Collecting inspection data methodologies (6 MS)
EMC	Switching power supplies (19 MS)	Solar inverters (14 MS)		
GAD				Gas appliances (8 MS)
LIFT				
LVD			LED Floodlights* (13 MS)	
MACHINE¹³	2012-2013: Log Splitters (about 8 MS) 2012-2015: Firewood Processors (about 7-8 MS) 2011-2015: Impact Post Drivers (3-4 MS)	Boom saws (3 MS)		Portable chain-saws and vehicle servicing lifts* (9-10 MS)
NOISE				
PED		Air receivers for compressors (2 MS)		
PPE				
PYROTEC				
REACH	1 big action/year involving all Member States. Additional pilot actions on a smaller scale			
RED		Mobile phone repeaters (14 MS)	Drones (18 MS)	
RCD			Small inflatable crafts (6 MS)	
TOYS				
TPED				
WELMEC WG5		Electric energy meters* (11)	Heat meters* (10)	

* project co-financed by the European Commission.

1.5. Joint actions co-financed by the European Commission

As mentioned in the point above ADCO sometimes organise joint market surveillance campaigns; in a few cases those actions have been financed by the European Commission on the basis of financing provisions included in the current legal framework¹⁴. In particular, the following calls for proposals were made since 2013:

13 Joint actions organised in previous periods were: NOMAD Survey of machinery instructions on noise information and noise declarations (original survey work 2007-2012) about 10 Member States participating; Pinspotters/Pinsetters (machines in 10 pin bowling alleys), mostly between 2008 and 2012, about 5 Member States participating; Skid-steer Loaders, 2010-2012, 2-3 Member States; Scissor Lifts, 2010-2012, 5-6 Member States; Wind Turbine access (provision of lifts in towers), 2010-2012, about 4-5 Member States.

14 Chapter V of Regulation (EC) No 765/2008.

- In 2013 the Commission launched the first call for proposals for joint enforcement actions under the multi-annual plan for market surveillance of products in the EU. The grant was awarded to project focussed specifically on active electrical energy meters and heat meters. The grant took the form of a 70% reimbursement by the Commission of the eligible costs of the action (amount approximately allocated 350 000 EUR) and was fully managed by Member States. The action was carried out by a consortium of authorities under the coordination of a Spanish authority.
- In 2014 a new call for proposals for joint enforcement actions was launched and led to funding by the Commission of two proposed actions respectively the field of machinery safety and LED floodlights. The grants that have been awarded are in the form an 80% reimbursement by the Commission of the eligible costs of the actions (total amount allocated is approximately 1000 000 EUR). One of the actions was coordinated by a Finish authority, while the other was coordinated by the private company "Prosafe"¹⁵.
- In July 2015 a call for proposals was launched with a maximum budget foreseen for EU financing of 500 000 EUR. One proposal was received by the deadline of 1 October 2015 but did not lead to the award of any grant since the proposal received did not address the objectives as stipulated in the call.
- In March 2016 a call for proposals was launched with a higher maximum budget foreseen for EU financing of 750 000 EUR to maximum 3 projects coupled with a maximum EU financing rate of eligible costs of up to 80% of the action for joint actions involving bodies from 10 or more EU-EEA Member States, and 50% involving bodies from less than 10 EU-EEA Member States. No proposal was received by the deadline of 9 June of this year.
- In July 2016 a further call for proposals was launched. The maximum budget of 540 000 EUR was set with maximum financing rates of 95% and 80% respectively. For this call no proposal was received by the deadline for submission of 30 September 2016.

When discussing with market surveillance authorities the reasons why three calls for proposals went void why authorities do complain about limited resources, authorities stressed they welcomed the principle of joint actions financed through grants, and also their outcomes. However they pointed out the administrative complexity of managing these projects (e.g. heavy administrative requirements, problems in coordinating work by partners in other Member State authorities, and taking financial commitments on their behalf). They pointed out that the Commission should offer an administrative framework for the management of these actions and of the available money - money is not enough if it is not accompanied by some sort of infrastructure to allow for the management of the project.¹⁶

Furthermore, joint actions are regularly financed by the Commission under the Consumer Programme¹⁷. The following table summarises those carried out or launched during the 2013-2016 period. The projects financed under the Consumer Programme have always been coordinated by Prosafe.

15 <http://www.prosafe.org/about-us/contentall-comcontent-views/what-is-prosafe>

16 <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=28611&no=1>

17 http://ec.europa.eu/consumers/eu_consumer_policy/financial-programme/index_en.htm

Table 11-4: Joint actions financed under the Consumer Programme

	Member States + EFTA countries	Authorities		Product categories	Budget (in M€)	Grant (70%) (in M€)	Workdays
JA2010	21	23	5	Food imitation child-appealing products Children's Fancy Dresses (chemicals in textiles) Laser Pointers Ladders Visibility Clothing & Accessories	2.03	1.42	3462
JA2011	19	28	4	Child Care Articles Fireworks Battery chargers Lawnmowers	2.49	1.69	3995
JA2012	24	31	5	Nanotechnology and Cosmetics Childcare Articles- Highchairs, Cords and Drawstrings, Ladders, CO and smoke detectors)	2.14	1.48	3169
JA2013	21	25	5	Toys Children's Kick Scooters Childcare Articles- Cots, Chemicals risks in Clothing, Smoke Detectors	2.27	1.59	3664
JA2014	27	35	5	Noisy toys Fireworks Power tools CFL and LED Lighting Childcare Articles - Safety Barriers	2.87	1.99	4410
JA2015	26	35	5	Plasticised Toys Power Tools Electrical Appliances (incl. electric irons) Child Care Articles- Soothers and soother- holders; Playgrounds	3.12	2.18	243.35 person / month

The Commission has also financed the following initiatives under the Horizon2020 programme:

- ECOPLIANT¹⁸ – joint action in the area of ecodesign legislation (many products covered) running from 2012 to 2015 and involving 10 Member States; cost of the project: approximately € 2.4 mln; grant by the European Commission: € 1.8 mln under the Intelligent Energy Europe program.

18 <http://www.ecopliant.eu/wp-content/uploads/2012/10/Final-Publishable-Report.pdf>

- EEPLIANT¹⁹ – joint action in the area of ecodesign and energy labelling (heaters, LED lamps, printers): 2015-2017, 13 authorities from 12 MS- cost of the project: approximately € 2.5 mln entirely funded by the European Commission under the Horizon 2020 programme.
- INTAS (ecodesign, power transformers and large fans): 2016-2019, not a traditional joint action as about half of the 12 participants are not surveillance authorities, but energy agencies, research institutes, consultancies and civil society organisations cost of the project: approximately € 1.9 mln entirely funded by the European Commission under the Horizon 2020 programme.
- MsTyr15²⁰ joint action concerning tyre labelling launched in March 2016 (until February 2018) with 13 MS plus Turkey- cost of the project: approximately € 2 mln entirely funded by the European Commission under the Horizon 2020 programme.

The ECOPLIANT was successfully coordinated by a UK authority, however it revealed an important administrative burden for them. For the EEPLIANT and Ms Tyr15 projects the coordination was ensured by Prosafe. INTAS which does not constitute an enforcement activity is coordinated by an organisation with experience in managing projects from EU funds.

1.6. Views of market surveillance experts on cross-border cooperation

In the context of the consultation of market surveillance experts carried out within the IMP-MSG expert group prior to the 1 February 2016 meeting Member States expressed their views on the problems affecting cross-border cooperation and the possible solutions. The following excerpt is taken out of document 2016-IMP-MSG-07rev01 (section 4.3.3) summarising the results of this consultation:

*[Member State A] underlines the need for consistent implementation of the **guidelines on cross-border-cooperation**, complemented if necessary by the set-up of additional legal arrangements. Furthermore, under the **safeguard clause procedure** all European market surveillance authorities must take, where necessary, measures to enforce requirements under European law. [Member State A] also suggests that where a public authority prohibits the making available on the national market, this should **automatically apply in all MS**, with the ECJ possibly acting as appeal. Member States should reflect on the possibility of **specialising in specific fields**. In order to achieve an effective market surveillance system, the adaptation of **national legislation** to the EU legislation will be necessary in a number of areas (cross-border cooperation, mutual recognition of activities of the market surveillance authorities of other Member States - for example, recognition of test reports, etc.). The **organisation** of market surveillance **at national level** should be reconsidered in order to reduce the fragmentation of responsibilities.*

*[Member State B] stresses the need for **guidance on cross-border cooperation** to improve and optimize the results of authorities' actions. According to [Member State B], to achieve better results in trans-border cooperation between the Member States, in cases of non-compliant products a **contact points list for each product group** should be prepared which could provide fast and easily accessible communication.*

19 <http://www.eepliant.eu>

20 <http://www.mstyr15.eu/index.php/en/>

*According to [Member State C], a **mandatory harmonized procedure for MSA cooperation** will facilitate cases of cross-border cooperation and will further harmonize existing market surveillance approaches. The administrative burden for MSAs of this procedure should nevertheless be as minimal as possible.*

*[Member State D] stresses that prior to setting additional requirements for mutual change of information, the Commission should ensure that all Member States **actively use the present procedures** and notes that for example EMC and LVD notifications are made by only a few States.*

*[Member State E] would find it useful to receive **more feedback on safeguard notifications**. In general, more cooperation and exchange of information is needed at EU and **national level**.*

*[Member State F] notes that '**language borders**' are the main obstacle to day-to-day cooperation among authorities.*

2. PRODUCTS IMPORTED FROM THIRD COUNTRIES (BASELINE)

Points of entry to the EU are relevant to stop non-compliant and unsafe products coming in from third countries. Being the place where all products from third countries have to pass by, they are the ideal place to stop unsafe and non-compliant products before they are released for free circulation and subsequently circulate freely within the European Union. Thus, customs have an important role in supporting market surveillance authorities in carrying out product safety and compliance controls at the external borders.

The most effective way to avoid making available non-conforming or unsafe goods imported from third countries in the Union market is to carry out adequate checks during the import control process. This requires involvement of customs and cooperation between customs and market surveillance authorities.

The authorities in charge of the control of products entering the Union market, customs or market surveillance authorities depending on the national organisational structure, are very well placed to carry out initial checks, at the first point of entry, on the safety and compliance of the imported products. There are specific guidelines for import controls in the area of product safety and compliance. To ensure such controls, the authorities in charge of controls of products at the external borders need an appropriate technical support in order to carry out the checks on the characteristics of the products on an adequate scale. They can perform documentary, physical or laboratory checks. They also need appropriate human and financial resources.

2.1. The control procedure laid out in Regulation (EC) No 765/2008

Regulation (EC) No 765/2008 on checks for conformity with Union harmonisation legislation in the case of products imported from third countries requires the customs authorities to be closely involved in the market surveillance activities and information systems provided for under EU and national rules. Article 27(2) of Regulation (EC) No 765/2008 foresees the obligation for cooperation between customs officers and market surveillance officers. Obligations for cooperation are also included in Article 13 of the Community Customs Code which establishes that controls performed with customs and other authorities are undertaken in close cooperation between each other. In addition, the principles of cooperation between

the Member States and the Commission established in Article 24 of the Regulation are extended to authorities in charge of external controls, when relevant (Article 27(5)).

Cooperation at national level should allow for a common approach taken by customs and market surveillance authorities during the control process. This should not be hampered by the fact that various ministries and authorities may be responsible for the implementation of Regulation (EC) No 765/2008.

Customs authorities have the following responsibilities under Regulation (EC) No 765/2008:

- to suspend the release of products when there is a suspicion that the products present a serious risk to health, safety, environment or other public interest and/or do not fulfil documentation and marking requirements and/or the CE marking has been affixed in a false or misleading manner (Article 27(3)),
- not to authorise the release for free circulation for the reasons mentioned in Article 29,
- to authorise the release for free circulation for any product in compliance with the relevant Union harmonisation legislation and/or not presenting risks to any public interest,
- where the release for free circulation has been suspended, customs have to immediately notify the competent national market surveillance authority which is given 3 working days to perform a preliminary investigation of the products and to decide:
- if they can be released since they do not present a serious risk to the health and safety or cannot be regarded as being in breach of Union harmonisation legislation,
- if they must be detained since further checks are necessary to ascertain their safety and conformity.

Customs authorities must notify their decisions to suspend release of a product to the market surveillance authorities, which in turn must be in a position to take appropriate action. Four hypotheses must be distinguished as from the moment of the notification.

1. The products in question present a serious risk

If the market surveillance authority ascertains that the products present a serious risk, it must prohibit their placing on the EU market. The market surveillance authorities have to request the customs authorities to mark the commercial invoice accompanying the product, and any other relevant accompanying document, with the words 'Dangerous product — release for free circulation not authorised — Regulation (EC) No 765/2008'. Member State authorities may also decide to destroy the products or otherwise render them inoperable, where they deem it necessary and proportionate. The market surveillance authority must use in those cases the system for rapid exchange of information — RAPEX. As a consequence, market surveillance authorities in all Member States are informed, and they may in turn inform the national customs authorities about products imported from third countries, which display characteristics giving rise to a serious doubt as to the existence of a serious risk. This information is of particular importance for customs authorities where it involves measures banning or withdrawing from the market products imported from third countries.

Feedback from market surveillance authorities on whether goods are considered as unsafe or non-compliant is crucial for customs risk management and control processes. It ensures controls can be concentrated on risky consignments, allowing for the facilitation of legitimate trade.

Furthermore, when non-compliant or unsafe products are found in the internal market, it is often extremely difficult to identify how they entered the EU. Cooperation between customs and market surveillance authorities is encouraged to improve tracing in those cases.

2. The products in question do not comply with Union harmonisation legislation

In this case the market surveillance authorities must take appropriate measures, if necessary prohibiting the placing on the market under the rules in question. In cases where placing on the market is prohibited, they must ask the customs authorities to mark the commercial invoice accompanying the products, and any other relevant accompanying document, with ‘Product not in conformity — release for free circulation not authorised — Regulation (EC) No 765/2008’.

3. The products in question do not present a serious risk and cannot be considered as not conforming to the Union harmonisation legislation. In this case the products must be released for free circulation, provided that all the other conditions and formalities regarding release for free circulation are met.

4. The customs authorities have not been notified of any action taken by the market surveillance authorities.

If, within 3 working days of the suspension of release for free circulation, the market surveillance authority has not notified customs of any action taken by them, the product has to be released for free circulation provided that all the other requirements and formalities pertaining to such release have been fulfilled.

The entire procedure from the suspension until the release for free circulation or its prohibition by customs should be completed without delay to avoid creating barriers for legitimate trade but does not necessarily have to be completed within 3 working days. The suspension of release can remain valid for the time required by the market surveillance authority to carry out appropriate checks on the products and allow them to take the final decision. Market surveillance authorities must ensure that the free movement of products is not restricted to any extent greater than that which is allowed under Union harmonisation legislation or any other relevant EU legislation. To that end market surveillance authorities perform their activities regarding products originating from third countries — including the interaction with the relevant economic operators — with the same urgency and methodologies as for products originating from within the EU.

In this case, the market surveillance authority notifies customs within these 3 working days that their final decision on the goods is pending. The release for free circulation has to remain suspended until the market surveillance authority has made a final decision. That notification empowers customs to extend the initial suspension period. The products will remain under customs supervision even if they are allowed to be stored at another place approved by customs.

2.2. Cooperation and coordination of action among Customs

2.2.1. Administrative assistance

Customs cooperation based on the UCC enables exchanging information among customs to ensure correct application of the customs legislation and customs rules as well as creating a level playing field for business operators.

In 2015, almost 2 000 requests for administrative assistance were sent within the EU. There is an upward trend linked to cooperation in the form of administrative assistance between individual customs administrations.

2.2.2. The Customs Risk Management Framework (CRMF)

A sophisticated common customs risk management framework (CRMF) had been introduced into the previous customs legislation and is now covered by Article 46 UCC.

The CRMF is based on the recognition of a need to establish an equivalent level of protection in customs controls for goods brought into or out of the EU and to ensure a harmonised application of customs controls by the MS. It aims to support a common approach so that priorities are set effectively and resources are allocated efficiently with the aim of maintaining a proper balance between customs controls and the facilitation of legitimate trade.

The CRMF therefore comprises:

- the identification and control of high-risk goods movements using **common risk criteria** - see section 2.2.2.1.;
- the identification of **priority control areas** subject to more intense controls for a specific period; - see section 2.2.2.2.;
- systematic and intensive **exchange of risk information** between customs- see section 2.2.2.3.;
- the contribution of **Authorised Economic Operators** (AEO) in a customs-trade partnership to securing and facilitating legitimate trade; and
- **pre-arrival/pre-departure security risk analysis** based on cargo information submitted electronically by traders prior to arrival or departure of goods in/from the EU **specifically to cater primarily for security and safety risks.**

2.2.2.1. The common risk criteria and standards

The Commission has adopted a set of criteria to be applied in the Member States' risk analysis systems in order to continuously screen electronic advance cargo information for security and safety purposes. The criteria are set out in an implementing act based on the empowerment of Article 50(1) UCC, which is not public for obvious reasons. The CRC are aimed primarily towards identifying high-risk consignments/goods that could have serious implications for the security and safety of the EU and its citizens and providing equivalent protection throughout the external frontier based on common risk analysis.

While in all other types of movements, the customs office where goods and declaration are presented is responsible for the processing of the declaration and for the risk analysis, customs at the first point of EU entry has a legal obligation to carry out the security and safety risk analysis on all the cargo regardless of the country of EU destination. Consignments crossing the EU border are thus screened on the basis of those criteria 365 days a year.

2.2.2.2. Priority Control Areas

Priority Control Areas (PCAs) are the key mechanism in the CRMF allowing the Union to designate specific areas to be treated as a priority for customs control. The identified areas are subjected to reinforced customs controls carried out in a co-ordinated manner based on common risk assessment criteria and real-time exchange of risk information.

Priority areas may relate to any customs procedure, types of goods, traffic routes, modes of transport or economic operators. The chosen areas are to be subject to increased levels of risk analysis and customs controls for a pre-determined limited period with a start and end date and possibility for interim review.

Priority control areas have built-in assessment procedures and flexibility for Member States in order to ensure that the control action to be taken is not disproportionate or unduly disruptive in terms of the effect on trade flows within a Member State or a particular port or frontier point.

2.2.2.3. The exchange of risk information

The Common Customs Risk Management System (CRMS) is designed to provide a fast and easy-to-use mechanism to distribute and exchange customs control and risk-related information directly amongst operational officials and risk analysis centres in the 28 Member States.

It facilitates EU-wide customs intervention for the highest risks at the external frontier and inland and is thus an integral element in the development of a Union risk management framework. It consists of a form (Risk Information Form, called RIF) to be filled in on-line and instantly made available to all customs offices connected.

The RIF is a means of ensuring a consistent level of customs control is applied at the external frontier of the Union in relation to identified risks thereby offering the necessary level of protection to citizens and to the financial interests of the EU and MS while ensuring equivalent treatment of traders throughout the Union.

2.2.2.4. Authorised Economic Operators

The AEO concept is based on the Customs-to-Business partnership introduced by the World Customs Organisation (WCO). Traders who voluntarily meet a wide range of criteria work in close cooperation with customs authorities to assure the common objective of supply chain security and are entitled to enjoy benefits throughout the EU.

The EU established its AEO concept based on the internationally recognised standards, creating a legal basis for it in 2008 through the 'security amendments' to the "Community Customs Code" (CCC) ([Regulation \(EC\) 648/2005](#)) and its implementing provisions.

The programme, which aims to enhance international supply chain security and to facilitate legitimate trade, is open to all supply chain actors. It covers economic operators authorised for customs simplification (AEOC), security and safety (AEOS) or a combination of the two.

On the basis of Article 39 of the Union Customs Code (UCC), the AEO status can be granted to any economic operator meeting the following common criteria:

Conditions and criteria	AEOC	AEOS
Compliance with customs legislation and taxation rules and absence of criminal offences related to the economic activity.	X	X
Appropriate record keeping.	X	X
Financial solvency.	X	X
Proven practical standards of competence or professional qualifications.	X	
Appropriate security and safety measures.		X

The AEO status granted by one Member State is recognised by the customs authorities in all Member States (Article 38 (4) UCC). The conditions and criteria to grant the status do not take explicitly into account the economic operators' compliance with EU product harmonisation legislation.

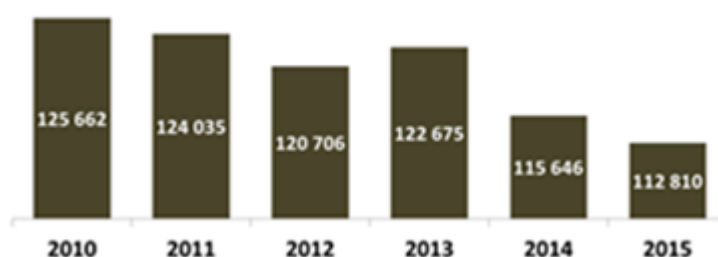
AEO benefits are an integral part of the EU legislation governing the AEO status. The AEO benefits, dependent on the type of the authorisation, are summarised in the table below:

Benefit	AEOC	AEOS
Easier admittance to customs simplifications	X	
Fewer physical and document-based controls <ul style="list-style-type: none"> • related to security & safety • related to other customs legislation 	X	X
Prior notification in case of selection for physical control (related to safety and security)		X
Prior notification in case of selection for customs control (related to other customs legislation)	X	
Priority treatment if selected for control	X	X
Possibility to request a specific place for customs controls	X	X
Indirect benefits (Recognition as a secure and safe business partner, Improved relations with Customs and other government authorities; Reduced theft and losses; Fewer delayed shipments; Improved planning; Improved customer service; Improved customer loyalty; Lower inspection costs of suppliers and increased co-operation etc.)	X	X

Benefit	AEOC	AEOS
Mutual Recognition with third countries		X

2.2.2.5. Customs resources

Customs face a significant challenge to manage increasing volumes of goods and tasks while facing a downward trend in resources²¹. The total number of personnel working in Customs Administrations in EU was 112.8 thousand at the end of 2015, this is a 10% decline since 2010 and a reduction of 2% in comparison to 2014.



**When interpreting these figures, it should be taken into consideration that not all the MS are able to provide the exact data on the allocation of their staff. This could be due to merged organisations where the customs are mixed together with tax administrations, etc. In such cases, data was only estimated by the MS.*

3. RESOURCES AND EXPERTISE OF AUTHORITIES (BASELINE)

EU rules on market surveillance for products contain an obligation for Member States to entrust market surveillance authorities with the power, resources and knowledge necessary for the proper performance of their tasks. No definition is provided for the concept of 'proper performance' of the tasks of market surveillance authorities. The provision does not set out an obligation to indicate the desirable level of performance or the amount of resources allocated. Common rules simply specify that authorities' should perform 'checks on the characteristics of products on an adequate scale'. In order to increase transparency on available resources the Commission in collaboration with Member States has proposed specific market surveillance indicators concerning budget and staff and developed methodology to estimate them.

3.1. Information on resources based on national reports for the 2010-2013

The analysis²² of the information on budget and staff provided by the member states for the 2010- 2013 period allowed the identification of the following findings:

- The total **budget available to MSAs** in nominal terms at EU level:²³
- The total **budget available to MSAs** in nominal terms at EU level:²⁴
 - Decreased during 2010-2013 (from €133.4 mil. to €123.8 mil.),

21 Developing the EU Customs Union and its governance, COM(2016)813 final, 21.12.2016.

22 Source: Final report of the Ex-post evaluation of the application of market surveillance provisions of regulation (EC) No 765/2008.

23 Not all EU-28 Member States provided reliable data for this indicator. Therefore, figures do not include Austria, Cyprus, Estonia, Greece, Croatia, Luxembourg, Slovenia, the United Kingdom and Hungary.

24 Not all EU-28 Member States provided reliable data for this indicator. Therefore, figures do not include Austria, Cyprus, Estonia, Greece, Croatia, Luxembourg, Slovenia, the United Kingdom and Hungary.

- It was concentrated in a reduced number of countries and large differences could be noticed in terms of budget available to each country during the four year-period;
- It represented around 0.1-1.33%²⁵ out of the total national budget;
- A similar evolution was registered by the **human resources**. During the period 2010-2013 a reduction of FTEs available to MSAs can be registered as well as a concentration of FTEs on a reduced number of countries;
- However, the analysis revealed an increasing trend in the **number of inspectors**, though specific interviews are needed to further investigate differences across countries and to triangulate data.

More details on each of these findings are presented below. Moreover, they should be considered only preliminary findings that will be further investigated and correlated with results from other study activities (market analysis and field research).

3.1.1. Financial resources available for market surveillance activities

As for the **total budget available to MSAs in nominal terms**, the data indicates reduced annual fluctuations at the EU level, though in a negative direction. The figures refer to 19 out of 28 EU Member States, as Austria, Cyprus, Estonia, Greece, Croatia, Luxembourg, Slovenia and United Kingdom have not included this data in their national reports. Moreover, Hungary has reported values since 2011, therefore it was not considered the lack of data for 2010 would have created a different perspective on the 2010-2013 trends.

Table 11-5: Budget available to market surveillance authorities in nominal terms (€) for selected sectors in the 2010-2013 period

Sectors	Number of Member States providing budget information	Average amount of resources per Member State and per year (simple average)	Average amount of resources per 1000 inhabitants (population on 1 January 2015) ²⁶
SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	8 ²⁷	1,391,889 €	34.14 €
SECTOR 2 - Cosmetics	8 ²⁸	4,993,718 €	43.21 €
SECTOR 3 - Toys	8 ²⁹	1,917,787 €	17.48 €

25 The figures refer to 10 countries that provided reliable data, precisely: Denmark, Estonia, Spain, Finland, Italy, Latvia, Malta, Poland, Sweden and Slovakia.

26 Population on 1 January 2015 as provided by Eurostat

27 Denmark, Ireland, Cyprus, Latvia, Portugal, Slovenia, Finland and Sweden.

28 Denmark, France, Hungary, Portugal, Slovenia, Slovak Republic, Finland and Sweden

29 Bulgaria, Denmark, Ireland, France, Hungary, Slovenia, Finland and Sweden. For Ireland, the budget across is the total NCA budget for all activities (excluding financial awareness and education), since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities. For France, the number provided doesn't include the budget for product testing. Slovenia has provided the overall authority budget. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

Sectors	Number of Member States providing budget information	Average amount of resources per Member State and per year (simple average)	Average amount of resources per 1000 inhabitants (population on 1 January 2015) ²⁶
SECTOR 4 - Personal Protective Equipment	7 ³⁰	270,913€	2.53 €
SECTOR 5 - Construction Products	8 ³¹	425,273 €	3.39 €
SECTOR 6 - Aerosol dispensers	4 ³²	9,635 €	0.50 €
SECTOR 7 - Simple pressure vessels and Pressure Equipment	6 ³³	355,540 €	3.39 €
SECTOR 8 - Transportable pressure equipment	6 ³⁴	274,912 €	2.86 €
SECTOR 9 - Machinery	7 ³⁵	564,028 €	5.27 €
SECTOR 10 - Lifts	4 ³⁶	425,111 €	15.08 €
SECTOR 11 - Cableways	2 ³⁷	741,722 €	57.67 €
SECTOR 12 - Noise emissions for outdoor equipment	4 ³⁸	169,647 €	1.94 €
SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	6 ³⁹	210,451 €	2.04 €
SECTOR 14 - Pyrotechnics	5 ⁴⁰	336,074 €	3.90 €
SECTOR 15 - Explosives for civil uses	4 ⁴¹	196,517€	2.44 €
SECTOR 16 - Appliances burning gaseous fuels	8 ⁴²	186,410 €	1.70 €

- 30 Bulgaria, Denmark, France, Hungary, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 31 Bulgaria, Denmark, France, Cyprus, Hungary, Romania, Finland and Sweden.
- 32 Bulgaria, Denmark, Cyprus and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 33 Bulgaria, Denmark, France, Hungary, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 34 Bulgaria, Denmark, France, Cyprus, Hungary and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 35 Bulgaria, Denmark, France, Hungary, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 36 Bulgaria, Denmark, Hungary and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 37 Bulgaria and Denmark. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 38 Bulgaria, Italy, Hungary and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 39 Bulgaria, Denmark, France, Hungary, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 40 Bulgaria, Denmark, France, Cyprus and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 41 Bulgaria, France, Cyprus and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 42 Belgium, Bulgaria, Denmark, France, Cyprus, Hungary, Slovenia and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

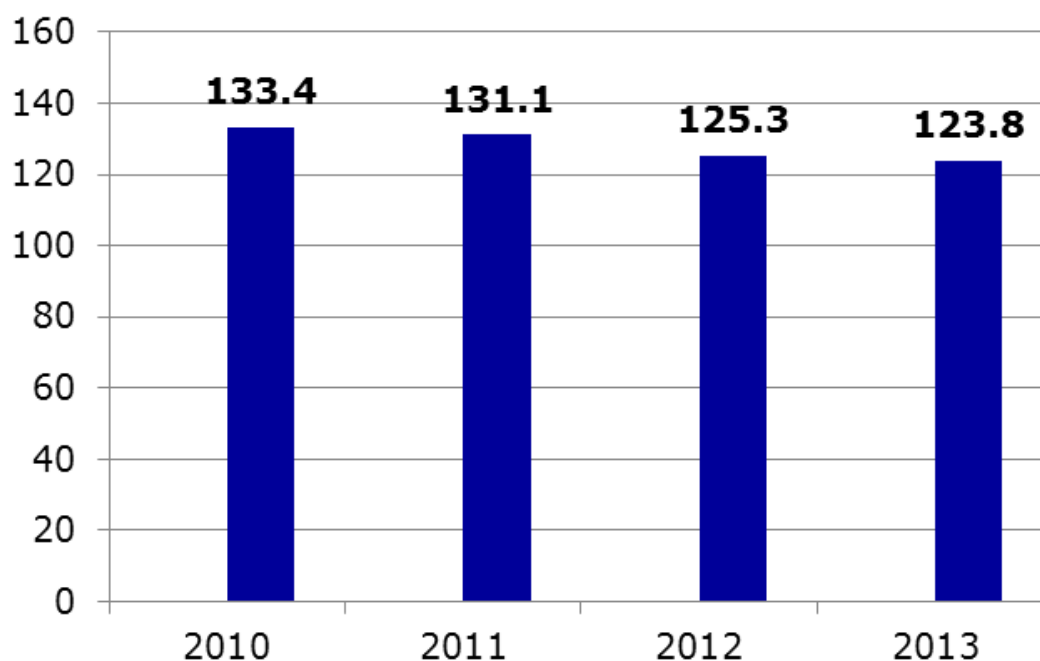
Sectors	Number of Member States providing budget information	Average amount of resources per Member State and per year (simple average)	Average amount of resources per 1000 inhabitants (population on 1 January 2015) ²⁶
SECTOR 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	8 ⁴³	331,374 €	2.87 €
SECTOR 18 - Electrical equipment under EMC	11 ⁴⁴	1,213,247 €	5.51 €
SECTOR 19 - Radio and telecom equipment under RTTE	11 ⁴⁵	1.630.901 €	7.37 €
SECTOR 20 - Electrical appliances and equipment under LVD	10 ⁴⁶	663,663 €	5.74 €
SECTOR 21 - Electrical and electronic equipment under RoHS, WEEE and batteries	5 ⁴⁷	191,120 €	5.83 €
SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)	7 ⁴⁸	145,000 €	1.50 €
SECTOR 23 - Ecodesign and Energy labelling	8 ⁴⁹	215,344 €	1.99 €
SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	4 ⁵⁰	120,924 € €	2.65 €
SECTOR 25 - Recreational craft	4 ⁵¹	284,264 €	2.86 €
SECTOR 26 - Marine Equipment	2 ⁵²	75,854 €	2.97 €
SECTOR 27 - Motor vehicles and tyres	6 ⁵³	456,843 €	4.30 €
SECTOR 28 - Non-road mobile machinery	2 ⁵⁴	14,324 €	0.73 €
SECTOR 29 - Fertilisers	9 ⁵⁵	135,641 € €	1.06 €

- 43 Bulgaria, Denmark, France, Hungary, Austria, Slovenia, Finland and Sweden. Bulgaria calculated the budget by multiplying the number of staff available to market surveillance authorities by the average amount per unit applicable to the year concerned. France included budget only for pre-packaged products.
- 44 Belgium, Bulgaria, Denmark, Germany, France, Cyprus, Hungary, Romania, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 45 Belgium, Bulgaria, Denmark, Germany, Estonia, France, Portugal, Romania, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 46 Belgium, Bulgaria, Denmark, France, Cyprus, Latvia, Hungary, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities. For Slovenia, the number of the budget includes also the costs of laboratory tests and payment for samples taken, with a corresponding claim from the liable party for the reimbursement of costs in the case of a compliant product.
- 47 Bulgaria, Denmark, Ireland, Hungary and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 48 Denmark, Ireland, France, Latvia, Hungary, Slovenia and Finland.
- 49 Belgium, Bulgaria, Ireland, France, Cyprus, Hungary, Slovenia and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 50 Belgium, Ireland, Hungary and Romania.
- 51 Bulgaria, France, Romania and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 52 Denmark and Romania.
- 53 Belgium, Bulgaria, Denmark, France, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 54 Hungary and Sweden.
- 55 Czech Republic, Denmark, France, Latvia, Hungary, Romania, Slovenia, Slovak Republic and Finland. Belgium provided also figures but this has not been taken into account, since the FASFC submitted its total annual budget which covered integrated inspection services covering the whole of the food chain.

Sectors	Number of Member States providing budget information	Average amount of resources per Member State and per year (simple average)	Average amount of resources per 1000 inhabitants (population on 1 January 2015) ²⁶
SECTOR 30 - Other consumer products under GPSD	5 ⁵⁶	1,514,284 €	15.26 €

Source: national reports

Figure 11-3: Total budget available to MSAs in nominal terms during 2010-2013, € millions⁵⁷



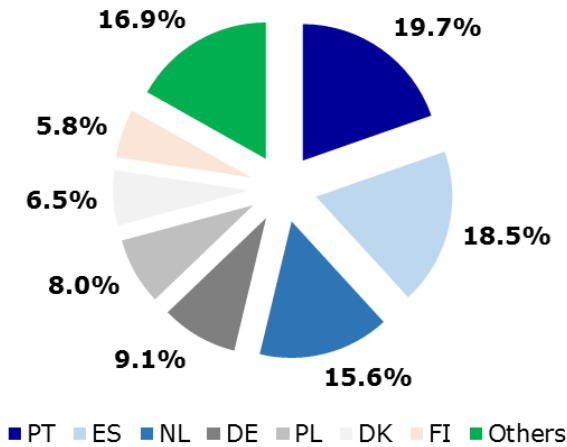
Source: National reports

As emerged from the national reports, the budget reflects all financial resources assigned to market surveillance and enforcement activities, including related infrastructures as well as projects and measures aimed at ensuring compliance of economic operators with product legislation. These measures range from communication activities (consumer/business information and education) to pure enforcement and market surveillance activities. They include the remuneration of staff, direct costs of inspections, laboratory tests, training and office equipment cost. Enforcement activities at regional/local level should also be reported. Other activities undertaken by these authorities not related to the enforcement of product legislation should be excluded from the calculation.

⁵⁶ Bulgaria, France, Hungary, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

⁵⁷ The data correspond to 19 out of 28 EU Member States (please see the explanation in the paragraph above the figure)

Figure 11-4: Contribution of each MS to the total budget available in nominal terms to MSA at EU level over 2010-2013⁵⁸

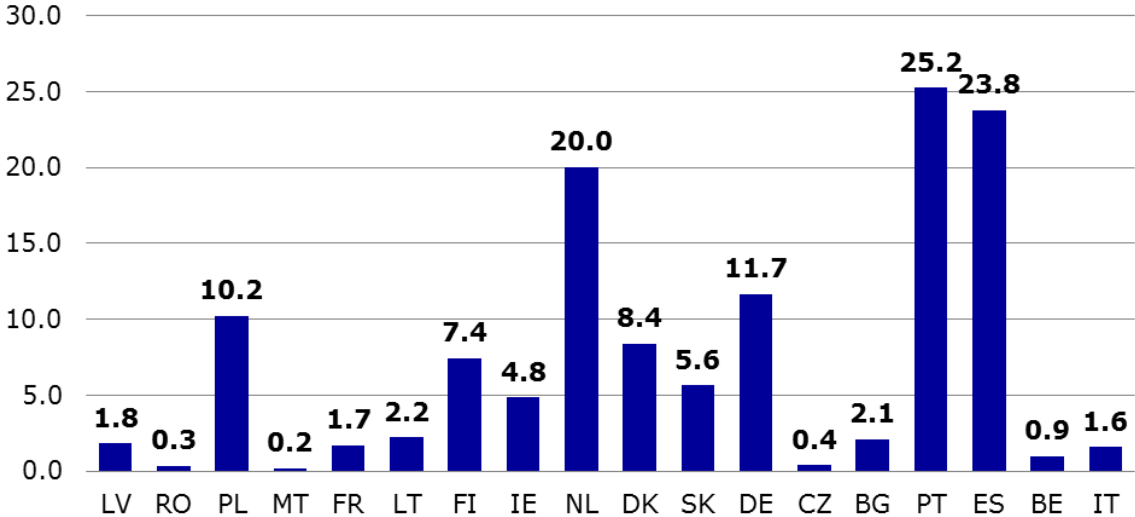


Source: National reports

At country level, during 2010-2013, the following findings emerged:

- More than 80% of the total budget available to the 18 MSAs reporting data in nominal terms is concentrated in seven Member States;
- More than half of the Member States providing data had an available annual budget smaller than €10 million;
- Only three countries (Portugal, the Netherlands, and Spain) declared an annual budget allocated to market surveillance activities equal to or greater than €20 million.

Figure 11-5: Annual budget available to MSA in nominal terms, average 2010-2013, € millions



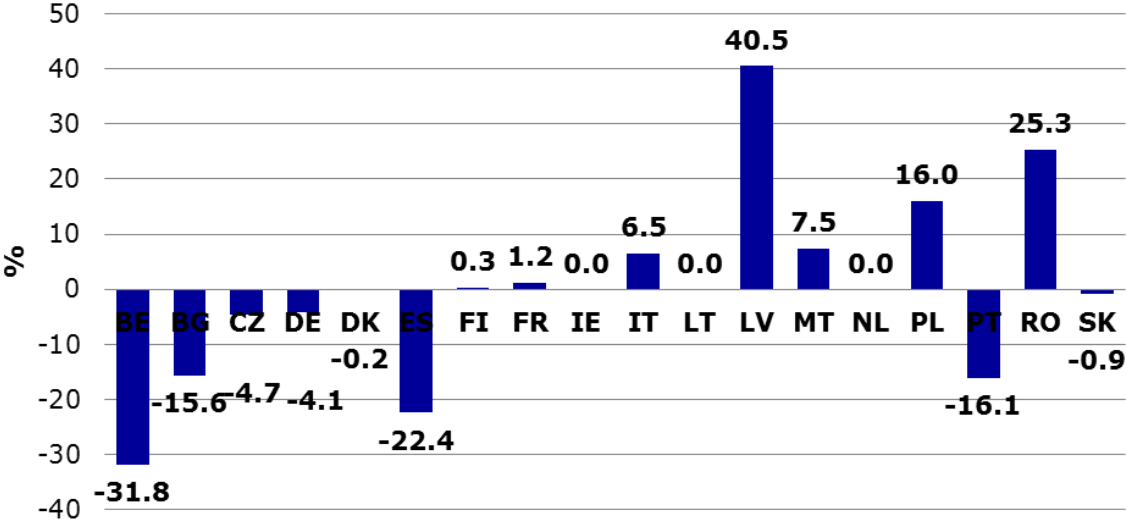
Source: National reports

58 Please consider that data for the UK are not available. "Others" includes France.

As shown in the figure below, over the period considered the total budget allocated annually to market surveillance activities increased in eight Member States⁵⁹ and decreased in seven Member States.⁶⁰ In other countries (Ireland, the Netherlands and Lithuania) the budget remained stable over the period 2010-2013. The magnitude of reduction and increase of the total budget available to national MSAs also differs. On a three-dimension scale (0-10% – limited, 10-30% – moderate, 40-50% – high) the variation of total budget (both in positive and negative terms) was:

- High in two Member States (Belgium -32% and Latvia +40.5%);
- Moderate in five Member States (increase in Romania and Poland, reduction in Bulgaria, Spain and Portugal);
- Limited in more than half of the Member States, i.e. in 12 out of 18.

Figure 11-6: Variation (%) of the average annual budget available to MSAs in nominal terms average 2010-2013, € M



Source: National reports

Compared to the total national budget, the total budget allocated per country for market surveillance activities (**total budget available to MSAs in relative terms**) represents no more than 0.2% in half of Member States reporting data. There are also countries that concentrated a higher percentage of financial resources on the functioning of market surveillance activities, namely: Estonia (an average of 0.52%) and Poland (1.33%). Bulgaria and the Czech Republic also provided data on the total budget available to MSAs in relative terms, though they were not considered in the analysis as their reliability is questionable (the values being significantly higher than the ones reported by the other Member States: the national authorities from Bulgaria declared values that amount to an average of 47.2%, while the Czech authorities values around 92.58% of the total national budget). As mentioned also for the first indicators, Hungarian authorities have not reported data for 2010, therefore the country was not included in the analysis.

59 FI, FR, IT, LT, LV, MT, PL, RO.
 60 BE, BG, CZ, DE, ES, PT, SK.

3.1.2. Human resources available for market surveillance activities

The **staff available to MSAs (FTE units)** is another indicator relevant for computing the enforcement costs incurred by national authorities. The uninterrupted negative trend registered by the budget available for MSA expressed in nominal terms can be observed also in this case, potentially as a result of the budget decrease. Consequently, the costs incurred by the national authorities in their endeavours to enforce the implementation of the Regulation related to the staff are lower starting in 2013 compared with 2010. Nineteen countries compliant with the Regulation provision to provide the data for all four years have been considered in the data processing; Hungary, as stated before, did not provide all necessary data.

Table 11-6: Staff available to market surveillance authorities for selected sectors in the 2010-2013 period

Sectors	Number of Member States providing staff information	Average amount of staff available per Member State and per year (simple average)	Average amount of staff available per 1000000 inhabitants (population on 1 January 2015) ⁶¹
SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	12 ⁶²	58.60	0.46
SECTOR 2 - Cosmetics	11 ⁶³	255.55	1.33
Sector 3 - Toys	9 ⁶⁴	32.28	0.26
Sector 4 - Personal Protective Equipment	8 ⁶⁵	12.38	0.10
SECTOR 5 - Construction Products	11 ⁶⁶	17.94	0.11
SECTOR 6 - Aerosol dispensers	6 ⁶⁷	21.82	0.53
SECTOR 7 - Simple pressure vessels and Pressure Equipment	8 ⁶⁸	23.40	0.18
SECTOR 8 - Transportable pressure equipment	8 ⁶⁹	23.27	0.21
Sector 9 - Machinery	8 ⁷⁰	71.67	0.41

61 Population on 1 January 2015 as provided by Eurostat

62 Czech Republic, Denmark, Ireland, Italy, Cyprus, Latvia, Hungary, Portugal, Slovenia, Slovak Republic, Finland and Sweden.

63 Czech Republic, Denmark, Ireland, France, Italy, Hungary, Portugal, Slovenia, Slovak Republic, Finland and Sweden.

64 Bulgaria, Denmark, Ireland, Greece, France, Hungary, Slovenia, Finland and Sweden. For Ireland, the number includes the number of authorised officers in Product Safety Unit with additional authorised officers available to assist on specific projects if required. Slovenia has submitted the total number of employees. Bulgaria has submitted the total number of employees.

65 Belgium, Bulgaria, Denmark, Greece, France, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

66 Belgium, Bulgaria, Czech Republic, Denmark, Greece, France, Cyprus, Hungary, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.

67 Belgium, Bulgaria, Denmark, Greece, Cyprus and Finland. Bulgaria has submitted the total number of employees.

68 Belgium, Bulgaria, Denmark, Greece, France, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

69 Bulgaria, Denmark, Greece, France, Cyprus, Hungary, Slovenia and Finland. Bulgaria has submitted the total number of employees.

Sectors	Number of Member States providing staff information	Average amount of staff available per Member State and per year (simple average)	Average amount of staff available per 1000000 inhabitants (population on 1 January 2015) ⁶¹
SECTOR 10 - Lifts	5 ⁷¹	22.51	0.58
SECTOR 11 - Cableways	6 ⁷²	18.41	0.42
SECTOR 12 - Noise emissions for outdoor equipment	6 ⁷³	13.54	0.14
SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	7 ⁷⁴	12.41	0.12
SECTOR 14 - Pyrotechnics	9 ⁷⁵	10.30	0.06
SECTOR 15 - Explosives for civil uses	8 ⁷⁶	9.62	0.08
SECTOR 16 - Appliances burning gaseous fuels	9 ⁷⁷	9.82	0.08
Sector 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	9 ⁷⁸	10.91	0.09
SECTOR 18 - Electrical equipment under EMC	11 ⁷⁹	17.45	0.08
SECTOR 19 - Radio and telecom equipment under RTTE	11 ⁸⁰	18.49	0.08
Sector 20 - Electrical appliances and equipment under LVD	10 ⁸¹	16.64	0.13

70 Bulgaria, Denmark, Greece, France, Italy, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees. France provided an estimate of the staff available to market surveillance activities. Sweden submitted numbers for both the Swedish Work Environment Authority and the Swedish National Board of Housing, Building and Planning.

71 Bulgaria, Denmark, Greece, Hungary and Finland. Bulgaria has submitted the total number of employees.

72 Bulgaria, Denmark, Portugal, Slovak Republic, Finland and Sweden. Bulgaria has submitted the total number of employees.

73 Bulgaria, Denmark, Italy, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

74 Bulgaria, Denmark, France, Cyprus, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

75 Bulgaria, Czech Republic, Denmark, Ireland, Greece, France, Italy, Cyprus and Finland. Bulgaria has submitted the total number of employees.

76 Bulgaria, Czech Republic, Ireland, Greece, France, Cyprus, Hungary and Finland. Bulgaria has submitted the total number of employees.

77 Belgium, Bulgaria, Denmark, Greece, France, Cyprus, Luxembourg, Hungary and Finland. Bulgaria has submitted the total number of employees.

78 Bulgaria, Denmark, France, Hungary, Austria, Slovenia, Slovak Republic, Finland and Sweden. Bulgaria has submitted the total number of employees.

79 Belgium, Bulgaria, Denmark, Germany, Greece, France, Cyprus, Hungary, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.

80 Belgium, Bulgaria, Denmark, Germany, Estonia, France, Cyprus, Portugal, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.

81 Belgium, Bulgaria, Denmark, Greece, France, Cyprus, Latvia, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

Sectors	Number of Member States providing staff information	Average amount of staff available per Member State and per year (simple average)	Average amount of staff available per 1000000 inhabitants (population on 1 January 2015) ⁶¹
SECTOR 21 - Electrical and electronic equipment under RoHS, WEEE and batteries	6 ⁸²	13.54	0.31
SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)	9 ⁸³	64.44	0.55
SECTOR 23 - Ecodesign and Energy labelling	10 ⁸⁴	14.53	0.11
SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	6 ⁸⁵	9.18	0.15
SECTOR 25 - Recreational craft	7 ⁸⁶	12.35	0.12
SECTOR 26 - Marine Equipment	5 ⁸⁷	1.58	0.01
SECTOR 27 - Motor vehicles and tyres	10 ⁸⁸	17.43	0.12
SECTOR 28 - Non-road mobile machinery	3 ⁸⁹	0.43	0.02
SECTOR 29 - Fertilisers	12 ⁹⁰	9.19	0.06
SECTOR 30 - Other consumer products under GPSD	5 ⁹¹	46.94	0.47

Source: national reports

82 Bulgaria, Denmark, Ireland, Greece, Hungary and Finland. Bulgaria has submitted the total number of employees.

83 Czech Republic, Denmark, Ireland, Greece, France, Latvia, Hungary, Slovenia and Finland.

84 Belgium, Bulgaria, Czech Republic, Ireland, Greece, France, Cyprus, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

85 Belgium, Ireland, Greece, Hungary, Romania and Finland.

86 Bulgaria, Denmark, Greece, France, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.

87 Denmark, France, Italy, Romania and Finland.

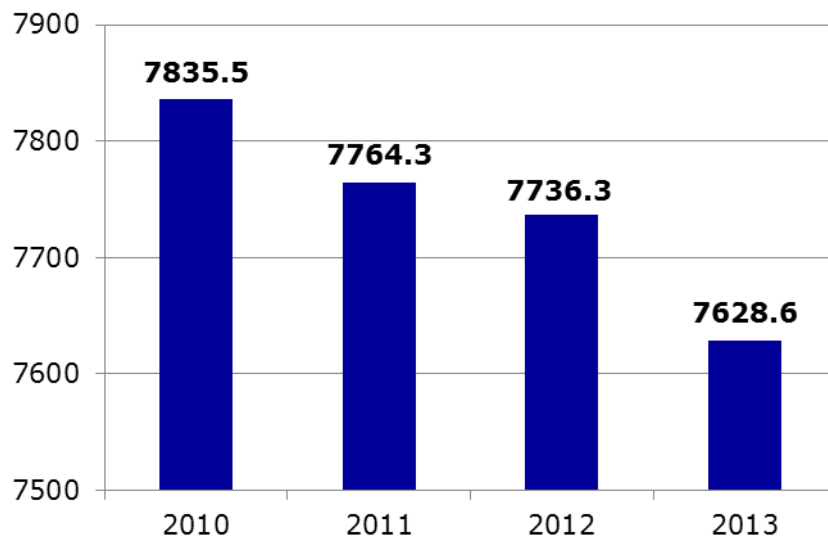
88 Belgium, Bulgaria, Denmark, France, Cyprus, Portugal, Romania, Slovenia, Finland and Sweden. Bulgaria has submitted the total number of employees.

89 Denmark, Hungary and Sweden.

90 Belgium, Czech Republic, Denmark, Ireland, Greece, France, Latvia, Hungary, Romania, Slovenia, Slovak Republic and Finland.

91 Bulgaria, France, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

Figure 11-7: Total staffs available to MSAs (FTE units) during 2010-2013 at EU level⁹²



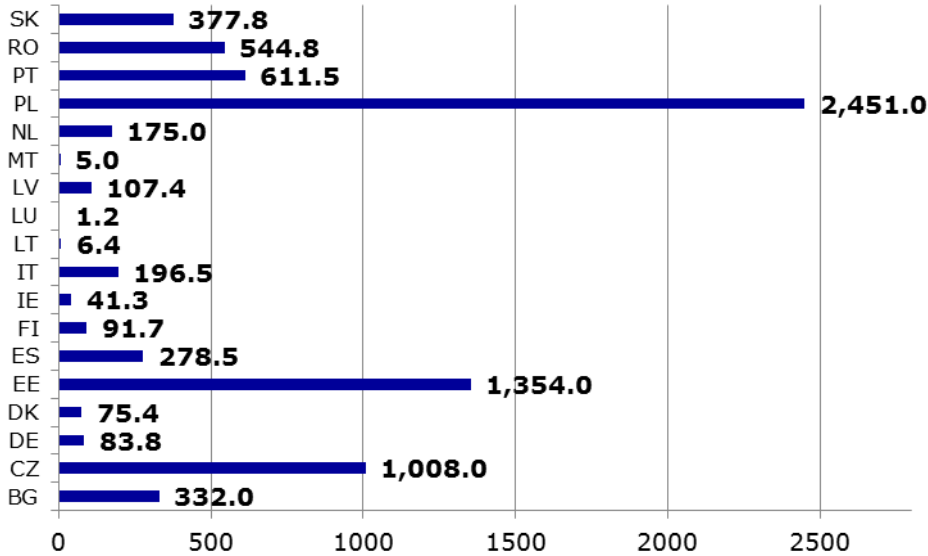
Source: National reports

The analysis at country level concerning the total staffs available to MSAs (FTE units) revealed the following:

- On average, 7,741 staff resources (FTEs) were available for the MSAs of 18 EU countries during the period 2010 – 2013;
- 86.3% of staff resources (6,679) were based in seven Member States (Poland, Estonia, the Czech Republic, Portugal, Romania, Slovakia, and Bulgaria);
- More than 30% of total staff resources were based in one country (Poland);
- There were large differences among countries in terms of total staff resources available over the period 2010-2013. On the one hand, a large number of Member States (15 out of 18) involve less than 1,000 FTEs in market surveillance activities. On the other hand, Poland reported a significantly greater number of FTEs available to the MSAs, more than five times higher than staff resources declared by the majority of the countries.

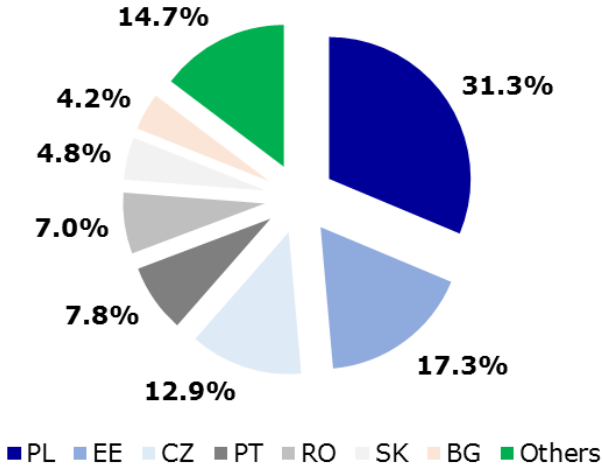
⁹² The analysis includes the following countries: Bulgaria, Czech Republic, Deutschland, Denmark, Estonia, Spain, Finland, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Poland, Portugal, Romania, Sweden, Slovakia; the other EU Member States have not provided complete and reliable data in their national reports

Figure 11-8: Total staff available to MSAs at country level (average 2010 – 2013), FTEs



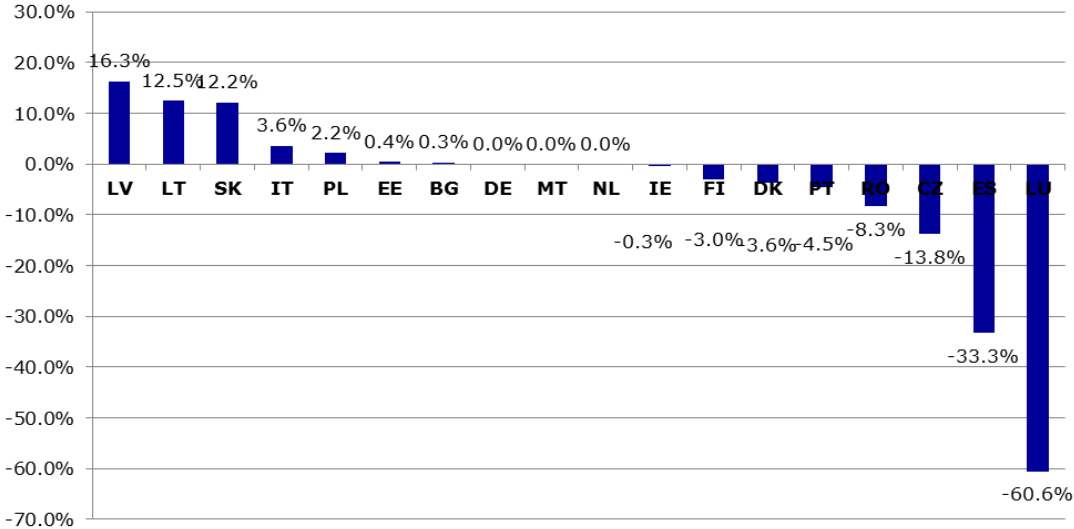
Source: National reports

Figure 11-9: Total staff available to MSAs (FTE units) per country over 2010-2013



Source: National reports

Figure 11-10: Variation of total staffs available to MSAs (FTE units) over 2010-2013



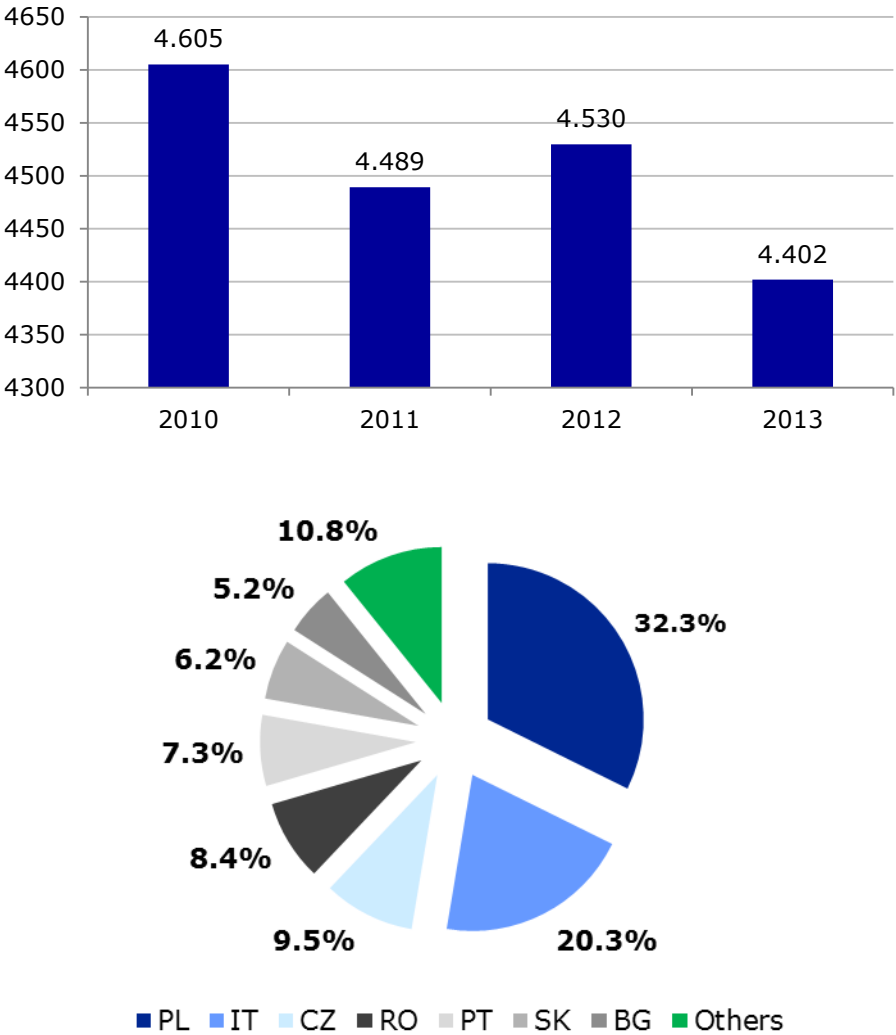
Source: National reports

The highlights of the analysis concerning the **variation** of total staff resources available to MSAs (FTE units) over the period 2010-2013 are:

- More than half of the Member States considered (11) displayed a relatively stable trend in the number of staff resources available to MSA (FTE units) with a variation of less than 5% of the value registered in 2010;
- three Member States (Latvia, Lithuania and Belgium) declared an increase between 12.2% and 16.3%;
- The magnitude of total staff reduction was very different: the largest percentage decrease (-60.6% - Luxembourg) was almost twice as high as the second largest percentage reduction (33.3% - Spain) and 202 times higher than the smallest reduction (0.3% - Ireland).

While at the EU level the budget available to market surveillance activities suffered continuous adjustments and the total staff resources available to MSAs (FTE units) registered a negative trend, the **number of inspectors (FTE units)** followed a fluctuating trend (decreasing one year, increasing in the next one, then decreasing again) which could be translated into fluctuating staff costs during this period (Figure 20). In this case, only 16 Member States provided completed data and were included in the analysis.

Figure 11-11: Total number of inspectors available to MSAs (FTE units) over 2010-2013 at EU level and Total number of inspectors (FTE units) available to MSAs per country over 2010-2013



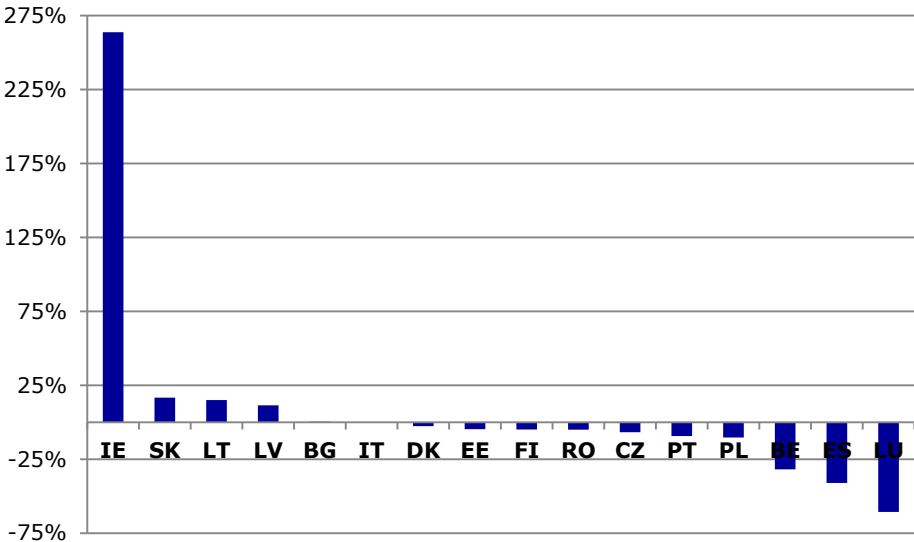
Source: National reports

Regarding the total number of inspectors (FTE units) available to MSAs over 2010-2013 at country level, the following emerged:

- On average, 4,506 inspectors were available to the 16 Member States considered for inspection activities;
- The majority (90%) of inspectors (4,019) were based in six Member States - Poland, Italy, the Czech Republic, Romania, Portugal, and Slovakia;
- Around half (2,372) of the FTEs dedicated to inspection activities were employed in two Member States (Poland, and Italy);
- The magnitude of the costs derived from the number of inspectors (FTE units) varies across Member States, as for instance in Luxembourg and Lithuania (included in the Others category) only 4.6 and 21.74 FTEs, respectively, have been allocated to market surveillance activities, while Poland involved 5,822 FTEs.

The reasons behind all of the differences presented in this section of the study will be further investigated during the interviews, the details to be required depending on the interviewee's experience and expertise.

Figure 11-12: Variation of total number of inspectors (FTE units) available to MSAs per year, during 2010-2013



Source: National reports

At country level, the analysis of the change in the number of inspectors available to MSAs annually reflects the following:

- In the majority of countries (10 out of 16) the number of inspectors decreased;
- Six countries (Bulgaria, Italy, Denmark, Estonia, Finland, and Romania) had relatively stable trends, with the increase or decrease in the number of inspectors not being higher than 5% of the number of inspectors available to MSAs in 2010;
- A significant increase (263.8%) was registered in Ireland.
- Except for two countries (Ireland and Poland), the overall trend in the total inspectors available to MSAs during the four years considered tends to be aligned with the one for the total staff available to MSAs..
- On the basis of the figure on budgets and number of inspections provided by Member States the following estimates of costs of enforcement are provided. It is noted they are largely variable due to the limited number of data points and some issues of comparability.

Table 11-7: Indicative estimate of costs of inspections in Member States

MS	Nominal budget (Av. '10-'13) €	Δ% 2010 - 2013	Number of inspections (Av. '10-'13)	Δ% 2010 - 2013	Average cost of inspections €	Number of tests performed in laboratories (Av. '10- '13)	Δ% 2010 - 2013	Average cost of tests €
	(a)		(b)		(a)/(b)	(d)		(a)/(d)
BE	946,903	-32%	4,701	94%	201	386	-45%	2,452
BG	2,114,559	-16%	10,953	58%	193	466	21%	4,535
CZ	384,594	-5%	6,200	-4%	62	166	-55%	2,313
DK	8,386,750	0%	1,754	14%	4,782	561	0%	14,950
FI	1,417,861	0%	7,448	0%	996	2924	6%	2,537
FR	1,680,000	1%	16,119	-1%	104	1147	-1%	1,465
IE	4,825,000	0%	15,401	32%	313	193	-58%	25,000
IT	1,561,372	6%	6,110	11%	256	581	153%	2,690
LV	1,818,645	40%	3,221	-1%	565	361	63%	5,038
MT	163,592	7%	939	-7%	174	:	:	:
PL	10,229,088	16%	7,605	5%	1,345	926	44%	11,047
PT	25,229,517	-16%	12,670	174%	1,991	411	-9%	61,348
RO	320,108	25%	12,071	-14%	27	2716	-35%	118
SE	14,258,602	n/a	3,593	-3%	3,968	367	-14%	38,852
SK	5,634,232	-1%	3,610	-31%	1,561	352	-30%	15,995
Aver	5,264,722	0.92%	7,493	21%	703	770	-7%	6,837

Source: Evaluation study

3.2. Information on resources based on reports for the chemicals area

REACH and Classification and Labelling of Products regulation (CLP), 22 countries provided information on the resources allocated to enforcing authorities for tasks related to the enforcement of REACH. Among them, 12 indicated that it was difficult, and in most cases impossible to provide an estimate of the annual budget and staff dedicated to REACH enforcement, since inspectors carry out tasks related to more than 1 legislation, often in joint inspections, and no separate budget is allocated specifically to REACH. 15 countries provided an estimate of annual staff and/or budget dedicated to REACH enforcement.

Table 11-8: Staff and budget allocated to REACH enforcement

Country	Staff dedicated to REACH enforcement	Budget allocated to REACH enforcement
Austria	In average, a resource of 1 man-year is available for enforcement activities related to the whole chemical legislation in the competence of the inspectorates in each of the Lander (9 man-year in total).	
Croatia	4 inspectors on national level 30 inspectors on regional level	
Czech Republic	13 regional inspectors responsible for chemical legislation	
Denmark	The Chemical Inspection Service: 3 man-years enforcing REACH Danish Working Environment Authority special unit on market surveillance: 2 man-year enforcing SDS and ES; 0.1 man-year for general inspection in which REACH is discussed Danish Maritime Authority: 0.1 man-year for general inspection in which REACH is discussed	
France	Ministry of Ecology: 26 environment inspectors enforce REACH	
Greece	55 chemists in NEA perform tasks related to REACH	
Hungary	There are approximately 90 chemical safety inspectors responsible for the whole chemical safety legislation in the competence of the NEA	
Ireland	EPA: ~0.2FTE for work associated with REACH DAFM: 27 staff enforcing REACH related to pesticides HSA: 12.9 FTEs inspectors for chemical legislation (approximately 3.2 FTE for REACH and CLP)	EPA: Approximately €6,200 (not including labour costs) for REACH and Detergents Regulation HSA: 250,000 - 300,000 Euros (including only human resources)
Liechtenstein	1 inspector in NEA	
Lithuania	State environmental protection service has 3 inspectors specialised in enforcing chemical legislation	
Norway	There is approximately 8.6 FTE in the NEA working on REACH	
Poland	The Inspection of Environmental Protection has allocated 20 full-time jobs dedicated to enforcement of REACH to regional (Voivodship) inspectorates of Environmental Protection. The State Labour Inspectorate and the District Labour Inspectorates all have a REACH coordinator.	
Portugal	IGAMAOT has 7 inspectors allocated to REACH, CLP, Seveso Directive and other environmental legislation	

Country	Staff dedicated to REACH enforcement	Budget allocated to REACH enforcement
Slovenia	4 inspectors in NEA	
United Kingdom	The Compliance Team of HSE has 3 FTEs to work on REACH. There are other Enforcers also working on REACH. HSENI has 0.1 FTE. NIEA has 4 staff (not full time on REACH). Environmental Agency has 5.4 staff (not full time on REACH).	

Cells were left blank when CAs have not reported any information.

Out of the 22 countries which provided information on the level of resources dedicated to the Classification and Labelling of Products regulation (CLP), 13 have reported the same information as for the enforcement of REACH. As previously mentioned, a lot of countries do not have resources specifically allocated to the enforcement of CLP or REACH, which is covered by the CA's budget. 5 countries provided specific data for CLP:

Table 11-9: Staff and budget allocated to CLP enforcement

Country	Staff dedicated to CLP enforcement	Budget allocated to CLP enforcement
Belgium	Federal Environmental Inspection: 2011: 7 FTE; 2012: 5 FTE; 2013: 6 FTE; 2014: 7.2 FTE	General budget (including analysis) 2011: €276,000; 2012: €289,000; 2013: €223,000; 2014: €160,350 (total cost for the inspection service (inspectors, technical experts and controllers on the transit of waste).
Croatia	4 inspectors at national level 20 inspectors at regional level	
Denmark	2 man-year	
Iceland	0.1 FTE in the Environment Agency	
Latvia	Impossible to distinguish resources only dedicated to CLP. However Health Inspectorate has indicated that they have 10 persons involved in CLP control.	Annual budget of Health Inspectorate for enforcement of chemicals and cosmetics legislation is approximately 300,000 EUR.

ANNEX 12: BACKGROUND INFORMATION ON OBJECTIVE 2 – INCREASING OPERATIONAL ENFORCEMENT CAPACITY

1. PROBLEM ANALYSIS AND BASELINE

- *Low and increasingly constrained resource levels for market surveillance in Member States*

Staff and budgets dedicated to market surveillance show a consistent **downward trend** throughout the EU Member States over the period 2010-2013⁹³. A year after the adoption of Regulation (EC) N° 765/2008, 21 (of then 27) Member States had not allocated additional resources or considered resources sufficient⁹⁴. The 2016 public consultation results confirm that lacking **human and financial resources** are now a **major factor constraining the market surveillance authorities' control activity** (51% of all respondents, and 63% of authorities themselves). While imports are on the increase⁹⁵ and constitute a source of non-compliant goods entering the EU⁹⁶, customs faced a 10% decline in human resources in the period 2010-2015⁹⁷.

The lack of sufficient **technical means**, in particular lacking testing capacity, is also at play, be it to a somewhat lesser extent (by all respondents 36% and by 44% of authorities themselves). In case a market surveillance authority lacks in-house testing capacity, it can in principle purchase tests from private laboratories and obtain the necessary substantive compliance tests. However if the authorities' financial resources are limited also this option is compromised.

Laboratory, physical testing of product samples constitutes a major cost component especially for complex products or certain type of tests. Costs of testing equipment and (outsourced) laboratory test represented 30 to 50% of recent co-funded projects⁹⁸. Moreover, availability of testing capacities is not ensured in all member states and/or for all type of products and tests: MSA and customs survey results⁹⁹ show that in-house is often not available to authorities and sharing of laboratory capacity between MSA and customs does not often occur.

93 Annex 11 Technopolis, Final report, Ex-post evaluation of the application of the market surveillance provisions of Regulation N°765/2008, May 2017.

94 Page 19, European Parliament, DG Internal Policies of the Union, study Effectiveness of market surveillance in Member States, 2009 <http://www.europarl.europa.eu/document/activities/cont/201108/20110825ATT25294/20110825ATT25294EN.pdf>

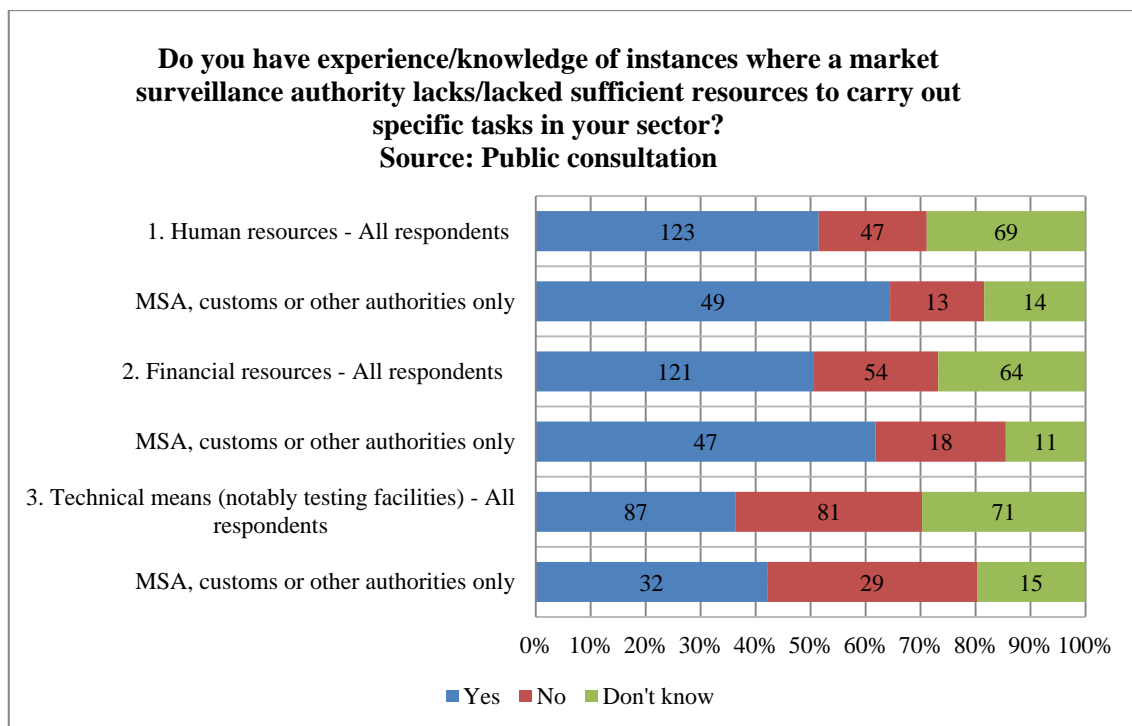
95 Technopolis, Final report, Ex-post evaluation of the application of the market surveillance provisions of Regulation N°765/2008, May 2017

96 In the period 2010-2016 68% to 78% of all RAPEX notifications concerned imported products.

97 Annex 11.2; Developing the EU Customs Union and its governance, COM(2016)813 final, 21.12.2016.

98 Joint actions on heat and electricity measuring instruments; LED floodlights; vehicle service lifts, chain saws resulting from the 2013 and 2014 call for proposals, DGGGROW.

99 Technopolis, Final report, Ex-post evaluation of the application of the market surveillance provisions of Regulation N°765/2008, May 2017; Report Mapping the differences in dealing with safety and compliance controls for products entering the Union, DGTAXUD, June 2016.



The state-of-play of available resources for market surveillance shows an **uneven coverage of sectors and significant variance in member states**. In general there is a **low level of human and financial resources** with on average a few euros (1-5€) per thousand inhabitants (with the exception in particular of medical devices, cosmetics and toys) and from 0 to maximum 0.5 inspectors per million inhabitants dedicated to market surveillance in the EU member states¹⁰⁰.

While co-funding possibilities exist in principle for joint projects of several Member States' authorities¹⁰¹, options for funding support to national market surveillance controls and capacity building are rare, unlike in other areas such as food chain controls^{102 103}.

- *Limited resources negatively impact control activities and reduce the deterrence effect of market surveillance*

The level of **available resources to market surveillance authorities directly influences the number of control activities** they can undertake and hence on the possible intelligence gathering, detection, investigation and ultimately sanctioning of instances of non-compliance. **Respondents place more and more efficient use of resources among the top 3 ways to improve deterrence** (72 and 73% agree or strongly agree, more publicity to restrictive measures ranking first with 75% agree or strongly agree answers). Authorities rank an increase in their resources as the best way to improve deterrence (87%). Resources constraints also impact on the possibilities for

100 Annex 11.

101 See Annex 11, co-funding sources for cross-border projects have been e.g. Consumer Programme, research programme Horizon 2020, and dedicated call for proposals by DGGROW, Internal market budget line dotation.

102 https://ec.europa.eu/food/funding_en.

103 Although there are no specific examples of use for products' market surveillance and actual control campaigns, EU funding sources could be available under the objective institutional capacity building (objective open for certain Member States in the European social fund) or compliance assistance activity by market surveillance authorities could be part of support programmes for SME. The Commission proposed programme to support structural reform could be also of relevance for institutional capacity building http://ec.europa.eu/europe2020/pdf/2016/ags2016_structural_reform_support_programme.pdf

authorities to engage in pro-active guidance and compliance assistance schemes for economic operators¹⁰⁴.

There is no simple reference to determine a sufficient or necessary level of controls and a corresponding budget. Although Regulation (EC) N° 765/2008 requires Member States to ensure controls at an "adequate level", both in domestic markets and for controls on product entering the EU, this requirement is not further specified. An overall indicative target, linked to population size and covering all products, applies in Germany and is found to be useful to plan and benchmark controls and resources in the different Länder¹⁰⁵. Most member states rely on risks assessments to determine priorities and voice reservations on the validity of a single, **prescriptive quantitative target** to cover all product sectors. Customs controls also rely on risk-based assessment to select consignments for inspection without a pre-set quantitative target of inspections¹⁰⁶. Besides risk profiles of products, market surveillance authorities and customs confirm that they **determine the "adequate scale" of controls mainly on the rationalisation of financial and human resources available**¹⁰⁷.

- *Weak information on financing and enforcement gaps in Member States to target controls better and exploit efficiency gains*

Despite the important limitation to enforcement stemming from resources constraints, the large majority of respondents (67% of all replies, 65% of authorities) could not provide a reliable quantitative estimate the **financial resources gap** that the market surveillance authorities face¹⁰⁸. This mirrors the findings of the assessment of Member State reports on the implementation of Regulation (EC) N° 765/2008 which show a great variability in the available human resources, budgets and the number or inspections performed. The budgets member states allocated to market surveillance over the past years show little correlation with the size of the markets or the number of enterprises active in harmonised product sectors¹⁰⁹. Similar findings and persistent difficulties to obtain coherent data sets on enforcement resources and activity and to correlate resources to output figures are also reported from other policies areas¹¹⁰. Nonetheless across the variety of member states, authorities and their economic context, a **positive trend linking increased resources to the issuing of more enforcement decisions** is observed in the competition policy area¹¹¹. That being said, at present the research into the **effectiveness of market surveillance systems** does not allow a conclusion on an authoritative model linking resources input to an optimum level of controls and their ultimate effectiveness¹¹². However the setting of objectives and

104 BSI, Study on Good practices in the area of Compliance assistance and compliance schemes (Annex 14.3)

105 The target applies to pro-active controls and is indicative: actual levels of controls are not achieved to the target level across the sectors or in all Länder. The depth and type of inspection (documentary check, testing, etc.) and the selection of sectors and operators is based on risks assessment, complaints and other information.

106 Article 46, Regulation (EU) N°952/2013, Union Customs Code <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0952&rid=1>

107 Technopolis, Final report, Ex-post evaluation of the application of the market surveillance provisions of Regulation 765/2008, May 2017.

108 The remaining responses do not give a clear pattern with estimates of financial gaps ranging from 5 to over 50%.

109 Technopolis, Ex-post evaluation of the application of the market surveillance provisions of Regulation (EC)n° 765/2008, Final report, May 2017.

110 European Competition Network ECN+ draft impact assessment - Annex XIV (to be published); Consumer conditions scoreboards, 5th edition 2011 and 7th edition 2012; ICF Consulting Services, Support study for the impact assessment on the review of the CPC Regulation 2006/2004/EC, 2015. http://ec.europa.eu/consumers/consumer_evidence/consumer_scoreboards/index_en.htm

111 European Competition Network ECN+ draft impact assessment - Annex XVI (to be published).

112 Market Surveillance Model Initiative, UNECE working party on Regulatory Cooperation and Standardization Policies; Annex, point 1.

targeting of enforcement action based on intelligence and evidence stand out as critical elements of effectiveness.

Respondents in the public and targeted consultations recognise that simply adding "more" resources will be difficult in a context of overall pressure on public budgets. Among alternative ways to increase resources to fund market surveillance, **additional administrative fees** levied on operators are the least favoured option (only 26% agreement and 65% disagreement¹¹³). Such general administrative fees would merely place additional costs on law-abiding businesses, who already operate in a difficult economic climate and who are facing stark competition from 3rd country imports and rogue traders. However, by working differently, market surveillance authorities could achieve efficiency gains or savings and this could help to alleviate pressure on their resources. Authorities identify **more dialogue with businesses and better targeting of enforcement actions** as the areas where most **efficiency gains** can be obtained (70% of the respondents in the targeted surveys in the ex-post evaluation of Regulation (EC) N°765/2008. 61% sees potential efficiency gains in the inspection process itself). Practical ways to realise efficiency gains may include **pooling of efforts** between authorities in Member States and between different Member States in intelligence and knowledge gathering to underpin priority setting or cooperation agreements with intermediaries¹¹⁴ and sharing of work in joint investigations. Another way is adopting different approaches to the enforcement intervention in Member States, with more emphasis on regular auditing of manufacturers as well as large importers, and coordination of such audits between Member States for economic operators who sell their products in several Member States¹¹⁵.

The current reporting mechanism in Regulation (EC) n° 765/2008 focusses on communication of control programmes (Article 18(5)) and ex-post reviews and assessment of market surveillance programmes (Article 18(6)). While authorities see the reporting as a useful tool and starting point for coordination action, the administrative burden compared to the benefits is an area flagged for potential improvements¹¹⁶. The report template is being revisited to facilitate information collection. With clearer **information on compliance and enforcement gaps**, the reports' usefulness for coordination and strategic priority setting would further improve.

- *Limited resources for coordinated enforcement and tackling of cross-border infringements*

The enforcement landscape in the Single market is fragmented, with over 500 market surveillance authorities. This fragmentation is compensated only to a moderate extent by coordination structures in Member States, as evidenced by the difficulties they experience to report on enforcement activities or to provide assessments of compliance

113 The responses to this point in question 11 in the public consultation reveal particularly strong disagreement by businesses: 83% strongly disagrees or disagrees, 10% strongly agrees or agrees. On the same question, 50% of public authorities express agreement viz 39% disagreement. By contrast the recovery of control costs is supported more generally by all respondent categories in the case of non-compliant products – see measure 3 (f) cost recovery to add deterrence to enforcement tools.

114 E.g. Cooperation of customs with express carriers to obtain information on small parcels ordered online from 3rd countries; the use of big data analytics in Rotterdam port to significantly reduce the number of controls that do not result in any findings (false positives). Partial information on import controls from a selection of Member States show potential for improved targeting of controls and referral to market surveillance authorities for in-depth checking (DGTAXUD - Customs and MSA limited Report on customs controls in the field of product safety and compliance in 2015, July 2016)

115 E.g. Compliance assistance schemes and audit practice by surveillance authorities in France, Netherlands (BSI study, 2017; Annex 14.3); the Authorised economic operator scheme under the Union customs code.

116 Technopolis, Final report, Ex-post evaluation of the application of the market surveillance provisions of Regulation (EC) n° 765/2008, May 2017.

gaps in their markets. From a Single Market perspective, this leads to a **lack of comprehensive risks assessment and overview** to identify priorities and target enforcement action¹¹⁷. Conversely market surveillance authorities would benefit from more exchanges with other Member States on market trends and intelligence that may also be or become relevant in their national or sectoral context¹¹⁸. Similar trends can be seen regarding controls at the external borders. Customs would be better prepared for current and future challenges with stronger coordination mechanisms and common priority setting, supported by considerably expanded common IT tools to ensure that controls are based on more comprehensive risk assessment and increased risks information exchanges¹¹⁹. While fragmented risk information hampers prioritisation and may thus weaken detection of infringements, also at the other end of the enforcement spectrum the **visibility of enforcement** effort may be adversely impacted if information is scattered (stakeholders ranked publicity to restrictive measures as the best way to improve deterrence).

Despite simplifications in the grant management rules for EU co-funded projects and increased co-funding rates, market surveillance authorities have **difficulties taking up funding made available in the form of project grants**^{120 121}. Projects span over a relatively short time, but require intensive preparations. For each project a new partnership has to be constituted and associated administrative effort is incurred anew. The management of a project partnership with market surveillance authorities of other member states places a considerable burden on the lead authority, beyond the core inspection business and requires dedicated project management skills. Due to pressures on staff resources, authorities refocus on domestic priorities. Cross-border cooperation projects may seem more burdensome and their benefits may seem more diffuse and not delivered in the short term. As a result the co-funded joint actions cover only a few sectors, without continuity over time or recurrence of controls and with varying participation of Member States. Although the need for resources for cross-border joint actions is real, the current funding mechanism can only provide a patchy response.

Coordinated market surveillance campaigns are conducted in the context of Administrative Cooperation Groups. These campaigns rely on the input from participating authorities without EU co-funding¹²². However only in 2 sectors regular yearly campaigns can be organised, one sector being chemicals for which the administrative support is made available through the Enforcement Forum of the European Chemicals Agency¹²³. Market surveillance authorities find it also increasingly

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- 117 In a national context Ph. Hampton reports that the organisation of inspection in many, scattered services led to a failure to use risks assessment comprehensively and consistently, and as a consequence lack of overview and ineffective targeting of controls (in: Reducing administrative burdens: effective inspection and enforcement, UK HM Treasury, 2005). The Dutch Court of auditors points out that authorities insufficiently share intelligence and lack sufficient market information to conduct robust risk assessment (Algemene rekenkamer, Producten op de Europese markt: CE-markering ontrafeld, January 2017 http://www.courttofaudit.nl/english/Publications/Audits/Introductions/2017/01/Products_sold_on_the_European_market_unraveling_the_system_of_CE_marking).
- 118 Technopolis – Final report Ex-post evaluation, May 2017; Prosafe - Lesson's learned and ways forward, International product safety week, Brussels, November 2016.
- 119 Developing the EU Customs Union and its governance, COM(2016)813 final, 21.12.2016.
- 120 Since 2013 the calls launched by DGGROW only resulted in 3 joint actions (1 in 2013, 2 in 2014). Calls for proposals in 2015 and 2016 failed to attract applications from market surveillance authorities in the area of industrial products.
- 121 Other funding opportunities are sometimes used. On a regular basis the Consumer Programme co-funds joint actions for a value of around 2 M€/year related to the General Product Safety Directive, but which can often be in conjunction with harmonised product legislation. A few projects under the research programme H2020 included compliance verification issues (eco-design (3 projects) and tyre labelling (1 project)).
- 122 The Commission provides funding for meetings of the administrative cooperation groups through a service contract. This contract covers reimbursement of travel costs, meeting room hire, etc.
- 123 See Annex 11.

difficult to take up the function of chair of an administrative cooperation group or can only do so for a shorter period of time¹²⁴.

The pressure on resources in national authorities thus compromises cross-border cooperation and limits coordinated actions authorities should take together to stop non-compliant products from circulating in the Single Market.

Informal networks, ngo's or professional associations can help to design and manage cross-border projects to a certain extent¹²⁵. The recurrent and prolonged funding of an association or informal network can be problematic viz. the requirements of the Financial Regulation. For reasons of transparency and accountability the role of informal networks or associations will be limited when it comes to aspects of enforcement cooperation that touch on the exchange of (sensitive) enforcement information, such as inspection reports, (draft) restrictive measures against operators or risk profiles.

2. MEASURES TO REINFORCE OPERATIONAL ENFORCEMENT CAPACITY

The Commission recognises the essential role of enforcement networks and set out to encourage and help Member States to improve their capacity to enforce EU law and make sure that administrative authorities and inspectorates are sufficiently and adequately equipped to perform their tasks¹²⁶.

The problem analysis above shows that **resources constraints are a main barrier** to overcome both **within member states** regarding enforcement in domestic markets **as well as in relation to coordination and cross-border enforcement** in the Single Market.

In the baseline scenario, EU level support for market surveillance is mostly provided by Commission services. The 2013 proposed Market surveillance regulation formalised the existing ad-hoc coordination, expert and administrative cooperation groups into a 'Forum'. Although a slight evolution in the baseline could be possible in terms of some further reallocation of staff and financial support to coordinated market surveillance actions, significant additional operational support capacity to market surveillance activity throughout the Single Market, as warranted by the scale of the problem, would go beyond the administrative support structures that can readily be made available within the Commission without dedicated additional resources. For the purposes of this impact assessment measures are evaluated to deliver **significantly more operational enforcement capacity** throughout the Single Market and hence explore in addition to the baseline, new delivery mechanisms to increase better enforcement performance information, funding for national controls' activity and a new governance structure¹²⁷ to provide direct operational support to joint market surveillance actions of market surveillance authorities.

124 E.g. reported in ADCO Chairs Meeting, 14 December 2016.

125 E.g. Prosafe acts regularly as "lead" partner in EU co-funded projects and has thus been instrumental in supporting cross-border projects and dissemination of best-practice. Despite this, the obligations on participating authorities in a co-funded project remain high and cause them to refrain from taking part in joint actions.

126 Commission Communication "EU Law: Better Results through Better Application", 13.12.2016, Pages 5-6.

127 Reviews of customs and taxation cooperation confirmed the importance of an adequate governance structure and resources to effectively support operational cooperation, address problems of sub-optimal use of time/resources, and improve the management of IT systems, information/best-practices exchanges and uniformity of action. Different tasks or component considered in isolation may provide insufficient critical mass to overcome fragmentation and would not be viable options. See: Future business architecture for the Customs union and cooperative model in the taxation area in Europe - Final report Task 3 – Business case of selected options, Deloitte study for DGTAXUD, June 2011.

As set out in paragraph 1 of this annex, a *general administrative fee* levied on all harmonised products in the EU could provide resources for market surveillance. However such a measure would merely place additional costs on law-abiding businesses, and may further place EU manufacturers at a disadvantage over foreign manufacturers. The measure was consequently rated unfavourably in the public consultation and not further examined in this impact assessment. Also a single *prescriptive quantitative target* for controls by all member states to cover all product sectors would not be feasible and be contrary to risks assessment principles (e.g. of the Union Customs Code). Risk assessment criteria could however be better specified and Member States could share more information on how priority areas for controls are selected. This could be done as part of national enforcement strategies.

Two measures are considered for this impact assessment:

2.1. National Enforcement Strategies

Enforcement strategies would be proposed by Member States according to their needs and specificities, and based on an **assessment of actual enforcement and capacity gaps** they may face. The strategies would detail how risks assessment principles are applied and priorities for controls selected. Performance indicators could be built to compare enforcement across member states. The market context and needs, in closing enforcement gaps and capacity building of Member States may be very different, depending on various parameters (e.g. compliance gaps, number of operators, presence or not of large point of entry for imports, available governance and coordination structures).

Parameters to distinguish different Member States' market surveillance profiles and possible best-practice benchmarks could be as follows¹²⁸:



In the future these **national comprehensive enforcement strategies** could also be the basis for **funding support** to Member States, covering **capacity building**, modernisation and alignment of control systems as well as funding of **testing and controls** in the Member States.

Elements that could be part of such enforcement strategies and supported by funding would cover the full spectrum of enforcement activity (strategy building, enhancing coordination and technical capacities and the performance of actual control campaigns):

128 Based on the requirements on market surveillance set out in Regulation (EC) n° 765/2008; ISO/IEC 17020 General criteria for the operation of various types of bodies performing inspection; OECD (2014) Best Practice Principles for Regulatory Policy Regulatory Enforcement and Inspections; and goods markets assessment and statistics in Technopolis (2017) final report ex-post evaluation of Regulation (EC) n° 765/2008.

- Investments to improve the knowledge of domestic markets and the evidence basis for enforcement;
- National coordination fora, cooperation protocols;
- Toolkits and training for inspectors;
- IT tools, investments in testing and internet investigation capabilities in national market surveillance authorities;
- Development and implementation of compliance assistance schemes for businesses;
- National control campaigns, including laboratory tests and public communication of the results and restrictive measures.

Regulation (EC) N° 765/2008 contains funding provisions that provide the legal basis for funding support. To increase the level of funding and make it easier to access for national authorities, this option examines the type of funding and its delivery mechanisms via Member State 'strategies' rather than co-funding on the basis of projects that have been privileged for cross-border actions and little resources directed at enforcement in domestic contexts.

The possibility and in particular the definitive size of a fund or an enforcement component in a new, larger EU fund (e.g. COSME, Consumer programme) is not examined as such in this impact assessment given that such an option would depend on the new multi-annual financial framework for the EU budget from 2021 onwards for which the outlines will only become available in the next year(s).

2.2. EU Product Compliance Network

2.2.1. Scope, tasks and structure of the EU Product Compliance Network

The EU Product Compliance Network would provide an administrative support structure to coordinate and help implementing cross-border **joint enforcement activities of Member States** (e.g. joint sweeps, coordinated control campaigns or other coordinated forms of inspections).

The role of the Network would be to support coordination and the practical management of joint enforcement actions of Member State authorities. It will not modify, replace or in any way supersede the responsibilities for market surveillance that remain the competence of member states.

Based on the existing cooperation support activities and the consultation results, **the key tasks** of an EU Network would be as follows (a detailed breakdown is given in the further background element in this annex, points 3.2 and 3.3):

- Intelligence gathering and knowledge sharing to underpin a strategy and priorities for the joint actions;
- Coordination and management of joint actions, including cooperation with customs;
- International cooperation;

- Best-practice, compliance assistance promotion, guidance development and dissemination;
- Information and communication systems development and maintenance (e.g. ICSMS), including inter-linkage with customs;
- Development and delivery of common training programmes.

The public consultation showed that respondents rated sharing of intelligence and coordination *between* Member States higher than similar measures within Member States. The core tasks of the Network concur with measures that were rated strongly positively in the public consultation, and perceived to increase resources and efficiency for market surveillance (~ 80% strongly agree/agree, see point 3,2 below for detailed responses).

The **structure of the Network** would be as follows, building on existing groups and activities in the baseline:

- An EU Product Compliance **Board** - composed of Member States and Commission representatives. Where relevant the Board would invite business, consumer or other representatives to participate to its meetings. The 'Board' would steer the network and supervise the Network's activity. It would meet several times a year. This would build on the experience with the current Expert group on Market surveillance.
- Administrative **Cooperation Groups** (ADCO) – thematic and sectoral groups of market surveillance authorities' representatives. This part of the Network would consolidate and expand the current 25 ADCOs to more sectors, adding possible cross-cutting issues, and more participating Member States. These groups would conduct and coordinate common market surveillance campaigns, ensure coordinated application of product legislation, develop common practices, on identified issues of common interest.
- A **Secretariat** – to manage the network and IT tools, prepare the Network's priorities, prepare and assist the implementation of joint market surveillance campaigns, carry out all the technical, legal analysis necessary to the Network's actions, and take care of the administrative and financial handling of joint actions and meetings. This part of the Network would be the most significant new addition.

For the **size variants of the Network**, 3 scenarios are developed for the staffing and operational resources of the Network's secretariat.

The 3 scenarios are:

- a **lower estimate** of 32 FTE and 5.7 M€/year operational budget (~10M€ in total);
- a **medium estimate** of 59 FTE and 9.95 M€/year operational budget (~18 M€ total);
- and a **high estimate** of 90 FTE and 13.9 M€/year operational budget (~26 M€ total).

The most significant tasks and resources of the agency would be concentrated on the management of coordinated actions, market studies and common priority setting for these actions, as well as the management of communication and IT systems. The initial set-up costs of the interfacing between customs systems (DGTAXUD) and ICSMS and national market

surveillance systems amounts in addition to 3,2M€ over a 5 year period¹²⁹. However, the depth and impact of the tasks carried out critically depend on the staffing level and operational budget chosen (details of content and expected results by tasks, cost assumptions and phasing in of the Network over time are given in further background elements in this annex point 3.3).

The **Staffing profiles** envisaged for the Network secretariat would be predominantly **AD** staff (~75%): for Head of the Secretariat, market surveillance technical, legal analysis, IT and data-systems.

AST staff (~15%): Support staff for meeting organisation, financial management tasks
Contract agents (CA, ~10%): Supporting external staff for routine IT maintenance and specific development projects.

Seconded National Experts (**SNE**) could be valuable to the Network, but is more difficult to factor in specifically for the start-up of the Network. The number of staff that authorities could second to form a structural part of the Network is uncertain. A key problem which the Network should overcome is the very limited resources that authorities can make available for cross-border cooperation (i.e. limited candidates for ADCO chairs, project coordinators, and limited skills for EU project coordination). The possibility for secondments should nonetheless be kept open and in due course, SNE could be useful to support the coordination with the Single Liaison offices of market surveillance in MS that the proposal establishes.

2.2.2. *Governance and hosting of the EU Product Compliance Network*

As to the **form of governance for the EU Network**, two variants are considered to host the EU network: within the **Commission** and by an **existing agency** (decentralised body or executive agency). These variants, Commission and a formal body, would both provide sufficient transparency and accountability needed for the coordination of enforcement involving the handling of sensitive information. The variant hosting within the Commission would involve additional, dedicated resources¹³⁰, not merely a limited, incremental progression to the baseline.

The variant of outsourcing the Network to informal networks (associations like Prosafe) is not further considered in detail as it would provide insufficient guarantees for the handling of sensitive enforcement information and it may lack authority to engage more Member States cooperation so that the variant would be unlikely to make a substantial difference to the baseline itself.

In theory a separate, new agency could be considered, however this variant is discarded, as it is unlikely to be a realistic option in the current political and budget context and the limitations to new bodies or agencies that can be proposed.

Governance mapping:

Variants	Strength	Weakness
1. Baseline, i.e. management of	<ul style="list-style-type: none"> No additional administrative or 	<ul style="list-style-type: none"> Only limited resources can be mobilised

¹²⁹ An interface of ICSMS and the RAPEX Rapid Alert notification system for product safety of consumer product was developed from 2013-2016 and became operational early 2017 (baseline).

¹³⁰ The role of the Commission needs moreover to be carefully balanced. Respondents to the public consultation were more favourable to enforcement decisions taken in close coordination via a product compliance forum (63% strongly agree/agree) than enforcement decisions taken by the Commission (42% strongly agree/agree). Public consultation, section Cross-border market surveillance in the EU, Question 8. See also option 4.

the Network by Commission	political costs	<ul style="list-style-type: none"> • Insufficient response to solve the problem • It does not attain the objectives
2. Outsourcing, i.e. Network hosted by an association or informal network of Member States' authorities (e.g. Prosafe)	<ul style="list-style-type: none"> • Full ownership by Member States who can design and dimension the platform to fit it to their level of ambition for coordinated action • The private structure will have more flexibility in hiring staff and managing procurement processes 	<ul style="list-style-type: none"> • The association or network will be depended on EU funding (grants) • Insufficient accountability, in particular for the handling of sensitive enforcement information and management restricted IT systems • Informal character (lack of authority) may be a weak incentive for Member States to participate and more strongly engage in coordinated cross-border enforcement
3. Hosting within the Commission , i.e. with more resources in dedicated unit(s) to manage the Network	<ul style="list-style-type: none"> • Enhancement in management of support contracts for meetings, enforcement projects and IT tools • Hosting in the Commission facilitates contacts and coordination on product legislation issues 	<ul style="list-style-type: none"> • Additional administrative costs and staff, reverting the current trend of decreasing resources in DG GROW in particular (lead on most of the sector legislation and coordinating role for the internal market for products) • Commission remains de facto in the driving seat with heavy involvement in daily, operational enforcement activity by and between Member States
4. Hosting of the Network by a formal body , i.e. 4(a) an executive agency such as EASME/CHAFEA or 4(b) an existing agency or body (e.g. EU-IPO)	<ul style="list-style-type: none"> • Transparent and accountable governance structure, offering Member States a clear steer on operational priorities as well as due Commission participation to ensure consistency and coordination on legislation related issues • Progressive, significant upscaling of resources in the medium to long term providing sufficient critical mass to impact on the problem of non-compliance 	<ul style="list-style-type: none"> • Significant upscaling of costs for staff and operational actions to be covered by EU budget - including COM supervisory staff for executive agency; which are set up for time-limited periods (risks of discontinuity); - in the case of integration in a fully self-financing agency, a zero or reduced charge to the EU budget could be possible if the mandate and funding sources of the agency would be extended to cover market surveillance. • Adaption and set-up costs to allow existing body to carry out the new additional activities
5. New agency	<ul style="list-style-type: none"> • Same as formal body with additional visibility due to the single focus on product compliance 	<ul style="list-style-type: none"> • Higher set-up costs and less opportunities for overhead sharing compared to integration in an existing structure • Contrary to limitations on the set up of new structures and unlikely to be feasible in current budget and political context

Regarding the variant hosting by an existing **regulatory agency**¹³¹, currently only in the area of chemicals (REACH/CLP) a structure supporting enforcement coordination exists by way of the 'enforcement forum' in the **European Chemicals Agency**. To a smaller extent the **Maritime Safety Agency** could cover some enforcement support and coordination tasks related to the Marine Equipment Directive¹³². Although both agencies have experience in enforcement of product legislation, their scope is rather specific. Hosting of the Network would imply in both cases a considerable extension to numerous new different products domains.

The EU intellectual property office (**EU-IPO**) does not directly implement harmonised product legislation, however its scope of activities¹³³ in supporting enforcement and

131 https://europa.eu/european-union/about-eu/agencies_en

132 Coordination with these structures remain relevant (e.g. use of ICSMS, combined risks assessment and joint actions targeting for instance dangerous chemicals present in industrial products in conjunction with other risks/non-compliance issues).

133 EU-IPO tasks portfolio includes for instance: promotion of best-practices and common cooperation tools, stakeholder engagement, knowledge gathering and sharing ("Observatory"), enforcement information exchanges, including with customs and international partners (law enforcement databases), and training ("EU-IPO academy").

cooperation in the internal market, e.g. against counterfeited products, has significant similarities with enforcement and compliance for industrial products and could offer a good basis to host the Network. Counterfeit/IP infringements and non-compliance are often interlinked (cheap, imitation products; imports are an important source of infringements). The Office has strong experience in knowledge gathering and sharing and managing of robust and secure IT systems.

The law enforcement agency **EUROPOL** would offer strong experience and capability for coordination of enforcement action and intelligence gathering, including e-commerce and international enforcement cooperation. Its remit and operational focus however is primarily linked to organised crime and criminal law investigations.

The scope of the harmonised product legislation in the scope of this initiative extends to over 60 legislative acts and product families. Other than the cases of chemicals and marine equipment and intellectual property, the currently existing EU decentralised bodies or agencies operate in quite distinct policy areas. Among the existing regulatory agencies **EU-IPO** offers the most synergies on policy and activities, and would constitute the most viable option to host the Network.

Executive agencies are set up to manage specific tasks, usually in relation to programme management and remain under supervision of the European Commission. They are set-up for a defined period of time. Currently existing agencies that already manage tasks in policy areas relevant for enforcement, product compliance and/or the internal market are EASME¹³⁴ (internal market, support to SMEs/businesses, eco-efficiency/design) or CHAFAE¹³⁵ (consumer protection and product safety, certain actions in food safety).

The type of tasks and staffing profiles of the Network would be predominantly technical and legal AD staff with market surveillance expertise. A smaller part only would be support staff for meeting logistics, financial handling of joint actions etc. Tasks which can be attributed to executive agencies are recurrent, administrative and financial handling, linked to programmes in particular. This implies that apart from the envisaged support staff, these agencies would have insufficient possibilities to recruit other technical profiles to constitute the full range of staff profiles that would be needed for the Network. As a consequence, the hosting of the Network by an executive agency would not be a viable solution.

2.2.3. *Comparison of hosting of the Network in the Commission versus EU-IPO*

This section looks at the implications and pro's and con's of the most viable options to host the Network, either the Commission or the EU-IPO. The outputs of the Network would primarily depend on the resources that are allocated to it (see point 3(b) below, outputs by the 3 different size scenarios for the Network).

- Hosting option in the Commission

Hosting in the Commission would facilitate the contacts and coordination with product legislation issues. The Commission would retain firm control over policy issues, but invest in working with Member States on daily operational enforcement activities. While the Commission has relevant available expertise in product legislation and policy, technical market surveillance expertise is not readily available.

134 https://europa.eu/european-union/about-eu/agencies/easme_en

135 https://europa.eu/european-union/about-eu/agencies/Chafea_en

In this option the **legislative proposal** would refer to the Commission ensuring the Secretariat of the Network.

All **costs** would fall to the EU/Commission budget, for a total of 10 M€/year (low estimate size of the Network), 18 M€/year (medium estimate), 26 M€/year (high estimate).

- *Staffing* chargeable to the administrative budget (heading 5): 4M€/year (low estimate), 8 M€/year (medium estimate), 12 M€/year (high estimate);
- *Operational budget*, mostly charging the Internal Market lines (current budget heading 1A): 6M€ (low estimate), 10 M€/year (medium estimate), 14 M€/year (high estimate).

Although the integration of the Network into the Commission could be feasible as such, limitations on resources affect all staff categories in the Commission and are likely to continue beyond 2020. This could reduce the possibilities to reach and maintain sufficient staffing/resources levels for the Network. In particular, in the current situation there would be less flexibility within the existing establishment plan allocated to DGGROW (responsible for most of the product legislation), so that additional posts would need to be redeployed from other policy areas and/or additional ones requested. Some synergies with other DGs/services could be exploited, e.g. with other DGs with responsibility for product legislation and controls (ENER, ENV, MOVE, TAXUD), JUST for general product safety and the JRC for its technical expertise in certain product areas. In due course, topping up of staff with seconded national experts or additional contract agents could also be considered (although also these staff categories are subject to resource ceilings in the Commission). The lower estimate Network (32 FTE) could be feasible with significant redeployment effort; a fortiori, the medium and higher estimates (60-90 FTE) would need additional posts allocations.

- **Hosting option in EU-IPO**

Hosting in a decentralised agency would allow Member States to take more ownership of coordination among themselves and fit their aspirations better. An agency would be more appropriate to attract the technical, professional specialised staff that would be needed to make the Network successful and is geared to deliver operational outputs. EU-IPO has a strong track record in delivering high quality outputs, supporting Member States, stakeholder engagement and large scale networks.

In this option the **legislative proposal** would have to including amending provisions to add the market surveillance tasks, such as envisaged for the Network, to the EU-IPO's tasks set out in Article 151 of Regulation (EU) 2017/1001 of the European Parliament and the Council¹³⁶. Subject to integration of market surveillance among the tasks in the EU-IPO founding regulation, its resources can be used to cover new tasks associated with the Product Compliance Network. The existing formal governance structures of the agency (management board, executive director) would remain unaffected. For the market surveillance tasks, the dedicated EU Product Compliance Board would steer the Network, and ensure a sufficient representation of Member States' market surveillance policy perspective. Moreover, in the case of a (partial) subsidy or ad-hoc grant for specific projects, additional provisions would need to the

136 <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R1001>

added to the EU-IPO regulation to reinforce financial controls required for EU bodies receiving subsidies (e.g. possibility to receive grants in well circumscribed cases, repayment of any un-used part of a subsidy, discharge procedure via the budget authority and possible further alignment of the agency's financial rules to the framework financial regulation for agencies).

The **costs to the EU-IPO budget** for the Network would be the similar as for the Commission option. Only staff costs are slightly lower as they are corrected for cost-of-living at the location of the agency (coefficient for Spain: 88,1). In total the Network costs to the EU-IPO budget would be: 9,5 M€/year (low estimate size of the Network), 17 M€/year (medium estimate), 24 M€/year (high estimate).

The **costs for the EU budget** could be zero in the case of full self-financing of the market surveillance tasks using existing EU-IPO resources. On a case by case basis, ad-hoc grants could be foreseen to cover specific costly investments in certain years (e.g. IT developments). Alternatively a mixed financing model (part subsidy/part use of existing EU-IPO resources) could be applied in case in future years the own resources of EU-IPO would not suffice, up to - in the extreme - full subsidising of market surveillance tasks in EU-IPO.

Limited one-off set-up costs for the Commission budget would need to be factored in relating to the hand-over and integration of the new tasks to the agency, including migration of IT systems¹³⁷.

Given the existing budget and human resources¹³⁸ availability in EU-IPO, the integration into the EU-IPO of the lower estimate variant of the Network (32 FTE) is considered to be feasible, without the need for a balancing subsidy from the EU budget. The medium and high estimated variants (60-90 FTE) could require additional external and/or statutory staff, including possibly new posts to be made available on the establishment plan of the EU-IPO¹³⁹. While currently the EU-IPO budget runs a surplus, in case of need, in future years a partial or balancing subsidy from the EU-budget could be foreseen (e.g. to cover specific market surveillance tasks), or on an ad-hoc basis a specific grant (e.g. specific IT developments involving important costs in a short period of time)¹⁴⁰.

The advantage of this hosting variant is that upscaling to at least the medium size variant of the Network would be feasible. For a similar sized Network the charge to the EU budget would be far less than in the Commission hosting variant.

137 Overall less than €70.000 one-off costs. Estimated adaptation costs: 0,15 FTE*€138,000; IT systems migration 1*0,15FTE*€138,000 + 2*0,15FTE*€70,000. In addition some meeting and travel costs Brussels-Alicante, where EU-IPO is located. The changes to formal regulations would be part of a possible legal proposal resulting from this impact assessment and not included in these operational start-up costs.

138 End 2016 854 statutory staff, 62 national experts; yearly budget volume around 400M€ (average 2014/2015/2016), accumulated surplus 182 M€ https://euiipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/contentPdfs/about_euiipo/annual_report/ar_2016_annex_01_en.pdf

139 The current agreement that requires EU decentralised agencies and bodies to streamline staff levels (-5% for EU-IPO), ends 2017.

140 Informal contacts in the preparation of this impact assessment between the Commission and the EU-IPO Executive director have confirmed that in principle the lower size Network up to a cost of 10 M€ could be integrated without additional resources, and without prejudice to further exploiting synergies with existing tasks and activities of EU-IPO. Indicatively for further upscaling its preference would be to continue working on a self-financing model (i.e. using EU-IPO resources, possibly ad-hoc grants for specific investments or projects) which allow EU-IPO to have more certainty early on in the planning cycle over yearly allocated resources and retain more flexibility in programming specific resources as needed to deliver the Network outputs.

In summary:

The Commission hosting option would be easier as regards the legislative proposal, but a strong Commission role in operational enforcement may not meet with Member States' aspirations to retain political oversight of the Network's activities. The main drawback is the uncertainty over resources, especially human resources that could be redeployed, and the limited flexibility to recruit additional or specific expertise to form a Network of sufficient size. The resourcing would furthermore be subject to the new multi-annual financial framework.

The EU-IPO hosting option would lead to a more complex legislative proposal, as the founding regulation of the agency would need to be amended which in turn may reopen discussions over the level and use of EU-IPO trademark fees¹⁴¹. The main advantage of this hosting variant are the higher flexibility for the agency to recruit expertise, more certainty and available resources so that upscaling to at least the medium size of the Network could be envisaged, hence providing for more critical mass for the Network to make a difference. For a similar size Network the charge to the EU budget would be far less, and limited to possibly an ad-hoc grant or subsidy in the future in case EU-IPO own resources would not suffice. The impact of the future multi-annual financial framework would primarily concern a possible subsidy from the EU budget.

3. FURTHER BACKGROUND AND COST/RESOURCING ELEMENTS

1. Market surveillance model

Over the last decade market surveillance experts have examined modelling to find answers to their questions on how optimum level of controls and associated resources could be determined to achieve the best results. In 2009 the UNECE working party on Regulatory Cooperation and Standardization Policies updated the **Market Surveillance Model Initiative** proposing an outline of a market surveillance effectiveness model as a more quantitative modelling tool for MSA's to assess the effectiveness of their market surveillance actions¹⁴². The working group recognised the need for relating technical requirements (technical legislation, standards), risk assessment, statistical aspects (sampling), along with conformity assessment aspects (measurement uncertainty), including non-tangible effects of public relation actions (visibility to the public/stakeholders).

The UNECE Advisory Group on Market Surveillance (MARS Group) recently reviewed the model and discussed ways to **improve foresight and prioritisation of market surveillance actions**¹⁴³. At present research does not allow concluding unequivocally what constitutes an effective market surveillance system. Against this background, regulatory frameworks typically do not clearly define outcomes of MS actions, i.e. what is the need on human and financial resources to get an effective market surveillance system. The setting of objectives in market surveillance actions stands out however as a key factor pre-conditioning successful and effective market surveillance interventions.

Improvements to the model were discussed, in particular by the use of dynamic models in order to capture the 3-party dimension of market surveillance (economic operator, end-user and surveillance authority) and to include economic assessments of the costs of doing

141 The trademark regulations have recently been amended; Regulation (EU) No 2015/2424 entered into force in March 2016.

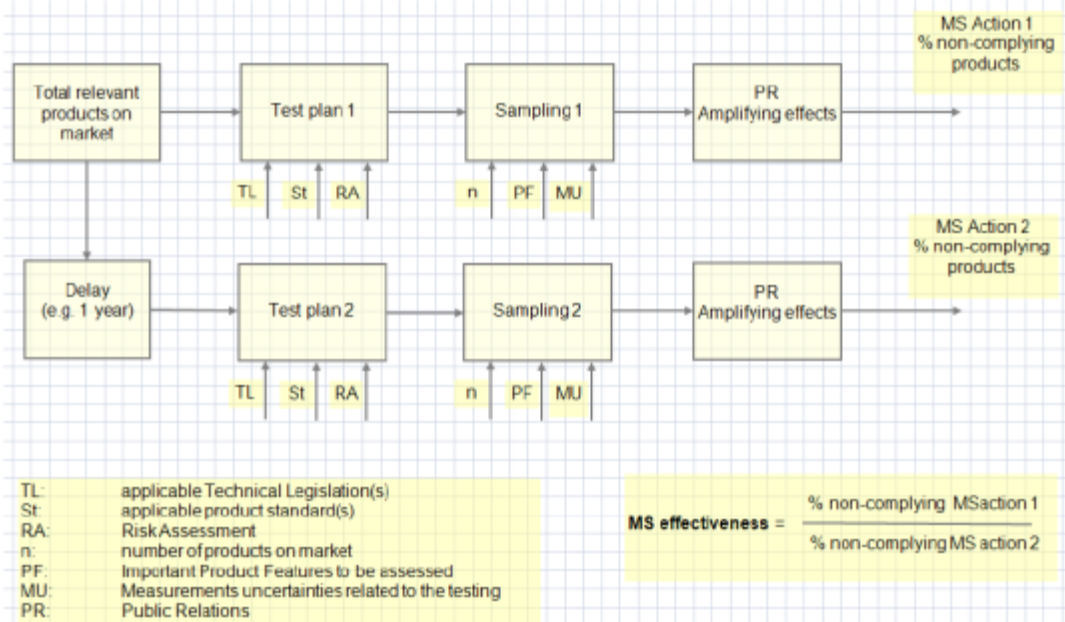
142 https://www.unece.org/fileadmin/DAM/trade/wp6/documents/2009/wp6_09_GMS_012E.pdf

143 14th meeting of the MARS group, 26-27 September, Geneva; <http://www.unece.org/index.php?id=43283#/>

testing/sampling together with the costs of incorrect decision making. Applying this approach to market surveillance actions, the model could become a tool to show if and when resources for market surveillance are sufficient.

Based on the first experiences with the enhanced model, the experts underline that simple conclusions cannot be made, in particular they caution that a larger budget does not necessarily mean a better market surveillance system. Besides continued research on the role of resources viz. market surveillance, the way forward would lie in promoting a broader view on critical elements that would underpin effective market surveillance systems and incorporating these into the Model like: setting objectives (“SMART” based general market surveillance strategy), setting and reporting on compliance rates, entry conditions, verification testing (sampling, pre-compliance testing), elements of a quality management system for market surveillance authorities and update to latest regulatory/standards developments.

Market surveillance effectiveness model (source, UNECE 2009¹⁴⁴):



144 https://www.unece.org/fileadmin/DAM/trade/wp6/documents/2009/wp6_09_GMS_012E.pdf

2. Public consultation: rating of measures to increase or improve efficient use of resources

Question 11: How could the resources for market surveillance activities be <u>increased</u> in your sector?; and Question 13: How could the resources for market surveillance activities be <u>used more efficiently</u> in your sector?				
Results for all respondents, sorted by percentage of agreement (strongly agree or agree)				
<u>All respondents</u>	Strongly agree or agree	Disagree or strongly disagree	No opinion	% Agree of total
13.6. Market surveillance authorities of <u>different Member States</u> should <u>share more intelligence</u>	207	15	17	87%
13.1. Market surveillance authorities should have <u>more knowledge about the relevant sector</u> (type and number of economic operators, market trends, etc.)	201	17	21	84%
13.8. Market surveillance authorities of <u>different Member States</u> should <u>better coordinate action</u>	201	16	22	84%
13.4. Market surveillance authorities' inspectors should receive more <u>standardised training</u> across the EU	189	24	26	79%
13.5. Market surveillance authorities <u>within a Member State</u> should <u>share more intelligence</u>	187	24	28	78%
13.7. Market surveillance authorities <u>within a Member State</u> should <u>better coordinate action</u>	185	27	27	77%
13.3. Market surveillance authorities' inspectors should receive <u>better training</u>	185	23	31	77%
11.3. Programmes at European level should <u>finance sufficient laboratory capacity</u> in each Member State	174	33	32	73%
13.9. Market surveillance authorities <u>within a Member State</u> should <u>share capacity of testing laboratories</u>	170	23	46	71%
13.10. Market surveillance authorities of <u>different Member States</u> should <u>share capacity of testing laboratories</u>	159	34	46	67%
11.1. Revenues obtained through <u>sanctions</u> should be <u>allocated</u> to market surveillance activities	155	52	32	65%
13.2. Market surveillance authorities should have <u>stronger powers</u>	125	76	38	52%
11.2. Market surveillance authorities should <u>levy administrative fees</u> on operators in their sector to finance controls	63	155	21	26%

3 (a) Key tasks and scope of a possible EU Product Compliance Network

Key tasks EU Body	Staffing levels			Operational budget		
	Lower estimate	Medium estimate	Upper estimate	Lower estimate	Medium estimate	Upper estimate
1. Work programme - strategy and priorities for coordinated action	1	3	5			
Market studies, intelligence gathering, knowledge sharing	2	3	5	1,000,000	2,000,000	3,000,000
2. Coordination joint actions, including online - support to MS network of authorities and sectors (ADCOS) and cooperation with customs	15	25	35	1,000,000	1,500,000	2,000,000
Management cooperation projects including financial support, studies, mapping lab capacities and joint procurement (e.g. testing capacity)				2,000,000	3,000,000	4,000,000
3. International cooperation	2	5	10	150,000	300,000	400,000
4. Best-practice, guidance, information and dissemination, promotion of compliance assistance	1	5	10	200,000	400,000	500,000
5. IT systems development and maintenance (incl. linkage to new customs systems)	10	15	20	600,000	750,000	1,000,000
- Information and communication system						
- Common digital tools						
6. Development and delivery of training programmes	1	3	5	750,000	2,000,000	3,000,000
Total	32	59	90	5,700,000	9,950,000	13,900,000
<i>average staff costs including overheads: 133.000€</i>	<i>4,256,000</i>	<i>7,847,000</i>	<i>11,970,000</i>			
<i>TOTAL HR, overhead, operational budget</i>				<i>9,956,000</i>	<i>17,797,000</i>	<i>25,870,000</i>

	Baseline	Projection references
1	Indicators, collection MS programmes, reporting (1 FTE); IMP-Market surveillance group and coordination (0.5 FTE)	
	<i>none</i>	Consumer programme scoreboards and market studies avg. 3M€ /year; EU-IPO Observatory 4M€/yr
2	Meeting support ADCO groups (1.5 M€/year, approx 50 meetings); 20 ADCO groups; customs-MSA meetings and guidance action plan activities TAXUD 1 FTE	Enforcement forum ECHA avg 7M€/yr (nb includes projects); EUROJUST operational expenses 5-6M€ (EJN, joint investigation teams meetings)
	Management 0.5 FTE - operational budget : approx. 2 M€/year project co-funding, studies (various sources GROW, consumer programme, H2020)	Product safety project grants 2-2.5M€
3	<i>limited</i>	RAPEX China, Authorised economic operators scheme/equivalence 3rd countries, EUROJUST/EUROPOL international operational MoUs
4	<i>ad-hoc/limited - BP guide, action plan activity online guidance JUST/GROW 1 FTE, 100K€/yr</i>	
5	ICSMS 600.000 €/year (400K development and 200K maintenance), 1.5 FTE oversight/coordination	Eurojust annual ICT projects, soft hardware,maintenance avg 2.5M€; interfaces and alignment Member States systems to ICSMS
	<i>Digital single gateway; otherwise limited - website EUROPA</i>	
	<i>none - only circabc for information exchange</i>	
6	<i>none - ad-hoc best practice dissemination</i>	Better training for safer food (SANTE/CHAFEA: 5 FTE; operational funding 16M€/yr); Customs/Fiscalis 2020 e-learning B-Train 10M€/4yr; Consumer law e-enforcement materials 2M€; consumer exchange of officials programme 150K€/yr

Notes:

An average **staff/overhead costs of 133,000 €/year** is used, covering all staff types – statutory (AD/AST) and contract staff. This average is based firstly on an assessment of the staff compositions and corresponding budgets in existing EU bodies and decentralised agencies (a sample of 26 bodies of different sizes, Single programming documents 2017-2019, titles 1 and 2 expenditure per capita of all AD/AST/Contract staff, corrected to a 100-weighting factor for location, i.e. corresponding to Brussels/Luxembourg). Secondly, the current applicable reference rates for Brussels/Luxembourg based Commission staff costs, which are: 138,000€/year per official and 70,000 €/year for contract agents (these amounts cover staff, plus building and office costs ("habillage"), November 2016, circular note DGBUDG). The proportion of administrative support or contract staff varies in the existing EU decentralised agencies and bodies examined for this impact assessment, but could be estimated at around 25% for the EU Network envisaged (meeting, administrative and IT support functions). An average cost of 133,000€ corresponds to these criteria and estimations.

The **estimations for the tasks** are based on extrapolating the Commission's experience in the implementation of the baseline with the current network of Member States (expert groups

IMP-Market Surveillance Group, ICSMS) and Administrative Cooperation Groups (ADCOs, ADCO Chairs group) and references from other relevant programmes and policy areas to gauge an adequate level of resources to fulfil the tasks (specific references are indicated in the table above).

The most significant tasks and resources would be **concentrated on the management of coordinated actions, market studies and common priority setting** for these actions, as well as the management of **communication and IT systems**.

Regarding coordinated enforcement actions, a significant increase in staff is projected to make human resources available to coordinate and assist in the management of cross-border actions. The lack of such resources is the main problem identified behind the low number of coordinated controls and the weak uptake of cross-border actions in the baseline:

- (i) in the lower estimate a stable number of ADCO groups, alternatively a larger number of ADCO groups and one FTE for 2 groups (lower estimate) or one FTE for each group (medium/higher estimates) is assumed given current demand and that more sectors need to be covered as well as new similar groups for cross-sector or cross-cutting issues (e.g. novel or complex product involving several legislations, customs, online issues). Additional staff are projected for overall work programme, direction, coordination and priority setting, which in the baseline accounts only for limited resources.
- (ii) meeting costs (e.g. travel) would need to increase with more groups and participants. A stable level to moderate increase is projected to take into account that digital communication tools (web-meetings, collaborative IT tools) could be exploited instead of reliance on physical meetings alone in the baseline;
- (iii) operational funding for actual coordinated control campaigns (e.g. test costs in such coordinated actions) is projected to be stable (lower estimate) to at least a moderate increase or doubling over the baseline (medium to higher estimates). With more available human resources to manage such funding, its effective uptake should be feasible. Resources for market studies, knowledge gathering are projected to comparable levels in consumer and intellectual property rights policy that are adequate proxies as regards type and scale of such actions.

Regarding communication and IT systems, only a moderate progression is projected in the lower estimate compared to the baseline (staff levels corresponding to current contractual expenditure, additional operational budget only to cover hard/software needs etc.). A more significant increase in resources compared to the baseline is projected in the medium and higher estimates to take into account that

- (i) the level of ICSMS usage by market surveillance authorities should increase, with mandatory use of ICSMS to improve enforcement coordination. This will require more capacity (higher numbers of concurrent users, storage), enhanced assistance to link up member states' systems and technical assistance to users (training, helpdesk);
- (ii) the functionalities of ICSMS, and its public website interface, would need to expand to support more extensive information exchange and monitoring of enforcement actions, requiring significant additional new programming (e.g. joint actions instead of single product/case records, adaptation to workflows, monitoring and reporting functionalities). In addition to direct input in the ICSMS database, also interfaces for

automatic data-feeding needs to be developed to allow more efficient inputs for Member States;

- (iii) the linkage with relevant customs systems is currently non-existent, several complex databases and communication systems would be involved and subject to strong data-protection and security requirements.

In addition to the running costs for the Network and its IT tools, the initial developments to allow interfacing of ICSMS and customs systems (including development of the Single Window environment) amounts to around 3,2M€ over a 5 year period, or ~640 000€/year (user requirements mapping and design, development, testing, and deployment - DGTAXUD). A similar interfacing of ICSMS with the Rapid alert system RAPEX was developed in 2013-2016 and is operational since 2017 (- DGJUST).

The phasing in over time of the Network, starting at the earliest from 2020 could be spread over 2 years (low estimate scenario), 3 years (medium estimate scenario) and 5 years (high estimated scenario).

EU Product Compliance Network																		
Low scenario (32 FTE)				Medium scenario (59 FTE)				High scenario (90FTE)										
Total	of which:			Total	of which:			Total	of which:									
32	20	AD		59	42	AD		90	60	AD								
	7	AST			10	AST			20	AST								
	5	CA			7	CA			10	CA								
Phasing in over 2 years:		2020	2021	2022 and onwards	Phasing in over 3 years:		2020	2021	2022	2023 and onwards	Phasing in over 5 years:		2020	2021	2022	2023	2024	2025 and onwards
1	AD 9-15	1	0	0	1	AD 9-15	1	0	0	0	2	AD 9-15	1	1	0	0	0	0
19	AD 5-12	12	7	0	41	AD 5-12	17	15	9	0	58	AD 5-12	20	15	10	8	5	
7	AST	4	3	0	10	AST	4	3	3	0	20	AST	5	5	4	3	3	0
5	AC (FG III/IV)	3	2	0	7	CA (FG III/IV)	3	2	2	0	10	CA (FG III/IV)	4	3	3	0	0	0
Added staff/year		20	12	0	Added staff/year		25	20	14	0	Added staff/year		30	24	17	11	8	0
Cumulative total		20	32	32	Cumulative total		25	45	59	59	Cumulative total		30	54	71	82	90	90

3 (b) Output by task of a possible EU Product Compliance Network

EU Product Compliance Network	Description tasks	Low Estimate	Outputs low estimate	Medium Estimate	Outputs medium estimate	High Estimate	Outputs high estimate
		Total staffing: 32 FTE Operational budget: 5,7 M€/year Total: ~10 M€		Total staffing: 59 FTE Operational budget: 9,95 M€/year Total: ~18 M€		Total staffing: 90 FTE Operational budget: 13,9 M€/year Total: ~26 M€	
Work programme – Strategy Market studies, intelligence gathering, knowledge sharing	<ul style="list-style-type: none"> • Organisation of EU Product Board meetings • Preparation of the work programme with priorities for joint actions • Performance indicators and peer review of member states' market surveillance strategies • Collecting statistics, drafting reports, terms of reference and procurement of market studies, dissemination • Consultation of the Network and stakeholders (e.g. emerging trends) 	3 staff 1 M€	<ul style="list-style-type: none"> • 1 Board meeting/year • 1 market study/year • 3 in-depth peer reviews/year (10 year cycle to cover all MS) 	6 staff 2 M€	<ul style="list-style-type: none"> • 2 to 3 meetings of the Board/year • 2 to 3 market studies/year • 5 in-depth peer reviews/year (6 year cycle to cover all MS) 	10 staff 3 M€	<ul style="list-style-type: none"> • 3 to 4 meetings of the Board/year • 3 to 5 market studies/year • 7 in-depth peer reviews/year (4 year cycle to cover all MS)
Coordination of joint actions - Support to ADCO groups, customs cooperation - Management of joint projects, procurement	<ul style="list-style-type: none"> • Organisation of ADCO group meetings, establishment new sectoral groups and thematic groups (e.g. online sales) - agenda, preparation legal/technical discussion documents, reports) • Preparation of joint actions of MSA and MSA/customs (research on topics, prepare product survey protocols, monitoring and reporting of results) • Monitoring and coordination of mutual 	15 staff 3 M€	<ul style="list-style-type: none"> • 15 coordinated control campaigns /year i.e. 1 every 2 years per existing product coordination groups • 1 joint procurement/partnership project (over a 5 year period) 	25 staff 4,5 M€	<ul style="list-style-type: none"> • 30 to 40 coordinated control campaigns /year i.e. 1/year per existing product coordination groups and controls on cross-cutting issues (online, joint actions with customs) • 2 to 3 joint procurement/partnership projects (over a 5 year period) 	35 staff 6 M€	<ul style="list-style-type: none"> • 70 to 80 coordinated control campaigns /year i.e. 2-3/year per existing product coordination groups and controls on cross-cutting issues (online, joint actions with customs) • 5 joint procurement/partnership projects (over a 5 year period)

EU Product Compliance Network	Description tasks	Low Estimate	Outputs low estimate	Medium Estimate	Outputs medium estimate	High Estimate	Outputs high estimate
	assistance requests <ul style="list-style-type: none"> • Financing of joint control campaigns • Coordination and development of partnership projects, memoranda of understanding with MSA and stakeholders (in areas of EU level relevance, e.g. internet platforms) • Mapping of laboratory testing capacity and needs • Joint procurement of tests for MSA 						
Operational enforcement information exchange with 3 rd countries authorities <i>These tasks could phase in later – to alleviate resources in start-up period</i>	<ul style="list-style-type: none"> • Exchange of information on cases and best-practice / guidance 	2 staff 0,15 M€	<ul style="list-style-type: none"> • Ad hoc review and exchange of cases 	5 staff 0,3 M€	<ul style="list-style-type: none"> • 2/year review and exchange of cases (<i>building on e.g. RAPEX China experience</i>) 	10 staff 0,4 M€	<ul style="list-style-type: none"> • 3-5 cooperation protocols over 5 year period with 3rd country/international partners, structural exchange of case information in priority areas
Best-practice, guidance, dissemination <i>These tasks could phase in later – to alleviate resources in start-up period</i>	<ul style="list-style-type: none"> • Prepare publications and disseminate reports, guidance, public information for professional and general public audiences (factsheets, website content) 	1 staff 0,2 M€	<ul style="list-style-type: none"> • Ad-hoc dissemination and information provision activity 	5 staff 0,4 M€	<ul style="list-style-type: none"> • ~25 dissemination actions/year (including control campaign results every month) 	10 staff 0,5 M€	<ul style="list-style-type: none"> • Information and variety of dissemination activities based on communication strategy by target audience (consumers, businesses, authorities, policy makers) • ~25 dissemination actions/year

EU Product Compliance Network	Description tasks	Low Estimate	Outputs low estimate	Medium Estimate	Outputs medium estimate	High Estimate	Outputs high estimate
							<ul style="list-style-type: none"> • 1 to 2 thematic communication campaigns/year • Guidance and on-line compliance assistance tools for businesses (product checklists) ~ basic set of tools in 5 years
IT systems development and maintenance - Information and communication systems - Common digital tools	<ul style="list-style-type: none"> • Maintenance and development of ICSMS and collaborative tools • Development of interfaces with MS market surveillance systems • Web-portal to relay publication of restrictive measures by MS • Linkage to customs IT systems (information exchange between customs and MSA – e.g. products/operators with high risk of non-compliance, suspension/refusal to release goods) 	10 staff 0,6 M€	<ul style="list-style-type: none"> • Increased number of investigation/evidence records (+50%) • Development of ICSMS to meet basic regulatory requirements • Additional functionalities and connection to MS and customs systems on an ad-hoc basis 	15 staff 0,75 M€*	<ul style="list-style-type: none"> • Increased number of investigation/evidence records (+75-100%) • In 5 years use by all MS and authorities (including interfaces with national systems) • In ~5-7 years : interface with relevant customs systems and public website (restrictive measures, banned products) 	20 staff 1 M€*	<ul style="list-style-type: none"> • Increased number of investigation/evidence records (+125-150%) • In 3 years use by all MS and authorities (including interfaces with national systems) and public website (restrictive measures, banned products) • In 5 years : interface with relevant customs systems
Development and delivery of training	<ul style="list-style-type: none"> • Mapping of training needs in different 	1 staff 0,75 M€	In 5 years: training mapping and basic	3 staff	<ul style="list-style-type: none"> • Training programme set-up in 1- 	5 staff 3 M€	<ul style="list-style-type: none"> • Training programme set-up in 1-

EU Product Compliance Network	Description tasks	Low Estimate	Outputs low estimate	Medium Estimate	Outputs medium estimate	High Estimate	Outputs high estimate
programmes	<ul style="list-style-type: none"> MS/sectors Development of training levels and skills (grid) Development/Procurement of training packages (e-learning, workshops) Management of training programmes 		programme design; procurement for outsourced delivery of basic trainings	2 M€	<ul style="list-style-type: none"> 2 years Build-up of e-learning resources: 5-10 courses/e-learning modules/year 3 to 4 learning events/year (workshop, webinars) 		<ul style="list-style-type: none"> 2 years Build-up of e-learning resources: 20-25 courses/e-learning modules/year 10-15 learning events/year (workshop, webinars)

* Additional set-up costs: 3,2 M€ over 5 years, i.e. 640K€/year for the initial development of the MSA-customs systems interfacing, including the Single Window environment.

In the event of hosting in EU-IPO, synergies could possibly be exploited with existing staff working on a number of activities in EU-IPO, in particular the Observatory (studies, intelligence gathering, outreach to stakeholders, enforcement database/links to customs) and the EU-IPO academy.

Similarly in the Commission hosting variant synergies could be exploited within the services of Commission. This corresponds more or less to the baseline situation, in which in addition to DGGROW staff specifically allocated to coordination of market surveillance and implementation of Regulation 765/2008 is complemented with varying resources in product sector units and scattered over other DGs. In addition, additional resources are made available as part of service contracts (especially for IT, logistics of meetings).

EU Product Compliance Network	Estimate sizes of the EU Network			Indicative potential synergies with existing COM staff (baseline)	Indicative potential synergies with existing EU-IPO resources
	Low estimate	Medium estimate	High estimate		
	32 FTE Total ~10 M€	59 FTE Total ~18 M€	90 FTE Total ~26 M€	~10 staff	~ 20 FTE
Work programme – Strategy Market studies, intelligence gathering, knowledge sharing	3 staff 1 M€	6 staff 2 M€	10 staff 3 M€	~2 staff	~ 2 staff <i>Knowledge sharing, studies (Observatory)</i>
Coordination of joint actions - Support to ADCO groups, customs cooperation - Management of joint projects, procurement	15 staff 3 M€	25 staff 4,5 M€	35 staff 6 M€	~ 5 product sector staff ~ 1-1,5 customs experts	-
Operational enforcement information exchange with 3rd countries authorities	2 staff 0,15 M€	5 staff 0,3 M€	10 staff 0,4 M€	-	~ 3 staff <i>Cooperation 3rd countries, agencies</i>
Best-practice, guidance, dissemination	1 staff 0,2 M€	5 staff 0,4 M€	10 staff 0,5 M€	-	~ 3 staff <i>Outreach, Observatory</i>

IT systems development and maintenance - Information and communication systems - Common digital tools	10 staff 0,6 M€	15 staff 0,75 M€	20 staff 1 M€	~1,5 staff	~ 10 staff <i>Extensive IT systems, enforcement databases (incl. customs)</i>
Development and delivery of training programmes	1 staff 0,75 M€	3 staff 2 M€	5 staff 3 M€	-	~ 2 staff <i>Trainings (EU-IPO academy)</i>

ANNEX 13: BACKGROUND INFORMATION ON OBJECTIVE 3 – STRENGTHENING THE ENFORCEMENT TOOLBOX

1. POWERS OF AUTHORITIES

1.1. Baseline

As regards to the tools currently available to market surveillance authorities to promote compliance and discourage non-compliance EU rules on market surveillance provides authorities (including customs) with the following powers:

- a) *Require economic operators to provide information and documentation, enter the premises of economic operators, take the necessary samples of products.*¹⁴⁵ The relevant provisions do not specify if authorities can take the samples for free or if they are expected to pay for them.
- b) *Take measures to restrict the marketing of products found to compromise the health and safety of users or those which are in any case non-compliant.*¹⁴⁶ Restrictive measures are subject to proportionality and other relevant requirements¹⁴⁷. The relevant provisions do not regulate the publication of the measures. Information on restrictive measures are shared among authorities by means of official notification mechanisms (see Annex 13 section 1.2), but it is limited to authorities. Measures concerning products presenting a serious risk are shared among Member States through the Rapid Alert system RAPEX¹⁴⁸, however only information about the product is published on the Commission's website¹⁴⁹ while the actual text of the measures and the name of the businesses concerned are not.
- c) Current rules do not state any common principles for *cost recovery* by market surveillance authorities. As regards customs Articles 189, 197 and 198 of the Union Customs Code regulate the sharing or recovery of costs related to the transport of goods to the place of examination, the handling and the taking of samples, as well as costs related to the confiscation or the destruction of goods.

Furthermore, the EU legal framework contains the obligation for Member States to:

- d) Ensure that market surveillance authorities *seek in the first place the cooperation of undertakings* and, only if the latter fail to take adequate action, adopt compulsory measures. As a matter of fact, where surveillance authorities find that the product does not comply with the requirements laid down in the Union harmonisation legislation, require the relevant economic operator to take voluntary corrective action to bring the product into compliance with those requirements, to withdraw the product from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe. Where the relevant economic operator does not cooperate to take adequate corrective action, the market surveillance authorities has to take all appropriate provisional measures to prohibit or restrict the product's being made available on their national market, to withdraw the product from that market or to recall

145 Article 19(1) of Regulation (EC) No 765/2008.

146 Articles 16(2) and 20(1) of Regulation (EC) No 765/2008.

147 Article 21 of Regulation (EC) No 765/2008.

148 Article 22 of Regulation (EC) No 765/2008.

149 https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/main/?event=main.listNotifications

it¹⁵⁰. Authorities can also destroy or render inoperable products presenting a serious risk. The relevant provisions do not regulate the issue of the cost of controls and corrective measures in case of lack of cooperation.

- e) Adopt rules on *penalties applicable to infringements by economic operators* of the provisions of national law adopted pursuant to the relevant Directive or Regulation. Member States must also take all measures necessary to ensure that these rules are enforced¹⁵¹. The general principle throughout EU harmonisation legislation is that the penalties provided for have to be effective, proportionate and dissuasive and may be increased for repeated infringements.¹⁵² The specific procedural rules and penalties applicable by market surveillance authorities are defined in national legislation.

As mentioned in the problem definition section authorities can use these powers vis-à-vis a broad range of economic operators making available products, however it is unclear whether new economic actors emerging in the online environment can also be addressed. Furthermore, a major challenge for authorities in the use of their powers is the fact that in the case of products supplied on line from third countries the relevant business may not be present in the EU and could not be forced to reimburse costs or pay penalties.

1.2. Possible common powers - Availability of power in Member States

A number of legal principles that are expected to help increasing incentives to comply, according to the academic literature on responsive regulation, and facilitate detection and corrective action by authorities (notably in relation to on-line sales imports from third countries). In particular, the following elements are identified:

- Recovery of market surveillance costs (e.g. for laboratory tests or product destruction) in case products checked are found to be non-compliant products
- A regime of publicity for decisions to restrict the marketing of products
- Rights of consumers/end users to return non-compliant products or to have them fixed at no charge,
- Possibility for authorities to request businesses on a case-by-case basis to compensate consumers and other end users
- Powers and corresponding businesses obligations allowing authorities to detect non-compliant products and take corrective action, notably in relation to on-line sales and imports from third countries. These include: powers to carry mystery shopping; the possibility for authorities to ask for information and request cooperation for corrective action to any party enabling the supply of products; the obligation for manufacturers located in a third country to have authorised representative (only) if they place products directly in the EU and not via an EU importer or manufacturer; when no manufacturer or authorised representative or importer is located in the EU, authorities could request customs declarant to cover the relevant costs.

150 Summary of reference provision R31 of Annex I of Decision No 768/2008/EC.

151 A more detailed overview of the provisions on penalties in Union harmonisation legislation is set out in Annex 1. Annexes 2, 3 and 4 set out how the provisions on penalties in the Directives on the safety of toys and on Pyrotechnic articles were transposed by the Member States.

152 Article 41 of Regulation (EC) No 765/2008.

- Specification of existing common criteria for penalties (e.g. proportionality, deterrence) that would lead to basic EU common principles for sanctions determined in Member States' legislation and applied by national authorities.

Table 13-1: Available investigative powers in Member States (based on ex-post evaluation Regulation (EC) No 765/2008)¹⁵³

Powers of Inspection	MS having this power in 14 or more sectors	MS who have this power in more than 14 sectors	MS who had this power in less than 14 sectors	MS who do not have the power in any sectors
<i>Carry out sector inquiries*</i>	17	BE, BG, CY, CZ, DE, DK, EE, FI, HR, LT, LU, NL, PL, RO, SE, SI, UK	AT, ES, IE, LV	0
<i>Do mystery** shopping</i>	10	BG, CY, CZ, EE, FI, LV, NL, SE, SI, UK	AT, DK, IE, IT, LT, LU	BE
<i>Request info/ cooperation by any possible natural or legal person</i>	14	BG, CY, CZ, DE, DK, EE, LT, LU, NL, PL, RO, SE, SI, UK	AT, BE, ES, FI, HR, IE, IT, LV	0
<i>Seize and detain products*</i>	14	CY, CZ, DE, DK, EE, FI, HR, LU, LV, NL, PL, RO, SE, UK	AT, BE, BG, ES, IE, LT, SI	0
<i>Seize documents*</i>	13	CY, CZ, DE, EE, FI, HR, LU, NL, PL, RO, SE, SI, UK	AT, BE, BG, DK, ES, IE, LT, LV, SI	0
<i>Take samples for free***</i>	13	CZ, CY, DE, DK, EE, FI, HR, LT, LV, NL, PL, SE, SI	AT, BE, BG, ES, IE, IT, LU, UK	0
<i>Make use of test reports made by other MSAs****</i>	13	BG, CY, CZ, DE, DK, EE, FI, LT, LU, LV, SE, SI, UK	AT, BE, HR, IE, NL, PL	0

* No information available for IT

** No information available for DE, ES, HR, PL and RO

*** No information for RO

**** No information for Es, IT, RO

Main Conclusions

22 Member States reported information.

- The investigative powers are widely available in the Member States, however not always in all or a majority of product sectors.
- On average 13 of the 22 reporting member states had all 7 powers in a majority of sectors (14 or more sectors).
- On average 7 of the 22 reporting Member States had the investigative powers in less than 14 sectors.
- Toys, electrical appliances and PPE were the most common sectors in which to have the various powers. Powers in these 3 sectors were commonly available.
- The following sectors have 2 of the powers: Recreational craft, machinery, and construction products and radio and telecommunications equipment.
- The following sectors have 1 of the powers: Medical devices, cableways and biocides, so powers in these sectors were less available.

Notes:

- For 6 member states there was no or too little information: EL, FR, HU, PT and SK are missing (5 member states) and there was very limited information available for Malta.
- All 33 sectors were covered.

Table 13-2: Available enforcement powers in Member States (based on ex-post evaluation Regulation (EC) No 765/2008)

	MS having this power in more than 14 sectors	MS having this power in 14 or more sectors	MS having this power less than 14 sectors	MS who do not have this sanction
<i>Destroy products</i>	15	BG, CY, CZ, DE, DK, EE, FI, HR, LT, LV, NL, PL, RO, SI, UK	AT, BE, ES, IE, LU, SE	IT
<i>Impose administrative economic sanctions (without resorting to national courts)</i>	14	BG, CY, CZ, EE, HR, LT, LU, LV, NL, PL, RO, SE, SI, UK	AT, BE, DE, FI, IE, IT	DK, ES
<i>Impose compensation for consumers/users of non-compliant products</i>	2	PL, SI	BE, BG, CY, CZ, DE, ES, FI, HR, IE, LT, SE, UK	AT, DK, EE, IT, LU, LV, NL, RO
<i>Impose provisional measures pending investigations</i>	13	BG, CY, CZ, DE, EE, FI, HR, LT, LU, LV, PL, SE, SI	AT, BE, DK, ES, IE, IT, UK	NL, RO

	MS having this power in more than 14 sectors	MS having this power in 14 or more sectors	MS having this power less than 14 sectors	MS who do not have this sanction
<i>Publish decisions on restrictive measures</i>	14	BG, CY, CZ, DE, EE, FI, HR, LT, LU, LV, NL, PL, SE, SI	AT, BE, DK, IE, IT, RO, UK	ES
<i>Recover from economic operators costs borne to test products found to be non-compliant</i>	14	BG, CY, CZ, DE, EE, FI, HR, LT, LU, LV, PL, RO, SE, SI	AT, BE, DK, IE, IT, NL, UK	ES
<i>Sanction economic operators that do not cooperate</i>	15	BG, CY, CZ, DE, EE, HR, LT, LU, LV, NL, PL, RO, SE, SI, UK	AT, BE, DK, ES, FI, IT, IE,	0
<i>Shut-down websites*</i>	1	LV	BE, BG, CY, EE, IE, UK	AT, CZ, DE, DK, ES, FI, HR, IT, LT, LU, NL, PL, SE, SI
<i>Take off or require to take off illegal content from a websites*</i>	8	BG, CZ, FI, LU, LV, NL, SI, UK	BE, CY, DE, DK, EE, HR, IE, LT, PL, SE	AT, ES, IT

* No information for RO

Main Conclusions

22 Member States reported information.

- With the exception of the power to order compensation for consumers and the power to take off content or to shut down websites, the enforcement are widely available in the Member States, however not always in all or a majority of product sectors.
- While sanctions are generally available in a majority of member states, some Member States lacked sanctioning powers.
- On average, 11 of the 22 reporting member states had all 9 enforcement powers in a majority of sectors (14 or more sectors).
- On average, 7-8 member states had the enforcement powers in a minority of sectors (less than 14 sectors).
- The majority of sanctions were available in the majority of sectors, except "*impose compensation for consumers/users of non-compliant products*" and "*shut-down websites*", which were available in a minority of sectors.

Notes:

- All 33 sectors were covered.
- EL, FR, HU, PT, MT and SK are missing (6 member states).

Conclusions on investigative and enforcement powers by Member States

While powers are generally widely availability, there is a variation by coverage of sectors and in particular some Member States currently have fewer powers in place than others. For each power the details are given in tables 13-1 and 13-2.

By Member State, this shows that 15 (68%) of the 22 reporting Member States have 10 to 14 of the total 16 powers. However **a group of 7 Member States have less than 10 of the 16 powers**, and would thus have to adapt more than others to these new powers if these powers would become part of the minimum toolbox for all market surveillance authorities.

Member States that currently report the least powers (either none or in fewer than 14 sectors) are: AT, BE, ES, IE, and IT (0-1 of the 16 powers in over 14 sectors). DK and RO have few powers (only to 6-8 of the 16 powers in over 14 sectors). For Italy and Romania information was provided but missing for specific powers – the conservative assumption taken here is that these powers would be lacking, but the categorisation of these Member States could be better than the available information suggests.

For 6 Member States no information was provided (EL, FR, HU, PT, MT and SK). No assumption is made for these Member States¹⁵⁴.

1.3. Power to order compensation to consumers

The fragmentation of competences has important consequences on the efficiency and effectiveness of controls by market surveillance authorities. First of all, when restrictive measures are ordered, market surveillance authorities find it is difficult to enforce their decisions in other Member States due to the territorial scope of administrative decisions, their enforceability and language issues. Respectively 52% and 55% of authorities participating in the consultation confirmed that businesses located in another Member State do not reply to requests for information/documentation and for corrective actions^{155 156}. Thus, in practice authorities can effectively address non-compliance issues only with businesses located in their national territory (e.g. national or local distributors)¹⁵⁷. Second, this atomisation of competences implies that authorities focus on products available in their jurisdiction and therefore a product that is found to be non-compliant in one Member State may in practice still be made available in another Member State. Thirdly, market surveillance authorities can reach easier manufacturers within jurisdictions of MS, than manufacturers established outside the EU. Last but not least, the increasing volume of online sales also triggers a significant share for personal imports from third countries (B2C).

As regards liability of traders vis-à-vis consumers for product non-compliance, national jurisdictions in the MS provide for non-contractual liability of manufacturers. Where a

154 Some of these member states indicated that their absence of response to the evaluation survey on powers was due to time constraints, and have indicated (e.g. FR) that the powers would be generally available.

155 Taking action against non-compliant products traded by businesses located in another EU Member State was considered difficult businesses do not reply to requests for information/documentation (52% of authorities agreed/strongly agreed, 22% disagreed/strongly disagreed, 26% no opinion/no experience /no answer) and for corrective actions (55% of authorities agreed/strongly agreed, 19% disagreed/strongly disagreed, 26% no opinion/no experience /no answer). Furthermore 57% of authorities declared no experience in imposing penalties on businesses located in another Member State, while 25% of authorities agreed/strongly agreed enforcement of penalties is difficult, 7% disagreed/strongly disagreed, 12% provided no answer. The previous percentages are based on the total number of participants to the consultation, including those not replying to this particular question.

156 Major high costs components for market surveillance authorities are collecting/assessing information from businesses, interacting with authorities from other member states perceived often to lead to a dead end (study on the impact of digital compliance, VVA April 2017, annex 14).

157 Interestingly, 26% of authorities participating in the consultation believe they are not even entitled to contact a business outside its jurisdiction.

consumer good is not in conformity with the contract, Directive 1999/44/EC provides for the rights of the consumer vis-à-vis the seller, i.e. contractual liability of the consumer's contract partner. Moreover, enforcement powers in the revised Consumer Protection Cooperation Regulation will provide the basis for the competent enforcement authorities to obtain commitments from trader to offer adequate remedies to the consumers, where appropriate (Article 9(4)(c)), and, where applicable, the power to inform consumers that claim that they have suffered harm as a consequence of an infringement covered by the Regulation about how to seek compensation under national law (Article 9(4)(d))¹⁵⁸. On a case-by-case basis the enforcement authorities can thus establish whether in specific cases as part of remedies a compensation would be adequate (e.g. for extra costs incurred due to an infringement) and request trader's commitment in this regard.

Consumers and other stakeholders often lack information about the compliance of products they respectively purchase, use, distribute or compete with. The general public and individual consumers are normally not aware of issues relating to product compliance, which are often not visible to non-experts, unless the product would be clearly dangerous¹⁵⁹. For instance compliance does not appear to be a main criterion when choosing a product to purchase.

According to Union legislation on products, distributors must act with due care in relation to the requirements applicable when they make a product available on the market. Thus they potentially play an important role in preventing the marketing of non-compliant products¹⁶⁰. In practice however, provided that distributors, who are to a large extent SMEs, are aware of the relevance of compliance, they rely mostly on documentation from the manufacturer or the importer, and only a minority of them uses information on non-compliant products such as the Rapex notifications or newsletters by association or consumer organisations¹⁶¹.

According to the review of the EU consumer law (Fitness Check)¹⁶², consumer organisations emphasised in the public consultation that enforcement of EU consumer rules must be clearly linked with substantive remedies/redress¹⁶³ and that the absence of contractual remedies of the Unfair Commercial Practices Directive 2005/29/EC was recognised as a gap¹⁶⁴.

For certain products non-compliance could result in additional financial costs for the consumer. For example non-compliant measuring instruments¹⁶⁵ could lead to inaccurate measurements and consequently erroneous cost or price calculations (e.g. scales, electricity meters, fuel pumps). Wrongly labelled products may similarly lead to undue costs for consumers (e.g. additional energy costs due to underperformance of a product compared to the declared energy class¹⁶⁶). Establishing financial compensation for such cost would require amongst others the identification of additional financial costs incurred by consumers that

¹⁵⁸ <http://www.consilium.europa.eu/en/press/press-releases/2017/11/30/consumer-protection-in-the-digital-age/>

¹⁵⁹ See figure 7 in Anne 9 to the Evaluation SWD.

¹⁶⁰ The general rule is that, before making a product available on the market, distributors have to verify that the product bears the required conformity marking or markings, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in the applicable Union harmonisation legislation.

¹⁶¹ Study on the promotion on the use of RAPEX information by importers, distributors and retailers in the field of consumer product safety, with a particular focus on SMEs, CIVIC Consulting, August 2015, p. 42.

¹⁶² Commission Staff Working Document SWD(2017) 209 final, http://ec.europa.eu/newsroom/just/item-detail.cfm?item_id=59332

¹⁶³ Ibid. pp. 118 and 128.

¹⁶⁴ Ibid. p. 118.

¹⁶⁵ Based on EU product rules (in particular the Measuring Instruments Directive (MID, 2014/32/EU); Non-automatic Weighing Instruments Directive (NAWID, 2014/31/EU), consumers and professional users should be able to trust that measuring instruments are accurate and safe to use.

¹⁶⁶ Relevant EU harmonisation legislation includes Regulation (EU) 2017/1369 of 4 July 2017 which sets out a framework for energy labelling http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.198.01.0001.01.ENG&toc=OJ:L:2017:198:TOC

could be linked to a confirmed non-compliance, a timescale over which to calculate such costs, and the possible evidence that could reasonably be asked from consumers to substantiate a request for compensation. These elements will vary from case-to-case and are highly depend on the type of product and usage. A definition of sufficiently clear and enforceable common criteria for fair and proportionate financial compensation to consumers across all harmonised products covered in this initiative is not feasible and consequently not further pursued. [Other policy instruments may need to be considered when non-compliance leads to additional financial costs for the consumer](#)

Avoiding court action seems to be further supported by business responses to the online public consultation in the review of the EU consumer law, with 80% of them indicating among benefits of complying with EU consumer rules the following: ‘Consumers whose rights are respected come back’, ‘consumers whose rights are respected bring/attract other consumers’ and ‘consumers whose rights are not respected discourage other consumers’, and 8 % indicating ‘other’ benefits such as avoiding lawsuits or other administrative procedures; comparing more favourably against competitors; and increasing consumer trust¹⁶⁷.

In practice not all consumers take action following the discovery of a faulty product, across the EU, and when they do they either address the seller or the manufacturer¹⁶⁸. The financial loss due to a faulty product is on average EUR 81, including travel costs, cost of repairs, cost of expert advice, reduction in value of the product, depending on the type of product.¹⁶⁹

Consumer detriment or harm arises when market outcomes fall short of their potential, resulting in welfare losses (financial, health, etc.) for consumers. As regards financial detriment, the consumer bear the cost of the original product; the cost associated with the reduced functioning of the goods concerned as a result of the problem; costs associated with actions taken to sort out the problem – including travel and legal costs, other type of expert advice or assistance, but also the cost of buying a replacement/substitute product, lost earnings, consequential damages to the consumer's property¹⁷⁰. To these, non-financial detriments are to be added, including loss of time and psychological detriment.

According to sectoral instruments of Union harmonisation legislation on products, distributors must act with due care in relation to the applicable requirements. They must verify, for example, that the products are accompanied by instructions and safety information and that the manufacturer or importer has complied with some packaging requirements. Where distributors have reasons to believe that the product does not meet the essential requirements, sector legislation prohibits them to make the product available on the market until it has been brought into conformity.

By way of concluding, the current framework provided by national jurisdictions allowing non-contractual liability for manufacturers along with contractual liability of sellers vis-à-vis consumers purchasing goods for the lack of conformity with the contract within the meaning of Directive 1999/44/EC and enforcement powers for competent authorities in relation to remedies under the proposed revised Consumer Protection Cooperation Regulation is sufficient to ensure appropriate remedies in the event of a decision of market surveillance on a product being not compliant with provisions of Union harmonisation legislation on products.

167 Ibid. p. 38.

168 Study on the costs and benefits of the minimum harmonisation under the Consumer Sales and Guarantees Directive 1999/44/EC and of potential full harmonisation and alignment of EU rules for different sales channels, available at http://ec.europa.eu/newsroom/document.cfm?doc_id=44638, p. 32.

169 Ibid, p. 32.

170 Ibid, pp. 69-70.

2. EXTRATERRITORIAL ENFORCEABILITY (OPTION 3(D))

2.1. Enforceability of Union Harmonisation Legislation and responsibilities of economic operators

a) Direct sales by manufacturers

In the traditional model, wholesalers made up an entire industry by serving as the middlemen between manufacturers and consumers. They would purchase items in bulk from the makers at a set price, then sell it to consumers at a higher rate, often doubling or tripling their output. Manufacturers continued this business model for years because it was the only way to get their products in front of customers. Wholesalers provided the manpower, infrastructure and retail space that the manufacturers just could not afford on their own. In this model, manufacturers made only small profits compared to wholesalers' profit margins. Because direct sale was their only option, manufacturers did not have much power to challenge the system. But with the internet's ability to connect them directly with people who want their goods, manufacturers can take the wholesalers' profits for themselves. Previously, companies needed interested wholesalers to be viewed as a legitimate company. They needed the validation of an established retailer to get in front of customers and make sales.

However, with the rise of the internet and small businesses leveraging websites, that business model is evolving rapidly. Manufacturers are increasingly skipping wholesalers altogether and are selling products directly to their consumers. With e-commerce, it is obvious that customers no longer buy just what is available; they are willing to seek out very specific items to meet their needs and interests. Companies of every size have made millions selling completely online, often shipping from private homes and garages. By skipping retail space costs and wholesaler fees, they can also afford to sell the products for a lower price, making them all the more attractive to consumers¹⁷¹. An online survey of 109 U.S. sales channel decision-makers at brand manufacturing organizations in 2014 showed that, overall, customer satisfaction drove manufacturers to launch a direct-to-consumer sales channel, with 72% of respondents citing a closer relationship with consumers as a reason for creating a direct-to-consumer sales channel. 82% of respondents said selling directly to consumers improved their customer relationships, and 76% reported that it improved customer experience¹⁷². For many manufacturers, an important reason to sell directly to consumers is the potential to collect massive amounts of customer data.

This constitutes a major challenge for the enforceability of market surveillance measures, especially when the manufacturer is established outside the EU.

b) Basic concepts of extraterritorial enforcement

In a world where businesses and individuals are increasingly operating in a global context, the issue of the extraterritorial application of legislation is assuming greater importance. Traditionally, the exercise of jurisdiction by a state was generally limited to persons, property and acts within its territory. However, the growth of multinational corporations doing business across borders and on a global scale, the ease of modern travel, the globalisation of banking and stock exchanges, technological developments such as the internet, and the emergence of transnational criminal enterprises and activities, have encouraged states to reflect on how to exercise jurisdiction beyond their territorial boundaries. The steady increase

171 <https://www.thebalance.com/manufacturers-selling-directly-to-consumers-3975412>

172 <https://www.digitalcommerce360.com/2014/06/10/when-manufacturers-sell-directly-consumers-online-retailers/>

in states exercising extraterritorial jurisdiction has not, however, resulted in an abatement of the controversies surrounding such exercises. Extraterritorial jurisdiction involves a fundamental dilemma. On the one hand, every state has the right to regulate its own public order, so it is entitled to legislate for conduct occurring within its territory. This principle is often considered to be a corollary of state sovereignty. On the other hand, businesses and individuals are increasingly acting, and producing effects, across state borders¹⁷³.

There are two approaches to distinguishing between different types of jurisdiction when exercised by a state. Outside the United States, the most common approach is to distinguish between prescriptive and enforcement jurisdiction. Prescriptive jurisdiction refers to the authority of a state to make its law applicable to particular persons or circumstances, usually through adopting legislation or, in some cases, through courts developing the law. Enforcement jurisdiction, which is the subject of this part of the impact assessment, refers to the authority of a state to take action to enforce those laws through, for example, arresting, detaining, prosecuting, convicting, sentencing and punishing persons for breaking those laws. There is general agreement that, subject to a permissive rule to the contrary, a state may not exercise executive jurisdiction in the territory of another state without the second state's consent. Thus, a state cannot investigate a crime, arrest a suspect, or enforce its judgment or judicial processes in another state's territory without the latter state's permission. That does not mean, however, that it cannot undertake enforcement measures within its own territory, such as by prosecuting an offender found within the state's territory even, potentially, for acts committed outside its territory. Nor would it prevent a state requesting extradition of a suspect from another state¹⁷⁴.

The starting point for jurisdiction is that all states have competence over events occurring and persons (whether nationals, residents or otherwise) present in their territory. This principle, known as the 'principle of territoriality', is the most common and least controversial basis for jurisdiction¹⁷⁵. In addition, states have long recognised the right of a state to exercise jurisdiction over persons or events located outside its territory in certain circumstances, based on the effects doctrine¹⁷⁶, the nationality or personality principle¹⁷⁷, the protective principle¹⁷⁸ or the universality principle¹⁷⁹. This list is not necessarily exhaustive, as other bases of

173 International Bar Association, Report of the Task Force on Extraterritorial Jurisdiction (2009), p. 5.

174 International Bar Association, Report of the Task Force on Extraterritorial Jurisdiction (2009), p. 8-10.

175 The principle has both subjective and objective limbs. Subjective territoriality describes the jurisdiction of a state over conduct that occurs entirely within that state's borders. Objective territoriality refers to the jurisdiction of a state over conduct that only partially occurs in that state's territory.

176 Commentators on extraterritoriality often refer to the effects principle as an additional basis for asserting extraterritorial jurisdiction. The effects principle allows states to assert jurisdiction over conduct occurring extraterritorially if that conduct has an effect on their territory. The effects principle is easily confused with objective territoriality. However, it differs from objective territoriality in that no constituent element of the offence takes place within the territory of the asserting state (Ireland-Piper D., 'Prosecutions of Extraterritorial Criminal Conduct and the Abuse of Rights Doctrine', <http://www.utrechtlawreview.org> | Volume 9, Issue 4 (September) 2013 | URN:NBN:NL:UI:10-1-112946, p. 78).

177 The nationality principle authorises extraterritorial jurisdiction by a state over its nationals, even where the conduct may have occurred extraterritorially. Like the territorial principle of jurisdiction, this principle also has two limbs. If jurisdiction is asserted over a national accused of being a perpetrator of extraterritorial conduct, this is described as 'active nationality'. If the national is a victim of extraterritorial conduct, then jurisdiction over that national is termed 'passive nationality' (Ireland-Piper D., 'Prosecutions of Extraterritorial Criminal Conduct and the Abuse of Rights Doctrine', <http://www.utrechtlawreview.org> | Volume 9, Issue 4 (September) 2013 | URN:NBN:NL:UI:10-1-112946, p. 73).

178 The protective principle is invoked to justify claims of extraterritorial jurisdiction by a regulating state for offences against its national interest. This might include the security, integrity, sovereignty or government functions of that state. In particular, a state may rely on the protective principle because acts that threaten its security or national interest may not be illegal in the state where they are being performed (Ireland-Piper D., 'Prosecutions of Extraterritorial Criminal Conduct and the Abuse of Rights Doctrine', <http://www.utrechtlawreview.org> | Volume 9, Issue 4 (September) 2013 | URN:NBN:NL:UI:10-1-112946, p. 77).

179 The universality principle refers to the right of states to assert jurisdiction over serious international crimes regardless of where the conduct occurs, or the nationality of the perpetrator(s). The theory is that some crimes are so offensive to international peace and security that all states are regarded as having a legitimate interest in their proscription and punishment.⁸¹ Unlike other grounds of extraterritorial jurisdiction, which demand some connection with the regulating state (such as the nationality of the perpetrator or the victim), this principle provides every state with a basis to prosecute certain international crimes (Ireland-Piper D., 'Prosecutions of

jurisdiction may be recognised in the future. Nor are all of these bases of jurisdiction equally well accepted.

In the online context, the enforcement of legislation about products is problematic: A country may lack the ability to enforce its laws against actors who are located outside the country and who locate their assets outside the country (“absent actors”). The internet makes it extremely easy for actors to act from remote locations, including from outside the country in which their internet acts cause effects, and to locate their assets outside the country. Although alternative means of enforcement exist that target other persons and entities, such as intermediaries, the alternative means also present challenges. There are at least two significant reasons to improve the enforceability of national laws on the internet and their enforceability against absent actors. First, as a general rule, effective laws require the possibility of effective enforcement; to the extent that laws should be followed, countries have to be able to enforce the laws, including laws in the online context and against absent actors. Second, improvements in the enforceability of national laws against absent actors are also desirable because alternative enforcement mechanisms have specific problems and cannot fully replace direct enforcement against absent actors¹⁸⁰. Yet, the lack of enforceability of product legislation, especially in an online and global context, is incompatible with one of the key objectives of the Digital Single Market Strategy for Europe. A Digital Single Market is one in which the free movement of goods, persons, services and capital is ensured and where individuals and businesses can seamlessly access and exercise online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of their nationality or place of residence¹⁸¹.

c) Basic concepts of enforcement of Union harmonisation legislation on non-food products

- (1) Enforcement of Union Harmonisation Legislation is done by market surveillance authorities, i.e. the authorities responsible for carrying out activities and taking measures to ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection. In most cases, their decisions and measures are of an administrative nature and neither judgements nor judicial decisions. Therefore, these decisions and measures usually fall outside the general framework of judicial cooperation and mutual recognition of judgements and judicial decisions.
- (2) Market surveillance measures and decisions need to be enforceable not only to address the immediate risks related to the products that are found to be non-compliant, but also to ensure that the manufacturer takes, on the one hand, all corrective measures to eliminate the non-compliance of other products that were made available on the market and, on the other, all possible steps to prevent any further non-compliance to occur in the future. This latter aspect which aims at preventing any future non-compliance is not less important than the former, the objective of which is to eliminate the immediate risks. Any reasonably circumspect manufacturer who is confronted with findings of non-compliance which he/she prefers not to challenge will use these findings to adapt the manufacturing process, to revise the conformity assessment

Extraterritorial Criminal Conduct and the Abuse of Rights Doctrine', <http://www.utrechtlawreview.org> | Volume 9, Issue 4 (September) 2013 | URN:NBN:NL:UI:10-1-112946, p. 76).

180 Trimble, Marketa, Extraterritorial Enforcement of National Laws in Connection with Online Commercial Activity (April 30, 2015). RESEARCH HANDBOOK ON ELECTRONIC COMMERCE LAW, John A. Rothchild ed., Edward Elgar, 2016; UNLV William S. Boyd School of Law Legal Studies Research Paper. Available at SSRN: <https://ssrn.com/abstract=2600925>, p. 1.

181 COM(2015)192.

procedure and/or to ensure that the storage or transport conditions do not jeopardise compliance.

- (3) Union Harmonisation Legislation on products can only be enforced with respect to, on the one hand, products falling within its scope and, on the other, economic operators who have to meet certain obligations laid down in the legislation. These obligations are set out in most instruments of current Union harmonisation legislation on products. These instruments regulate the supply chain and are usually built on two concepts:
- (a) **'placing on the market'**, i.e. the first making available of a product on the Union market and
 - (b) **'making available on the market'**, i.e. any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.

The core principles of **'placing on the market'** and **'making available on the market'** can be summarised as follows:

- (1) **All products that are subject to Union harmonisation legislation on products and that are placed on the Union market must comply with the Union rules.** The placing on the market is the most decisive point in time concerning the application of the Union harmonised legislation. Union harmonisation legislation does not distinguish 'active' sales¹⁸² and 'passive' sales¹⁸³. It covers both. Products offered for sale online by sellers based outside the EU are considered to be placed on the Union market if sales are specifically targeted at EU consumers or other end users. The assessment of whether or not a website located inside or outside the EU targets EU consumers has to be done on a case-by case basis, taking into account any relevant factors such as the geographical areas to which dispatch is possible, the languages available used for the offer or for the ordering, payment possibilities, etc¹⁸⁴. When an online operator delivers in the EU, accepts payment by EU consumers/end-users and uses EU languages, then it can be considered that the operator has expressly chosen to supply products to EU consumers or other end-users¹⁸⁵ (active sales). Products bought by a consumer in a third country while physically present in that country and brought by the consumer into the EU for the personal use of that person are not considered as being placed on the market¹⁸⁶.
- (2) Products can be **"placed on the market"** either by **manufacturers** in the EU or in third countries or by an **importer**, defined as *"any natural or legal person established within the Union who places a product from a third country on the Union market"*.

182 'Active' sales mean actively approaching individual customers by for instance direct mail, including the sending of unsolicited e-mails, or visits; or actively approaching a specific customer group or customers in a specific territory through advertisement in media, on the internet or other promotions specifically targeted at that customer group or targeted at customers in that territory. Advertisement or promotion that is only attractive for the buyer if it (also) reaches a specific group of customers or customers in a specific territory, is considered active selling to that customer group or customers in that territory (Commission Guidelines on Vertical Restraints, SEC(2010)411).

183 'Passive' sales mean responding to unsolicited requests from individual customers including delivery of goods or services to such customers (Commission Guidelines on Vertical Restraints, SEC(2010)411).

184 Judgement of the CJEU of 12 July 2011, case C 324/09 L'Oréal/eBay.

185 Section 2.3 of Commission Notice — The 'Blue Guide' on the implementation of EU products rules 2016, OJ C 272, 26.7.2016, p. 1.

186 Ibidem.

- (3) **The manufacturer and the importer are the only economic operators who are allowed to place products on the market.** The individual consumer is not an "importer" as he/she will not supply the product to anyone else (if they do, they become an "importer"). The concept of placing on the market refers to each individual product.
- (4) Most Union harmonisation legislation places **responsibility for compliance on the manufacturer of the product** concerned. Even where the manufacturer is outside the European Union, and therefore out of legal reaches of the EU enforcement authorities, the manufacturer has certain obligations (e.g. quality control) which they cannot pass to other parties.

2.2. Enforceability: baseline

2.2.1. Enforceability within the EU

Hence, the manufacturer has a key role in ensuring the compliance of the product and, correspondingly, in the enforcement process. Market surveillance is the most effective when the problem can be solved at its source, i.e. when the product is manufactured or finalised in view of its placing on the EU market.

Countries typically rely on their own enforcement power to enforce their national laws. When legislators legislate national laws they assume that their country will have the power to enforce the laws. This is indeed the case when the country's courts and authorities have jurisdiction over an actor, and the actor or his assets are located within the country. In such circumstances courts and authorities of the country can apply the country's law and, if necessary, order various enforcement actions against the actor to force the actor to comply with the law¹⁸⁷. Within the EU, the enforceability of market surveillance measures is feasible, though not always very easy in cross-border situations within the EU, with respect to manufacturers established in the EU, importers who, by definition, should be established in the EU and manufacturers outside the EU who appointed an authorised representative.

Manufacturers outside the EU who place major volumes of products on the EU market usually rely on an importer in the EU (scenario 1 in Table 13-3 below) or an authorised representative (scenario 2 in Table 13-3 below), and/or use a distribution network in the EU. Although there are no statistics on the number of importers and authorised representatives, it would be very difficult in practice to run a major commercial operation in the EU without an importer or an authorised representative who actually defends the exporters' commercial and legal interests in the EU, and without a distribution network.

In addition, there are several areas of the single market for products where enforceability of market surveillance measures can be effectively done, for example:

- through the withdrawal or the limitation of the type-approval of the motor vehicle,
- through the withdrawal or the limitation of the substance, mixture or article (REACH, CLP and biocidal products)
- where EU legislation already requires a responsible person in the EU (e.g. medical devices, cosmetics, energy efficiency labelling).

187 Trimble, M, o.c., p. 9.

2.2.2. Enforceability in other situations

However, market surveillance measures are very difficult to enforce when the product was placed on the market by a **manufacturer outside the EU without an importer, an authorised representative and without the involvement of a distributor in the EU** (scenario 3 in Table 13-3 below). In this case, the manufacturer remains outside the jurisdiction of European authorities. These manufacturers can easily ignore any measures taken against them and their products. Furthermore, the very short supply chain between the supplier and the consumer and the high number of small parcels that are used to ship the products to the consumers in the EU diminish the likelihood of market surveillance controls.

The lack of enforceability of market surveillance measures as regards manufacturers outside the EU is problematic for three reasons. The first is that the aim of Union harmonisation legislation is either to protect the Union consumers or the environment. The second is the level-playing field, i.e. the protection of Union-based businesses manufacturing non-compliant products against unfair competition from third country manufacturers who export products to the EU which do not comply with Union harmonisation legislation. EU manufacturers, importers, authorised representatives and distributors are subject to market surveillance, restrictive measures and possibly penalties while manufacturers outside the EU are not directly affected by market surveillance. The third is that it leads to undue costs for market surveillance authorities to implement their decisions.

Table 13-3: Summary					
Scenario 1		Scenario 2		Scenario 3	
Manufacturer established outside the EU					
↓ Importer (EU)		↓ Authorised representative (EU)		↓ Fulfilment centre (EU) (3A)	(3B) ↓
↓ Distributor (EU) ↓	↓	↓ Distributor (EU) ↓	↓	↓	
EU Consumer					

2.3. Cases in which enforceability is problematic (scenario 3)

Scenarios 1 and 2 are already covered by the baseline and therefore do not lead to additional obligations/costs. Scenario 3 is a steadily growing issue. The lack of enforceability of market surveillance measures against manufacturers established outside the EU mainly concerns items that are bought online from a supplier established outside the EU (section 3.1 below) which are then sent in small consignments to the consumer in the EU (section 3.2 below).

2.3.1. Items bought online from a supplier established outside the EU

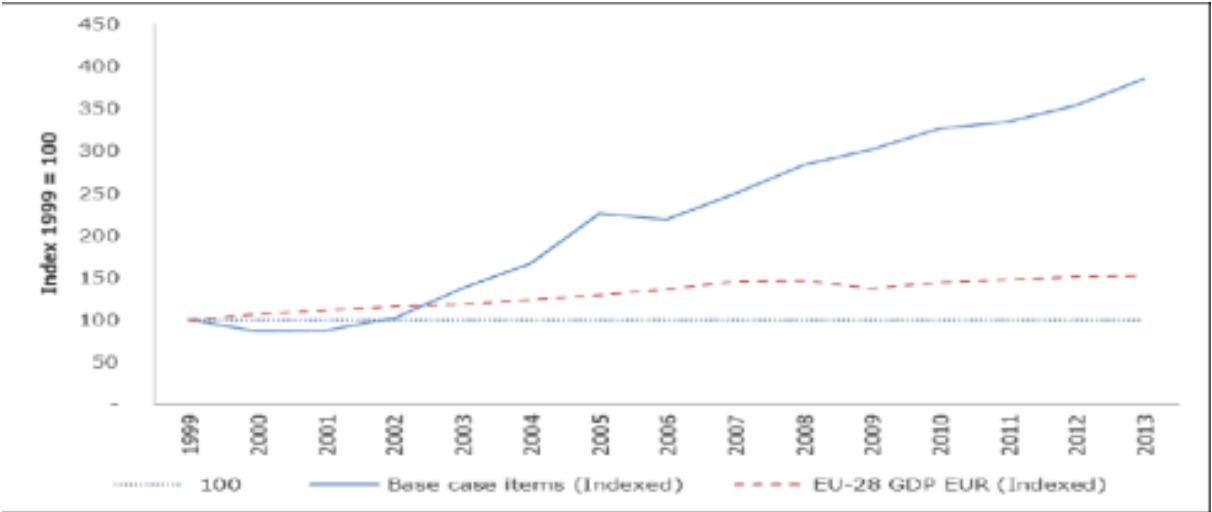
The e-commerce market is growing very rapidly within the overall retail sector. The value of retail e-commerce in the EU is estimated at €231 billion (around 1.8% of EU GDP)¹⁸⁸. E-

188 SWD(2015)274 Estimate based on the results of the "Consumer surveys identifying the main cross-border obstacles to the Digital Single Market and where they matter most", GfK, 2015, http://ec.europa.eu/consumers/consumer_evidence/market_studies/obstacles_dsm/docs/21.09_dsm_final_report.pdf.

commerce in goods is estimated at €212 billion and represents by far the biggest share of the online market. Most of this trade (80%) currently concerns goods¹⁸⁹ produced domestically, while 13.6% (€28.8 billion) concerns cross-border e-commerce inside the EU28 and only a 5.6% share concerns (€11.8 billion¹⁹⁰) purchases of goods originating outside the EU28. This includes both B2C and B2B trade.

However, over the last five years the number of European citizens ordering goods and services online has increased by 13 percentage points, to 53%¹⁹¹.

Figure 13-1: Growth in international receipts of small consignments from outside the EU vs GDP growth from 1999 to 2013¹⁹²



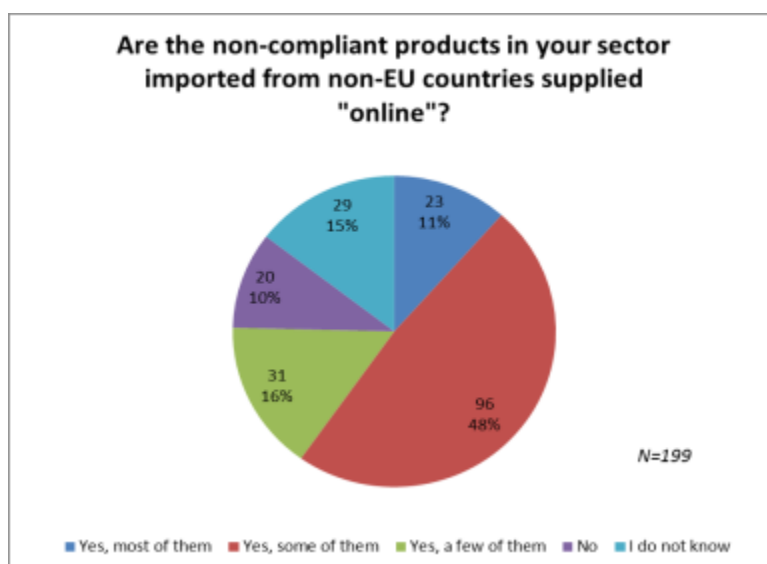
At very least a similar trend is expected over the next period. The share of goods purchased on line which is coming from countries other than the location of the purchasers is also expected to increase. Forecast show that by 2018, 83% of all EU cross-border buyers will choose to purchase from another EU country¹⁹³, due to natural market trends but also to policy (Digital Single Market strategy) aiming at removing existing barriers to cross-border trade. Based on the total volumes of international small consignment receipts originating from outside the EU in the table below, it is also reasonable to assume that the share of online trade from third countries will grow.

Table 13-4: Total volumes of international small consignment receipts originating from outside the EU (millions)¹⁹⁴

189 The survey was carried out in the first half of 2015 and refers to purchases made by consumers in the precedent 12 months.
 189 The estimate actually also includes in addition to goods also the purchases of off-line services (travel services and leisure events reservation).
 190 Interestingly Forrester reports a similar value (€ 10.8 billion) for online purchases by EU consumers which are imported from outside the EU in 2015. Forrester (2015), Western European Online Cross-border Retail sales Forecast, 2013-2018, reported in: Copenhagen Economics, "e-Commerce imports into Europe: VAT and customs treatment", May 2016
<https://www.copenhageneconomics.com/publications/publication/e-commerce-imports-into-europe-vat-and-customs-treatment>
 191 Digital progress report 2016, Internet use, Page 5 <https://ec.europa.eu/digital-single-market/en/european-digital-progress-report>
 192 https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/lvcr-study.pdf
 193 <https://www.forrester.com/European+Online+CrossBorder+Retail+Sales+To+Reach+40+Billion+By+2018/-/E-PRE8024>
 194 https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/lvcr-study.pdf

	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Austria	1.84	1.86	1.45	1.52	2.22	2.88	4.40	4.27	4.70	5.30	5.26	5.38	4.89	4.96	5.51
Belgium	0.46	0.46	0.45	0.61	0.90	1.16	1.64	1.83	2.12	2.44	2.65	2.91	3.04	3.26	3.58
Bulgaria	0.22	0.24	0.21	0.25	0.27	0.30	0.41	0.29	0.43	0.48	0.51	0.48	0.49	0.44	0.49
Croatia	0.08	0.11	0.10	0.11	0.16	0.18	0.31	0.27	0.31	0.36	0.38	0.41	0.45	0.46	0.61
Cyprus	0.14	0.13	0.12	0.14	0.15	0.19	0.33	0.37	0.43	0.55	0.58	0.56	0.58	0.54	0.52
Czech Rep.	0.57	0.61	0.59	0.66	0.77	0.77	0.93	1.03	1.21	1.54	1.54	1.66	1.42	1.30	1.28
Denmark	3.41	3.44	3.52	2.91	3.45	3.60	5.48	5.27	5.78	6.50	6.42	7.27	6.51	6.55	7.28
Estonia	0.10	0.10	0.08	0.11	0.12	0.13	0.20	0.14	0.17	0.21	0.25	0.27	0.29	0.36	0.45
Finland	0.75	0.65	0.56	0.54	0.76	0.68	0.90	0.97	1.13	1.30	1.34	1.41	1.38	1.44	1.59
France	1.35	1.32	1.37	2.01	3.10	4.05	5.66	6.46	7.54	8.70	9.55	10.47	11.10	12.00	13.13
Germany	3.66	3.68	3.61	4.02	5.54	6.77	9.72	10.39	11.79	13.45	14.22	15.39	15.53	16.48	18.12
United Kingdom	10.17	5.92	6.88	9.50	12.12	14.74	17.02	11.92	14.10	15.48	16.85	18.30	19.97	21.31	22.81
Greece	0.40	0.37	0.39	0.49	0.60	0.76	0.99	1.13	1.31	1.49	1.62	1.76	1.84	1.98	2.17
Hungary	0.29	0.31	0.24	0.16	0.18	0.31	0.46	0.51	0.62	0.65	0.74	0.71	0.86	0.78	0.87
Ireland	0.80	0.95	1.11	0.77	1.17	1.47	1.62	1.77	2.04	2.35	2.55	2.78	2.91	3.12	3.42
Italy	0.84	0.70	0.66	1.10	1.51	1.95	5.23	5.36	5.68	6.46	6.78	7.19	6.90	7.07	7.74
Latvia	0.08	0.09	0.09	0.11	0.13	0.16	0.18	0.18	0.22	0.23	0.23	0.24	0.25	0.23	0.26
Lithuania	0.08	0.08	0.08	0.13	0.17	0.22	0.31	0.35	0.42	0.47	0.49	0.56	0.62	0.67	0.72
Luxembourg	0.26	0.31	0.38	0.51	0.63	0.71	0.84	0.96	1.08	1.13	1.05	1.15	1.26	1.36	1.50
Malta	0.06	0.06	0.05	0.04	0.05	0.05	0.09	0.08	0.12	0.16	0.19	0.17	0.15	0.14	0.15
Netherlands	0.79	0.80	0.82	1.18	1.54	1.89	2.10	2.25	2.49	2.89	3.24	3.59	3.91	4.26	4.65
Poland	1.06	1.14	1.19	0.59	0.80	0.91	1.33	1.50	1.68	2.09	2.16	2.20	2.07	2.43	2.79
Portugal	0.35	0.31	0.31	0.31	0.36	0.38	0.42	0.48	0.52	0.61	0.67	0.73	0.78	0.84	0.89
Romania	0.55	0.49	0.49	0.62	0.68	0.69	1.03	0.75	0.83	0.78	1.07	1.28	1.39	1.31	1.28
Slovakia	0.12	0.15	0.18	0.35	0.77	1.08	0.40	0.44	0.66	0.69	0.93	0.99	1.06	1.10	1.17
Slovenia	0.01	0.07	0.06	0.11	0.16	0.20	0.21	0.29	0.28	0.33	0.43	0.49	0.62	0.91	1.05
Spain	0.96	0.97	0.86	1.16	1.65	2.26	3.58	4.16	4.74	5.43	5.73	6.13	6.17	6.54	7.19
Sweden	0.40	0.40	0.39	0.57	0.87	1.14	1.60	1.81	2.10	2.43	2.42	2.92	3.07	3.31	3.64
Total	29.78	25.70	26.24	30.57	40.83	49.62	67.39	65.20	74.47	84.48	89.84	97.39	99.47	105.15	114.85

E-commerce concerning products coming from another country could be an important source of non-compliant products. Respondents in the public consultation confirmed that e-commerce is now a noticeable channel through which non-compliant products reach the EU from third countries. 75% of the respondents indicated that 'most' or 'some' non-compliant products imported from non-EU countries were supplied online¹⁹⁵.



Although market surveillance investigation campaigns on products sold online are not systematically or regularly conducted in all product sectors and Member States, results

¹⁹⁵ Public consultation, question 3, section B5 Market surveillance of products imported from non-EU countries.

reported from past individual campaigns and projects nonetheless point to increasing trends of non-compliant and illegal products offered via e-commerce channels. For example, the OECD carried out an online 'product safety sweep' carried out in April 2015 that involved 25 countries inspecting a total of 1 709 products. Both in domestic and in cross-border e-commerce, the sweepers found that banned or recalled products could still be found for sale online (70% of inspected products), incorrectly labelled products (80%) and products that do not meet voluntary or mandatory safety standards (53%). In particular with respect to products that do not meet voluntary or mandatory safety standards, the level of non-compliance was twice as high at cross-border level (88% of inspected products) than at domestic level (44% of inspected products)¹⁹⁶.

2.3.2. *Types of consignments sent from outside the EU to consumers in the EU*

Items bought online from a supplier established outside the EU can be sent to the consumer by a fulfilment service provider established in the EU (scenario 3A above) or as a small consignment (scenario 3B).

2.3.2.1. Fulfilment service provider (scenario 3A)

Fulfilment centres are third party services that take care of fulfilling client orders on the business owner's behalf. Fulfilment centres take charge of receiving the products from the supplier, housing the inventory, receiving the orders from the business owner's clients, and packaging and shipping said orders to the business owner's clients.

The assumption is that these fulfilment centres are established in the EU and that the legislative proposal will ensure that they will be subject to market surveillance measures¹⁹⁷.

2.3.2.2. Small consignments (scenario 3B)

- Types of small consignments

For the purpose of this impact assessment, a small consignment consists of goods in a postal consignment, which benefit from a relief from import duty in accordance with Articles 23 to 27 of Regulation (EC) No 1186/2009¹⁹⁸.

The universe of small consignments is a playing field of both firms and consumers. Traditionally, the majority of recipients are businesses with a logistical need for fast and reliable import of goods in small quantities. However, the number of consumers has increased sharply in the past decade, following the rise of cross-border e-commerce.

Typical products sent in small consignments include spare parts, professional equipment, samples and consumer goods. Examples of highly traded consumer goods crossing international borders include books, electronic appliances (such as cameras and chargers), clothing and shoes, and sports equipment. The buyers in the universe of small consignments

196 OECD (2016), "Online Product Safety: Trends and Challenges", OECD Digital Economy Papers, No. 261, OECD Publishing, Paris. DOI: <http://dx.doi.org/10.1787/5jlnb5q93jlt-en>; OECD (2016), "Online Product Safety Sweep Results: Australian Competition and Consumer Commission", *OECD Digital Economy Papers*, No. 262, OECD Publishing, Paris. DOI: <http://dx.doi.org/10.1787/5jlnb5q64ktd-en>

197 See box 6 of the impact assessment and option 2(d).

198 Articles 138(f) and 141(3) of Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code. Article 23 of Regulation (EC) No 1186/2009 specifies that any consignments made up of goods of negligible value dispatched direct from a third country to a consignee in the Community shall be admitted free of import duties, except alcoholic products, perfumes and toilet waters and tobacco or tobacco products. According to the Regulation, 'goods of negligible value' means goods the intrinsic value of which does not exceed a total of EUR 150 per consignment.

include large firms, SMEs and private consumers, and the market thus deals with both business-to-business (B2B) and business-to-consumer (B2C) trade. The sellers are in most cases multinational firms and, particularly in B2C, typically large e-commerce companies located for example in the USA, Europe and China. Small consignments are typically carried by express operators and mail operators, due, for example to the type and quantity of products shipped, and the logistics requirements of customers (e.g. urgency for spare parts). The main driver in the growth of the universe of small consignments is e-commerce, which is a globally burgeoning industry that has led to a dramatic increase in B2C online sales. Recent years have witnessed a substantial growth in cross-border e-commerce as both internet-only and multi-channel retailers turn to overseas markets for new sources of revenue. The rapid growth of e-commerce has significantly changed the transportation patterns and lead to a high growth of small consignments being shipped globally¹⁹⁹.

From the customs perspective the universe of small consignments is highly relevant, since it involves an increasingly large number of shipments, representing a significant workload. This issue has been mediated, mainly for customs duties, by the stipulations of international agreements and conventions such as the WCO Revised Kyoto Convention, WCO Immediate Release Guidelines, and WTO Bali Agreement. The Revised Kyoto Convention (RKC), by the World Customs Organization (WCO), calls for Customs administrations to set de-minimis thresholds below which duties and taxes are waived. Shipments falling into this category enjoy expedited release with minimum documentary requirements. The WTO Bali agreement of 2013 supports the future development of trade facilitation, including setting relevant de-minimis levels across the globe.

Currently the system of imports of tangible goods to consumers in the EU is highly complex, is open to abuse and provides a competitive advantage to non-EU suppliers. There are in effect 3 types of treatment of commercial consignments to consumers in the EU:

- Consignments supplied directly to consumers below EUR 10/22 which benefit from an exemption of customs duties and can benefit from a VAT exemption²⁰⁰ i.e. they are supplied VAT free direct to consumers in the EU. It is estimated that in 2015 there was 144 million²⁰¹ consignments falling in this category (see table 13-5 below).
- Consignments between EUR 10/22 up to the customs duty exemption threshold of EUR 150 are subject to VAT but customs duties do not apply. It is estimated that there were 43 million such imports in 2015.
- Consignments above the customs threshold of EUR 150 require a customs declaration and are subject to VAT and customs duties if applicable. Similar to the situation above the customer is liable to the VAT and customs duties and is usually charged an administrative fee by the transport operator to cover the costs of clearing customs²⁰².

The volume and value of parcels imported to the EU from thirds countries due to B2C e-commerce purchases of EU consumers is set out in Table 13-5. This estimate relates to small

199 <http://www.euroexpress.org/uploads/ELibrary/CDS-Report-Jan2015-publishing-final-2.pdf>

200 Article 23 of Council Directive 2009/132/EC of 19 October 2009 provides that goods of a total value not exceeding EUR 10 shall be exempt on import. Member States may grant exemption for imported goods of a total value of more than EUR 10, but not exceeding EUR 22 and can exclude goods imported on mail order (including e-commerce channels). The exemption excludes excisable goods.

201 EY Study for the Commission - http://ec.europa.eu/taxation_customs/resources/documents/common/publications/studies/execsummary_lvcr-study.pdf. The 2013 figure of 115 million consignments has been increased by the Commission in line with the growth in e-commerce.

202 Given the complexity of the interaction between customs duties and VAT with very different legal bases and rules, as well as to take a stepped approach it is considered that any amendments to the customs thresholds are beyond the remit of this initiative.

value consignments, i.e. parcels below the 10-22 EUR threshold, and parcels above the small value consignment threshold and below the Customs threshold, i.e. parcels between 10-22 EUR and 150 EUR. The estimates are based on the data provided by two recent studies on volume and corresponding value of small value consignments (parcels below 10-22 EUR) in 2013²⁰³, and on the distribution of parcels by value²⁰⁴. The table below provides an overview of the volume and value of parcels below the customs threshold:

Table 13-5: Volume and value of parcels below the Customs threshold

	Volume	Value (EUR)
Small value consignments	144 067 840	2 967 797 504
Parcels between EUR 10-22 and EUR 150	43 220 352	1 685 593 728
Total parcels below EUR 150	187 288 192	4 653 391 232

- Customs treatment of small consignments

All EU Member States require a formal customs declaration for the importation of small consignments (below €150). The standard procedure applied in all EU Member States is the use of a Single Administrative Document (SAD). However, for consignments of negligible value under the VAT threshold, not all EU Member States require a formal customs declaration. For consignments of negligible value to be imported under the International Postal Agreements all EU Member States except for Portugal allow the replacement of the SAD with the form CN 22 which should be affixed to the consignment. Portugal allows for individual consignments (not being part of a combined shipment) with a value below EUR 1,000 to benefit from a simplification customs procedure called “Verbal or Mail Traffic Customs Declaration”. In addition to the customs declaration (i.e. the SAD or form CN 22) further documentation is required to be available upon entry of the consignments evidencing that the consignments meet the criteria for application of the customs duty relief. All Member States allow the use of an invoice or other document identifying parties involved as well as description and price for the goods for this purposes²⁰⁵.

National postal service providers generally use of the form CN 22/23 for customs clearance. On the CN 22/23 form the identification for exemption purposes is performed both on the basis of the goods description as well as the value declared thereof. Other operators, such as courier firms, generally use the paper based or electronic SAD. One of the elements enabling to identify in the SAD that these goods qualify as goods exempted from customs duty and/or VAT, is the mentioning of the additional customs procedure code ‘C07’ in box 37(2). Operators in Belgium and Denmark highlighted that in addition to the ‘C07’-code, they also mention a specific generic commodity code under box 33. In order to evidence that the consignments meet the criteria for the application of the customs and/or VAT duty relief,

203 European Commission (2015), Assessment of the application and impact of the VAT exemption for importation of small consignments, prepared by EY, accessed at http://ec.europa.eu/taxation_Customs/resources/documents/common/publications/studies/lvcr-study.pdf on June 12th 2015

204 Hintsä J., Mohanty S., Tsikolenko V., Ivens B., Leischnig A., Kähäri P., Hameri AP., and Cadot (2014), The import VAT and duty de-minimis in the European Union – Where should they be and what will be the impact?, accessed at <http://www.euroexpress.org/uploads/ELibrary/CDS-Report-Jan2015-publishing-final-2.pdf> on January 26th 2015. The corresponding value was estimated using an average value of EUR 20 per parcel, in line with available literature. It should be noted that these estimates do not reveal the content of the consignments which, for example, also contain products that are not subject to Union harmonisation legislation (e.g. books, music, ...).

205 https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/lvcr-study.pdf, pp. 16-17.

postal service providers and courier firms are required to maintain and potentially submit various documents to the Customs Authorities. These documents include invoices, manifests, airway bills and any other documentation that contains the information that is relevant to identify whether this relief applies.

Table 13-6: Customs clearance procedure in practice

Value	Import duties	Customs declaration	
		National Postal service (under the UPU)	Courier firms
Below EUR 10-22	<ul style="list-style-type: none"> ▪ No VAT ▪ No customs duties 	CN 22	Declaration by any other act, oral declaration, paper based or electronic manifest, simplified SAD
Above EUR 10-22, but below EUR 150	<ul style="list-style-type: none"> ▪ VAT payable ▪ No customs duties 	CN 22	Simplified electronic declaration or SAD
Above EUR 150	<ul style="list-style-type: none"> ▪ VAT payable ▪ Customs duties payable 	CN22/23 (depending on the value)	Full or simplified SAD

2.3.2.3. Other consignments

The postal operator may lodge a customs declaration for release for free circulation containing the reduced data set for postal consignments, the value of which does not exceed €1,000, provided inter alia that the goods are not subject to prohibitions and restrictions²⁰⁶.

2.4. Possibilities to enforce market surveillance measures with respect to all manufacturers selling in the EU

The enforceability of product harmonisation legislation with respect to economic operators established in the EU is discussed in detail in the accompanying evaluation and in the impact assessment. Yet, the question arises how non-compliance with Union harmonisation legislation could be enforced on all products sold in the EU, including those arriving in the EU in small or postal consignments addressed directly to consumers in the EU.

Even when an actor and his assets are located outside the country, the country might not be without recourse in enforcing its laws; as long as other persons or entities are located within the country and the actor uses the goods or services of these persons or entities for the actor’s online commercial activity, the enforcement efforts may instead target such persons or entities, who may be held secondarily liable for violations of the law and/or ordered to cease the provision of such goods or services to the actor²⁰⁷.

Traditionally, the EU has relied on three categories of trigger to justify bringing individuals within the EU’s legislative or regulatory net: the fact that a person engages in conduct in the EU, the fact that a person is legally or physically present within the EU, or the fact that a person holds the nationality of an EU Member State²⁰⁸. Whereas conduct and presence are

206 Article 144 of Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code.
 207 Trimble, Marketa, Extraterritorial Enforcement of National Laws in Connection with Online Commercial Activity (April 30, 2015). RESEARCH HANDBOOK ON ELECTRONIC COMMERCE LAW, John A. Rothchild ed., Edward Elgar, 2016; UNLV William S. Boyd School of Law Legal Studies Research Paper. Available at SSRN: <https://ssrn.com/abstract=2600925>, p. 1.
 208 Scott J., 'The new EU 'Extraterritoriality'', Common Market Law Review 51: 1343–1380, 2014.

strongly linked to the territorial principle, nationality forms a separate, well-established, jurisdictional base that is not relevant in this context.

Consequently, the following solutions could be considered, under the assumption that option 2d (Adapting the investigative and enforcement powers of market surveillance authorities to new market developments, the global supply chain and e-commerce'), option 2e ('additional enforcement tools') and option 3g ('mandatory digital publication of compliance information') are withheld:

2.4.1. Full control on imports of products from third countries to consumers

Union harmonisation legislation would be primarily enforced at the external borders of the EU, i.e. customs authorities would check systematically all incoming products and evaluate their compliance with Union law. Essentially, no distinction would be made between products sold by non-EU manufacturers to consumers and products to be placed on the market. Under this approach, the EU would be making the biggest effort to protect consumers, workers and Union-based businesses.

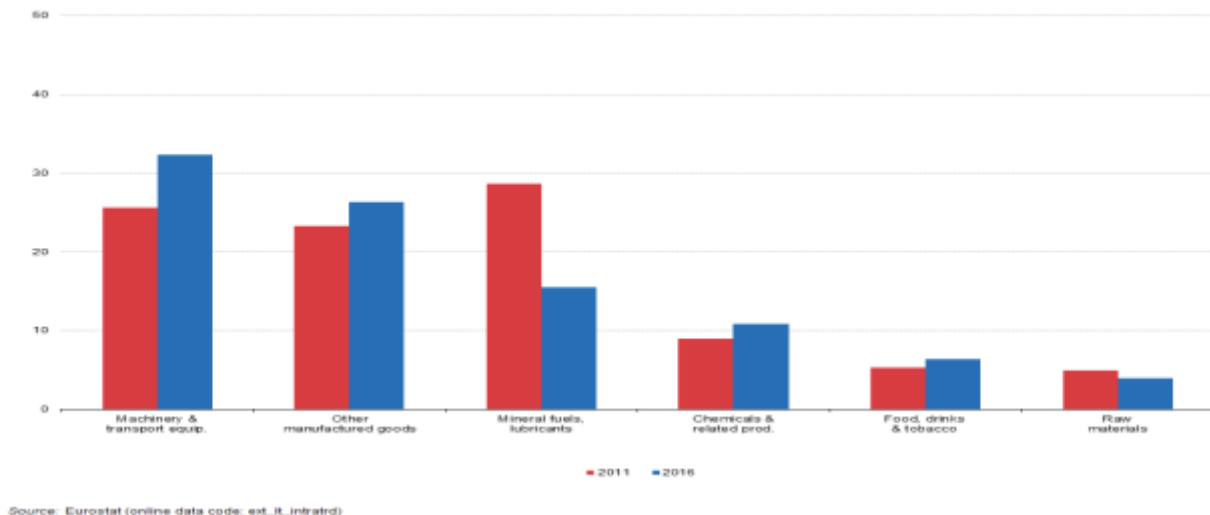
However, this approach completely ignores two main facts. Firstly, it ignores the fact that many products that arrive in the EU and are sent in small or postal consignments addressed directly to consumers in the EU actually comply with the applicable rules. Hence, there is no problem of enforceability for these products and no need to control all products. Secondly, it ignores the practical problem of very limited customs/market surveillance resources. Enacting such requirements is a far cry from effectively enforcing them. This approach may even offend the principle that unenforceable laws should not be enacted.

Table 13-7: Volume of parcels below the Customs threshold

	Total Volume	25%	10%
Small value consignments	144 067 840	36 016 960	14 406 784
Parcels between EUR 10-22 and EUR 150	43 220 352	10 805 088	4 322 035
Total parcels below EUR 150	187 288 192	46 822 048	18 728 819

Assuming that 25% of the small value consignments would contain products that are subject to Union harmonisation legislation, the volume of the small value consignments makes it impossible to control all parcels. Even in a very conservative assumption that only 10% of the parcels would contain products that are subject to Union harmonisation legislation, it is clear that this approach is neither feasible nor affordable for authorities. Furthermore, one of the largest changes between 2011 and 2016 in the structure of the EU-28's imports was that the share of machinery and transport equipment rose from 25.6 % to 32.3 % while the share of other manufactured goods rose from 23.3 % to 26.3 %.

Figure 13-2: Main imports by product, EU-28, 2011 and 2016 (% share of extra EU-28 imports)



This approach may be also be disproportionate and an example of the 'nanny State' going too far. Purchasers in the Union may not mind if the camera they buy from the USA is not fully compliant with Union rules for cameras. They will be unhappy if a usable camera is confiscated or destroyed by customs because of an aspect of non-compliance which does not matter to them.

2.4.2. Registration of the product and person responsible for compliance information in the EU

This solution would mirror the obligations that are laid down in the Union legislation on cosmetics and medical devices.

2.4.2.1. Responsible person for cosmetics

Regulation (EC) N° 1223/2009 on cosmetic products is the main regulatory framework for finished cosmetic products when placed on the EU market. It strengthens the safety of cosmetic products and streamlines the framework for all operators in the sector. Only cosmetic products for which a legal or natural person is designated within the EU as a “responsible person” can be placed on the market.

The Regulation requires the designation, in the European Union, of a Responsible Person for every cosmetic product placed on the EU market. This person must take responsibility to ensure that every cosmetic product it/he places on the EU market complies with all the requirements of the Regulation. Once the product has been put on the market, if any questions about its safety, its packaging or its labelling arise, the responsible person will be considered liable. If it is found that the requirements of the Cosmetics Regulation have not been properly met, this person or company may be penalised. Corrective actions and penalties vary according to the severity of the infraction and are commensurate to the risk that the infraction has created for the consumer. A formal labelling infraction may simply result in a fine and an obligation to correct the label for future productions. Incorrect safety procedures could result in imprisonment. In case of substantiated risk, the product will be immediately removed from the market resulting in bad publicity and lost revenue.

The Responsible Person may be a natural or a legal person. His/its name (or style) and address must be printed on the primary (container) and secondary packaging of each product for which he/it takes responsibility.

The concept of a single person responsible for ensuring compliance with the cosmetic legislation was already a key pillar of the Cosmetics Directive. With the Regulation, the central role of the Responsible Person remains and is further specified.

Depending on whether the product is manufactured or imported in the EU, the Responsible Person can be the manufacturer or the importer or a mandated person. As a default, the manufacturer is the responsible person for products manufactured in the EU and the importer is the responsible person for the products he imports into the EU. In practice, manufacturers and importers have some flexibility to decide who shall fulfil the role of Responsible Person for their products. Under certain circumstances they may mandate any person to assume this role, provided this person is:

- registered and located in the EU;
- adequately mandated;
- in a position to assure compliance under the Cosmetics Legislation including competent authorities' access, as and when appropriate, to the Product Information File at the address mentioned on the cosmetic products by the Responsible Person;
- indicated as the Responsible Person on the label with his name and address.

It is the responsibility of the Responsible Person to ensure that every product he/it places on the EU market complies with the requirements of the Cosmetics Regulation. His duties relate to all aspects regulated under the EU cosmetics legislation: Article 3 (safety), Article 8 (good manufacturing practice), Article 10 (safety assessment), Article 11 (product information file), Article 12 (sampling and analysis), Article 13 (notification), Article 14 (restrictions for substances listed in Annex), Article 15 (substances classified as CMR substances), Article 16 (nanomaterials), Article 17 (traces of prohibited substances), Article 18 (animal testing), Article 19(1)(2) and (5) (labelling), Article 20 (product claims), Article 21 (access to information for the public), Article 23 (communication of serious undesirable effects) and Article 24 (information on substances).

2.4.2.2. Responsible person for medical devices

Where a manufacturer who places a medical device on the market under his own name does not have a registered place of business in a Member State, he is obliged to designate a single authorised representative in the European Union. The authorised representative means any natural or legal person established in the Union who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Union instead of the manufacturer with regard to the latter's obligations under the Directives which include Directive 93/42/EEC concerning medical devices (MDD), Directive 90/385/EEC on active implantable medical devices⁴ (AIMDD) and Directive 98/79/EC on in vitro diagnostic medical devices (IVDD).

The authorized representative is required to maintain and provide upon request certain regulatory documentation to the competent authorities for the purpose of market surveillance, including the Declaration of Conformity and the technical file for devices. Implicit in the requirement for authorized representatives to furnish documentation to authorities upon request is the need for the information to be up to date. The authorized representative also is required to promptly communicate information from the competent authority to the manufacturer.

The authorised representative has certain obligations as defined by the relevant Directives, such as:

- informing the competent authorities of his registered place of business (MDD: class I, procedure packs and custom made devices; AIMDD: custom made devices; IVDD), and of the devices and certificates (IVDD);
- keeping certain information at the disposal of the national authorities, such as declarations of conformity and technical documentation (AIMDD Annex II 6.1; MDD Annex II 6.1, Annex III Section 7.3, Annex IV Section 7, Annex V Section 5.1, Annex VI Section 5.1, Annex VII Section 2; IVDD Arts 9(7) and 10(3)).

The manufacturers may instruct his authorised representative to initiate certain procedures provided for in the conformity assessment annexes (IVDD Art 9(6), MDD Art 11(9), AIMD Art 9(3)).

As the directives do not include a detailed description of the role and obligations of an authorised representative it will be of vital importance to both the manufacturer and the authorised representative to set up a contract specifying the task and authority the manufacturer will delegate to the authorised representatives, also where the authorised representative is a daughter company of the manufacturer established outside the EU.

The appointment of an authorised representative does not change the responsibilities of the manufacturer. The authorised representative must be duly selected and supervised by the manufacturer. However, in some Member States the authorised representative will have responsibilities directly under national law. For instance he might have the responsibility to ensure that the appropriate conformity assessment procedure has been carried out, that the device is properly CE marked and that information is provided in a specified national language. Another example may be that the authorised representative must have a vigilance system in place which is compatible with that of the manufacturer. An authorised representative must therefore be fully informed about the legal obligations included in the national legislation of the Member State in which he has his residence / where devices are placed on the market. Those “national” obligations should be reflected in the above mentioned contract with the manufacturer. Given the Authorised Representative's limited role with regard to the placing on the market of a medical device, he cannot be held responsible for actions by the manufacturer over which it has no control, unless national legislation specifies otherwise²⁰⁹.

These Directives on medical devices will be replaced by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Box 13-1: Summary of the role of the sole authorised representative in the new EU legislation on medical devices

Both Regulations (EU) No 2017/745 and 2017/746 confirm that, where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised representative. The designation will constitute the authorised representative's mandate, it will be valid only when accepted in writing by the authorised representative and will be effective at least for all devices of the same generic device group. Under the new legislation, the authorised representative will have to perform the tasks specified in the mandate

209 Guidance document. MEDDEV 2.5/10. January 2012

agreed between it and the manufacturer. The authorised representative will have to provide a copy of the mandate to the competent authority, upon request. The mandate must require, and the manufacturer must enable, the authorised representative to perform at least the following tasks in relation to the devices that it covers:

- verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;
- keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities;
- comply with the registration obligations laid down in the Regulations and verify that the manufacturer has complied with the registration obligations laid down in the Regulations;
- in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;
- forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;
- cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
- immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;
- terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.

However, the mandate may not delegate several manufacturers' obligations. Where the manufacturer is not established in a Member State and has not complied with his obligations, the Regulations specify that the authorised representative will be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.

An authorised representative who terminates its mandate on the grounds that the manufacturer acts contrary to its obligations under the Regulation will have to immediately inform the competent authority of the Member State in which it is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

Furthermore, the detailed arrangements for a change of authorised representative will have to be clearly defined in an agreement between the manufacturer, where practicable the outgoing authorised representative, and the incoming authorised representative. That agreement will have to address at least the following aspects:

- the date of termination of the mandate of the outgoing authorised representative and date of beginning of the mandate of the incoming authorised representative;
- the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;
- the transfer of documents, including confidentiality aspects and property rights;
- the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as authorised representative

2.4.2.3. Registration of the product

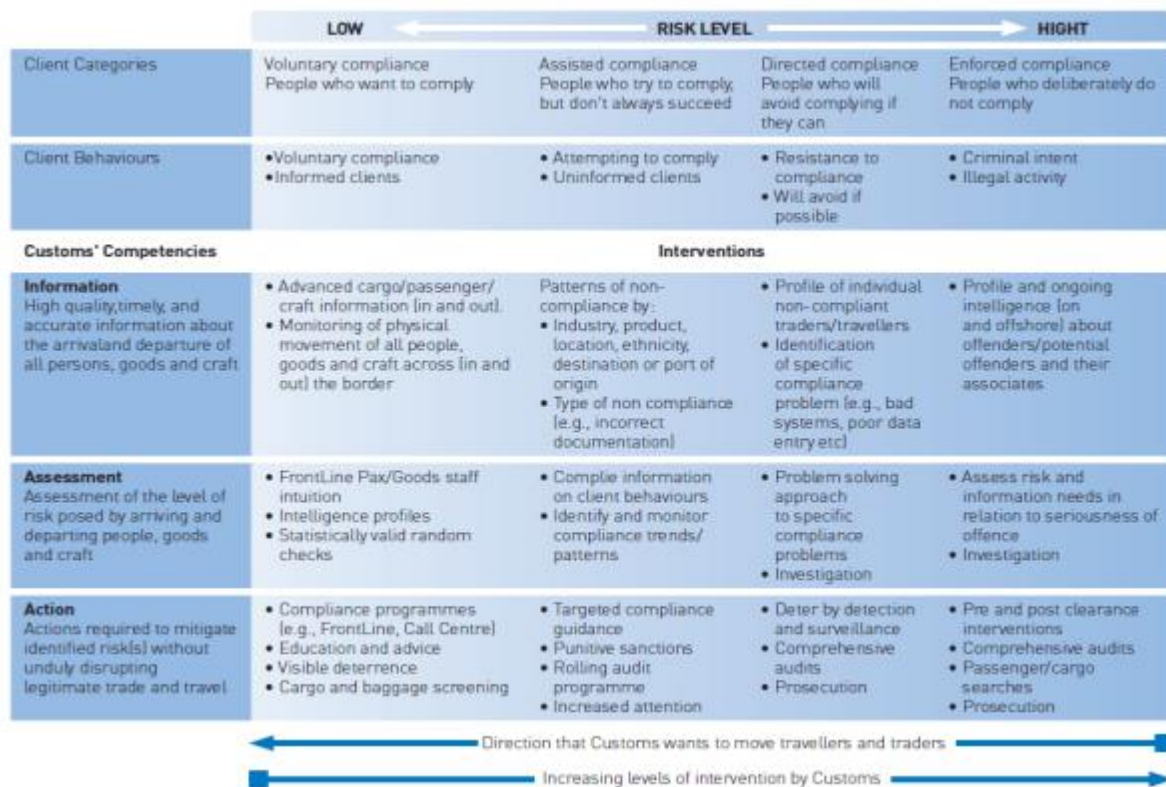
The various possibilities for a system registering products and compliance information can be found in the assessment in Chapters 5 and 6 of Annex 14, i.e. the option of mandatory basic compliance in a centralised database. These costs would have to be added to the costs of a person responsible for compliance information in the EU. There is no doubt that the registration of the product and essential compliance information (e.g. the declaration of conformity) would strengthen the effectiveness of any measure to ensure the enforceability of market surveillance measures and decisions, but this would entail some additional costs and administrative charges which, horizontally across all non-food sectors, might be disproportionate to achieve the objective of a better enforceability of market surveillance measures and decisions for products sold in the EU.

2.4.3. Controls on the basis of risk management

An intermediate solution would consist of targeted controls on the basis of a risk management system that would be closely connected to the common customs risk management framework (CRMF) laid down in Article 46 of the Union Customs Code²¹⁰.

2.4.3.1. Risk management system without a person responsible for compliance information in the EU

The benefits of a risk management system at the external borders are widely acknowledged and include better human resource allocation, increased customs revenue, improved compliance with laws and regulations, reduced release times and hence lower transaction costs and improved cooperation between traders and customs²¹¹. The key in relation to risk-based compliance management is to actively “steer” the client population towards the low-risk category. This can be achieved both by providing incentives for traders and travellers to comply, and by operating a credible enforcement regime which effectively and efficiently detects and punishes non-compliance. Affecting client behaviour and actively steering the population towards low risk will allow Customs to concentrate its control resources on high risks. The diagram below illustrates an example of a compliance management model²¹².



The EU customs risk management policy and strategic objectives as defined in the EU Strategy and Action Plan COM(2014)527 were endorsed by the Council in December

210 http://ec.europa.eu/taxation_customs/general-information-customs/customs-risk-management/measures-customs-risk-management-framework-crmf_en

211 Dunne M., 'Getting to grips with risk management', WCO News, No 62/2010, www.wcoomd.org, p. 16.

212 <http://www.wcoomd.org/~media/wco/public/global/pdf/topics/enforcement-and-compliance/activities-and-programmes/risk-management-and-intelligence/volume-1.pdf?db=web>

2014²¹³. The Strategy covers all threats and risks connected with international goods movements. It aims to mitigate them at the most opportune time and place in the supply chain ('assess in advance, control where required'), to improve operational risk analysis capacities, to improve access to and exploitation of risk and intelligence information from non-customs authorities and to improve targeting of high risks and facilitation of legitimate trade through strengthened cooperation with economic operators. EU customs implement risk management and controls under the common Union framework by deploying their national risk management capacities and expertise. The Strategy acknowledges the need to work further on increasing the risk analysis operational capacities at the national and EU level. Two main challenges need to be addressed: overcoming capacity variances across the EU Member States to be able to implement common risk criteria and standards, and capability to more effectively tackle trans-national threats. Capacity variances arise due to the existence of 28 different national electronic risk analysis systems and differences in expertise across the EU Member States. More broadly, as the Strategy reflects very well, the customs authorities of the Member States need to significantly improve the capacity, tools and methods (organisation) to address transnational risks posed by cross-border crime and terrorist organisations²¹⁴.

Yet, a pure risk management system is unlikely to address satisfactorily the problem of the enforceability of market surveillance measures:

Table 13-8: Advantages and drawbacks of a risk management system without a person responsible for compliance information in the EU to address the lack of enforceability of market surveillance measures	
Advantages for the non-EU manufacturer	Drawbacks for the non-EU manufacturer
The non-EU manufacturer would still be able to sell and ship the product to the EU without any additional formality or cost.	Union harmonisation legislation would be enforced on the product itself, which would have to be seized and possibly destroyed.
Advantages for consumers	Drawbacks for consumers
--	The financial risk would be borne by the consumer who would not receive the product for which a payment was already made when the product would be seized.
Advantages for market surveillance authorities	Drawbacks for market surveillance authorities
Risk management system reduces non-compliance and hence the need to enforce market surveillance decisions.	Enforceability problem only partly solved: <ul style="list-style-type: none"> • Costs on customs and/or MSA to trace and contact the responsible foreign manufacturer, extra effort required to obtain information/responses to questions. • There would be a risk that the economic operator would continue placing non-compliant products on the EU market, in the absence of any feedback from enforcement authorities. • Uncertainty whether the manufacturer would actually take the findings of the enforcement authorities into account. • The possibility of a dialogue between the

213 See also Commission Progress Report COM(2016)476 on the implementation of the EU Strategy and Action Plan for customs risk management and the accompanying Commission SWD(2016)242.

214 http://ec.europa.eu/research/participants/data/ref/h2020/other/guides_for_applicants/h2020-sec-policybackground_en.pdf

	<p>economic operator and the enforcement authorities would be minimal.</p> <p>Financial risk for customs or market surveillance authorities who would have to pay for the administration and destruction costs.</p>
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Consequently, this possibility puts the administrative and financial burden mainly on the authorities and the consumer.

2.4.3.2. Risk management system with a person responsible for compliance information in the EU

a) Preliminary assessment

Another possibility is that, whenever a product is placed on the market by a business outside the EU (i.e. when there is no importer or authorised representative) and when the product is not subject to any prior approval procedures, there should be a person responsible for compliance information in the EU²¹⁵. This person could be the fulfilment centre or any other person appointed by the manufacturer.

The 'person responsible for compliance information' should be the person who represents the manufacturer established outside the EU for the implementation of the Regulation. The 'person responsible for compliance information' should be established in the jurisdiction of any of the market surveillance authorities and should be responsible for the following tasks:

<i>Table 13-9: Possible tasks of a person responsible for compliance information in the EU</i>	
Obligations	Applicable legislation
<ul style="list-style-type: none"> Keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities and cooperate with them at their request; 	Only for products subject to 'New Approach legislation'
<ul style="list-style-type: none"> Upon a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product; 	All products
<ul style="list-style-type: none"> Cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by products covered by their mandate. 	All products

215 This possibility builds on the Commission's proposal COM(2016)757 amending Directive 2006/112/EC and Directive 2009/132/EC as regards certain value added tax obligations for supplies of services and distance sales of goods which proposes, inter alia, the removal of the existing VAT exemption for the importation of small consignments from suppliers in third countries. According to the proposal, a vendor not established in the Community should designate an intermediary except if he is duly authorised by the Member State of identification or if he is established in a country with which the EU has concluded an agreement on mutual assistance. Where VAT is declared under this special scheme, no VAT should be payable anymore upon importation of the goods. It is therefore necessary to provide for an exemption for such imports. This exemption is inserted in Article 143(1) of the VAT Directive. To allow customs to identify these consignments upon importation a valid VAT identification number proving that VAT is declared under the special scheme should be provided to customs at the latest upon lodging of the import declaration.

It is understood that manufacturers should make the identity and contacts details of the person responsible for compliance information with respect to the product publicly available either on their website or, in the absence of a website, by any other means that allows the information to be readily accessed by the general public in the Union free of charge. The identity and contact details of the person responsible for compliance information with respect to the product should also be indicated on or identifiable from information indicated on the product, its packaging, the parcel or an accompanying document.

The mere fact that the 'person responsible for compliance information' should be the person representing the manufacturer established outside the EU for the implementation of the Regulation implies that there would be no need for a 'person responsible for compliance information' in the following cases:

<i>Table 13-10: Cases where no person responsible for compliance information should be appointed</i>	
(1)	When there is an importer or an authorised representative, the manufacturer does not have to appoint a person responsible for compliance information (see scenarios 1 and 2 in table 13-3 above);
(2)	Where the manufacturer needs to obtain type-approval (motor vehicles) or needs to register a chemical substance (REACH), no person responsible for compliance information should be appointed;
(3)	When Union harmonisation legislation already provides for an obligatory authorised representative (medical devices) or a responsible person (cosmetics and Regulation (EU) No 2017/1369 on energy efficiency labelling), no other person responsible for compliance information should be appointed;
(4)	Where the product needs to be registered before being placed on the market (e.g. the registration of radio equipment types within some categories, as set out in Article 5 of the Radio Equipment Directive 2014/53/EU);

There are insufficient quantitative data to calculate the possible costs for appointing a person responsible for compliance information, also because the actual amount would depend upon the content of the mandate and the contractual arrangements between the parties (e.g. annual fees or payment per hour for services actually delivered). Businesses acting as authorised representatives consider their tariffs as commercially sensitive information. According to the result of the CATI interviews in the figure below for the purpose of Annex 14 Part 5, the cost of demonstrating compliance [i.e. administrative burden for answering requests from market surveillance authorities regarding documents needed to demonstrate compliance; Displaying (or publishing) the compliance information; Updating compliance information for existing products; Complying with different compliance procedures across Member States; IT costs; General labour cost] was estimated at 10% of the overall cost of compliance with Union harmonisation legislation. Furthermore, based on the Evaluation of the Internal Market Legislation for Industrial Products²¹⁶, the total cost of compliance with such legislation for a firm is approximately 0.48% of its turnover. The cost of demonstrating compliance is therefore estimated to be approximately 0.048% of turnover.

Considering Eurostat data from 2013²¹⁷, the turnover of the almost 350,677 companies within the scope of Annex 14 Part 5 is € 2.03 trillion (€2,026,565.10 million). Given this, a preliminary estimation shows that the total cost of demonstrating compliance is approximately € 842.374 m per year (€ 2.03 trillion* 0.48%*10%*86.6%incidence rate) or €1,807.41 per company per year on average. If one excludes the preparation and the updating

216 <http://ec.europa.eu/smart-regulation/evaluation/search/download.do?documentId=9966151>

217 Eurostat: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=sbs_na_sca_r2&lang=en

of the technical file which corresponds on average to 80% of the cost, the total cost of the tasks set out in Table 13-9 could be estimated at €361.48 per company per year on average where there is a declaration of conformity and a technical file, and €180.74 in all other cases. Assuming a profit margin equal to the actual cost, the total cost of the tasks set out in Table 13-9 could be estimated at €722.96 per company per year on average where there is a declaration of conformity and a technical file, and €361.48 in all other cases. When the profit margin would be the double of the actual cost, the total cost of the tasks set out in Table 13-9 could be estimated at €1445.92 per company per year on average where there is a declaration of conformity and a technical file, and €722.96 in all other cases. This estimation, however, may differ in situations where the authorised representative also fulfils other commercial functions for the manufacturer and performing these tasks is just part of its overall commercial role, both for the manufacturer and for other economic actors in the downstream supply chain, or in situations where being an authorised representative for several manufacturers is part of the core business of the enterprise concerned. An informal survey in the field of medical devices, and in-vitro diagnostic medical devices and active implantable medical devices under the current legislation for the tasks set out under point 2.4.2.2 show that annual fees can range between €1,500 and €4,000 which could also include the specific notification requirements, which are incumbent to the manufacturer, but which can be delegated to the authorised representative (e.g. the registration of the authorised representatives, manufacturers and devices and registration of clinical investigations (MDD and AIMDD) and the registration of the authorised representatives, manufacturers, devices and certificates and the registration of performance evaluations (IVDD)).

The possible costs for market surveillance authorities, if any, would at most be negligible. Persons responsible for compliance information would be expected to be businesses who would act as service providers vis-à-vis the manufacturers. Consequently, they might have an EORI number²¹⁸ and, as a general rule, they should have a VAT identification number that should also be easily verifiable²¹⁹. Companies acting as person responsible for compliance information should be registered in a business register²²⁰ and easy to trace²²¹.

Consequently, there are no indications that a risk management system with a s in the EU might create unjustified financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens. Furthermore, the costs would be limited in relation to the business turn-over of the manufacturer and commensurate with the objective to be achieved.

In case of missing information, suspected non-compliance, the authorities would turn to the person responsible for compliance information in the EU, within their jurisdiction, instead of having to search and contact operator(s), possibly via intermediaries in the supply-chain in

218 Economic Operators Identification and Registration system (EORI) required by the Union Customs Code – See https://ec.europa.eu/taxation_customs/business/customs-procedures/general-overview/economic-operators-registration-identification-number-eori_en and http://ec.europa.eu/taxation_customs/dds2/eos/eori_home.jsp?Lang=en

219 http://ec.europa.eu/taxation_customs/vies/vieshome.do?selectedLanguage=EN - Articles 213 to 216 of Council Directive 2006/112/EC on the common system of value added tax, as amended.. See also Council Directive 2010/24/EU of 16 March concerning mutual assistance for the recovery of claims relating to taxes, duties and other measures, Council Regulation N° 904/2010/EU of 7 October 2010 on administrative cooperation and combating fraud in the field of value added tax and Council Directive 2011/16/EU of 15 February 2011 on administrative cooperation in the field of taxation and repealing Directive 77/799/EEC.

220 Directive 2009/101/EC of the European Parliament and of the Council of 16 September 2009 on coordination of safeguards which, for the protection of the interests of members and third parties, are required by Member States of companies within the meaning of the second paragraph of Article 48 of the Treaty, with a view to making such safeguards equivalent. The interconnection of business registers in the EU is put in place by Commission Implementing Regulation (EU) 2015/884 of 8 June 2015 establishing technical specifications and procedures required for the system of interconnection of registers established by Directive 2009/101/EC of the European Parliament and of the Council.

221 https://e-justice.europa.eu/content_find_a_company-489-en.do?clang=en

foreign jurisdictions and administrative cultures. Benefits of the measure are therefore expected to outweigh the costs on the authorities. Automated (pre)checks on customs declarations and documents would assist customs and market surveillance authorities to target controls and could be expanded in the future to cover specific indications related to product compliance (including person responsible for compliance information, but also other elements e.g. registration or authorisation codes for certain products).

Table 13-12: Advantages and drawbacks of a risk management system with a person responsible for compliance information in the EU to address the lack of enforceability of market surveillance measures

Advantages for the non-EU manufacturer	Drawbacks for the non-EU manufacturer
Better contacts with, and easier feedback from market surveillance authorities. Compliance issues could be swiftly addressed for any other products sold in the EU.	Where there is no authorised representative or importer, the manufacturer would have to seek a person responsible for compliance information and remunerate the person for the services performed.
Advantages for consumers	Drawbacks for consumers
Easier contacts in case of problems.	--
Advantages for market surveillance authorities	Drawbacks for market surveillance authorities
<p>Market surveillance decisions would be enforceable vis-à-vis all businesses selling in the EU.</p> <p>Reduced costs relating to identifying, tracing, contacting and following-up compliance issues (simplification)</p> <p>The measure should incentivise foreign businesses trading non-compliant products to internalise costs (now borne by authorities/costs on the public purse to trace foreign businesses often leading to a dead end..</p> <p>Costs on authorities would be lower – enforcement is based on risk assessment, minimal additional work, however costs savings and simplification for them</p>	Risk of letter box companies although verifications could be made on the basis of the EORI number, the VAT identification number and the file opened in a central register, commercial register or companies register of the Member State.

b) Assessment of possible side-effects

Products may only be sold in the EU when they comply with the legislation applicable in the EU. When manufacturers design products that could be sold on the EU market, they ensure or should ensure that the products meet the European safety and environmental requirements and apply the conformity assessment procedures. They should also affix the marking provided for by EU legislation. Such marking is a key indicator (but not proof) of a product's compliance with EU legislation and enables the free movement of products within the EEA and Turkish market, whether they are manufactured in the EEA, Turkey or in another country.

Manufacturers who design products for the EU market normally do so for mass production or production in bigger series. Practice shows that many of them already place their products on the EU market through a representative (e.g. an importer or an authorised representative) and/or a distribution network (see Table 13-3 above), also to save transportation and logistics

costs and to ensure economies of scale. Products sold in volumes in the EU are stored in warehouses and distribution centres in the EU on behalf of the manufacturer or by a local branch or subsidiary, or in warehouses and distribution centres in the EU which are owned or managed by businesses that act as a representative for the supplier. These manufacturers would therefore already comply with the obligation of a person responsible for compliance information.

Yet, the question arises whether such obligation would discourage any other manufacturer or any other supplier to sell compliant products to the EU from outside the EU. As manufacturers normally provide for representation in the EU for products imported in larger volumes, this question would only be relevant for items that, at least in theory, fulfil two cumulative conditions, namely (1) (a) products that are not conceived to be sold primarily in the EU but nonetheless comply with the applicable EU harmonisation legislation, or (b) products that are conceived to be sold primarily in the EU in small volumes without a distribution network in the EU, and (2) sent in parcels or individual consignments to consumers in the EU.

Condition 1(a) is merely theoretical since for most products that are subject to EU product harmonisation legislation, specific obligations apply as regards technical documentation, the declaration of conformity and the CE marking²²² and additional markings and labelling requirements for the EU:

Box 13-2: Examples of additional markings required by EU legislation

- Directive 75/324/EEC relating to aerosol dispensers obliges the person responsible for the marketing of aerosol dispensers to affix the symbol '3' (inverted epsilon) to aerosol dispensers, as proof that they satisfy the requirement of the Directive and its Annex;
- Directives 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU and 2014/34/EU respectively specify that the identification number of the notified body must be affixed to pyrotechnic articles, explosives for civil use, simple pressure vessels, non-automatic weighing instruments, measuring instruments, lifts and equipment and protective systems intended for use in potentially explosive atmospheres, where the notified body was involved in the production control phase;
- The inscriptions referred to in point 1 of Annex III of Directive 2014/29/EU must be affixed to simple pressure vessels in accordance with Article 16 or point 1 of Annex III of the Directive;
- The inscriptions referred to in point 1 or in point 2 of Annex III of Directive 2014/31/EU must be affixed to the non-automatic weighing instruments concerned;
- The supplementary metrology marking must be affixed to measuring instruments pursuant to Article 22 of Directive 2014/32/EU;
- The information allowing identification of the lift or the safety component of for lifts must be indicated in compliance with Articles 7(5) or 8(5) of Directive 2014/33/EU;
- The specific marking of explosion protection, the symbols of the equipment-group and category and, where applicable, the other markings and information must be affixed to equipment and protective systems intended for use in potentially explosive atmospheres in accordance with point 1.0.5 of Annex II of

²²² The list of product groups subject to CE marking is published on https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en. According to Article 30(1) of Regulation (EC) No 765/2008, the CE marking may be only affixed by the manufacturer or his authorised representative. Union harmonisation legislation also specifies that the CE marking must be fixed visibly, legibly and indelibly to the product. Where that is not possible or not warranted on account of the nature of the product, the CE marking must be affixed to the packaging and to the accompanying documents. Furthermore, the CE marking must be affixed before the product is placed on the market.

Directive 2014/34/EU;

- The identification number of the notified body must be affixed to radio equipment, where the conformity assessment procedure set out in Annex IV of Directive 2014/53/EU is applied, in accordance with Article 20 of the Directive;
- The identification number of the notified body involved in the production control phase as well as the marking and labelling referred to in point 3.3. of Annex I or point 3.3 of Annex I must be affixed to pressure equipment in accordance with Article 19 or point 3.3 of Annex I of Directive 2014/68/EU.

Box 13-3: Examples of specific labelling requirements in EU legislation

- The Toys Safety Directive 2009/48/EC contains the obligation that the manufacturers must ensure that their toys bear a type, batch, serial or model number or other element allowing their identification, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy. Manufacturers must also indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy. The address must indicate a single point at which the manufacturer can be contacted. Similar obligations exist for importers. In addition, Directive 2009/48/EC specifies that toys should be marked with general and specific warnings, as set out in Article 11 and Annex V.
- Textile products must be labelled or marked whenever they are made available on the market. With the exception of trademarks or the name of the undertaking, information other than that required by the regulation must be listed separately. The labelling or marking must be provided in the official language or languages of the Member State on the territory of which the textile product is made available to the consumer, unless the national legislation of that country provides otherwise.
- For footwear, labels must convey information relating to the upper, the lining and insole sock, and the outer-sole of the footwear article. The information must be conveyed by means of approved pictograms or textual information, as defined by the directive. The label must be legible, firmly secured and accessible, and the manufacturer or his authorized agent established in the Union is responsible for supplying the label and for the accuracy of the information contained therein. Only the information provided for in the directive need be supplied.
- The Cosmetics Regulation contains several labelling provisions. Containers and/or packaging (in certain cases) must bear, in indelible, easily legible and visible characters, the name, trade name and address, or registered office of the manufacturer or person responsible for marketing the cosmetic product within the Union, the nominal contents at the time of packaging (by weight or volume), the date of minimum durability indicated by "Best before end", for products with a minimum durability of less than 30 months (with a specific symbol), the period after opening during which the product can be used without harm to the consumer, for products with a minimum durability of less than 30 months (indicated by a symbol representing an open cream jar), particular precautions for use, the batch number or product reference, for identification, the product's function etc.
- Regulation 1272/2008/EC on the Classification, Labelling and Packaging of Chemicals specifies labelling rules for substances and mixtures that are classified as hazardous. The label elements regarding hazard pictograms, hazard and precautionary statements are highly standardized and reflect the UN Globally Harmonized System of Classification and Labelling of Chemicals. Labels need to bear a certain obligatory elements regarding the identification of the substance and mixture, name and address details of the supplier and the nominal quantity. For small packaging and very small quantities a certain number of labelling derogations apply. Some mixtures require specific additional labelling elements.
- Directive 2000/14/EC on noise emission in the environment by equipment for use outdoors obliges the equipment listed in Articles 12 and 13 and defined in Annex I to carry the indication of the guaranteed sound power level following the model set out in Annex IV of the Directive.

- The WEEE Directive provides for an obligatory symbol that must be displayed on all products that fall under this directive. The symbol indicates that the product is not to be discarded with normal household waste.
- Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators provides that all batteries, accumulators and battery packs should be appropriately marked with the symbol shown in Annex II of the Directive. In addition, the capacity of all portable and automotive batteries and accumulators must be indicated on them. Batteries, accumulators and button cells containing more than 0,0005 % mercury, more than 0,002 % cadmium or more than 0,004 % lead, have to be marked with the chemical symbol for the metal concerned: Hg, Cd or Pb. The symbol indicating the heavy metal content has to be printed beneath the symbol shown in Annex II of the Directive and must cover an area of at least one-quarter the size of that symbol.
- Regulation (EC) No 1222/2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters requires that tyre manufacturers declare fuel efficiency, wet grip and external rolling noise performance of C1, C2 and C3 tyres (i.e. tyres mainly fitted on passenger cars, light and heavy duty vehicles).
- Bottles used as measuring containers are regulated by directive 75/107/EEC and here again it is up to the manufacturers to decide whether to use this legislation, which in turn guarantees free movement of the bottles. The reversed epsilon marking "3" is placed on the bottom of the bottle alongside the indicated volume contained in the bottle and the distance from the brim to which the bottle must be filled in order to achieve the indicated volume. The legislation contains the procedures and tests that the authorities may apply during market surveillance.
- The voluntary e-mark acts as a metrological "passport" to facilitate the free movement of pre-packaged goods. It guarantees that certain liquids and other substances, as defined in directive 76/211/EEC, have been packed by weight or volume in accordance with the directive. Where the manufacturer chooses to use the directive, free movement throughout the EU is guaranteed for pre-packaged products that do comply with the provisions of the directive. Containers with an e-mark also bear an indication of the weight or volume of the product, known as its "nominal" weight or volume. The packer (or importer, if the container is produced outside the EU) is responsible for ensuring that the containers meet the directive's requirements. The legislation contains the procedures and tests that the authorities may apply during market surveillance.
- Regulation (EC) No 66/2010 on the EU Ecolabel allows any producer, manufacturer, importer, service provider, wholesaler or retailer to place the EU Ecolabel on the product, provided that the operator concluded a contract with the competent body covering the terms of use of the EU Ecolabel. When the EU Ecolabel is placed on the product, the registration number must also be placed on the product.
- Directive 2008/43/EC sets up a system for the identification and traceability of explosives for civil uses. Each manufactured or imported article falling under the scope of this Directive shall bear a unique identification, comprising the mandatory information and components described in the Annex to the Directive.
- Implementing Directive 2014/58/EU sets up a system for the traceability of pyrotechnic articles. Pyrotechnic articles must be labelled with a registration number structured in a uniform way according to the indications of the Directive.

Consequently, there are hardly any products that could meet condition 1(a) as all products that are compliant with Union harmonisation legislation can only be products that are expressly designed to comply with this legislation as a result of an explicit decision by the manufacturer.

In theory, there could be many categories of products that fulfil condition 1(b), i.e. products that are conceived to be sold primarily in the EU in small volumes without a distribution network in the EU. In practice, however, this would be fairly exceptional since these products should be, to be economically viable or commercially meaningful, products that do not

require the involvement of so-called 'notified bodies', i.e. conformity assessment bodies approved by the authorities of the Member States. Products that do not require the involvement of so-called 'notified bodies' are subject to conformity assessment procedure of module A²²³, i.e. essentially low voltage electrical equipment, products subject to electromagnetic compatibility requirements, pressure equipment of category I, personal protective equipment of category I, machinery not listed in Annex IV of Directive 2006/42/EC and other machinery that complies with harmonised standards that cover all essential health and safety requirements and the references of which were published in the Official Journal of the EU, and toys and radio equipment for which the manufacturer applied harmonised standards the references of which were published in the Official Journal of the EU. Footwear and textiles also fit in this general category.

Looking more specifically at the range of products that could fulfil condition 1(b), it is necessary to consider which of these products could be sent in small parcels or individual consignments to consumers in the EU as low value consignments. The value of pressure equipment of category I, some of the personal protective equipment of category I, and machinery not listed in Annex IV of Directive 2006/42/EC and other machinery that complies with harmonised standards that cover all essential health and safety requirements and the references of which were published in the Official Journal of the EU and most radio equipment is too high to be considered as small value consignments and are subject to the usual customs controls. Only some low voltage electrical equipment and some products subject to electromagnetic compatibility requirements, some personal protective equipment of category I, footwear, textiles, toys and some radio equipment for which the manufacturer applied harmonised standards the references of which were published in the Official Journal of the EU could be sent to consumers in the EU as low value consignments. Yet, it should be recalled that, according to the findings summarised in section 1.2 of the impact assessment, the level of non-compliance for many of these products is high. For instance, on the basis of data reported by Member States in the period 2010-2013 non-compliance was found on average in 32% of inspections conducted in the field of toys, 34% in the field of low voltage electrical equipment, 58% in the field of electromagnetic and radio equipment and 40% in the field of personal protective equipment. The complete overview on non-compliance found by national authorities during national inspections in 30 different groups of sectors can be found in section 5 of Annex 9.

Overall, it is highly unlikely that an obligation to appoint a person responsible for compliance information in the EU would discourage any manufacturer who, before having placed the product on the EU market, took the necessary steps to design a product that meets the EU safety and environmental requirements, who affixed all markings as set out above and who applied the labelling requirements as set out above, who made the technical documentation and who signed the EU declaration of conformity. This obligation, however, might discourage the sales of products that are not designed to be sold in the EU or that do not meet the EU safety and environmental requirements. This discouraging effect should be counterbalanced by the consideration that compliance and the corresponding business opportunities of selling

223 See Annex II of Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC. The other conformity assessment modules require the intervention of a notified body. Module A is internal production control, i.e. the conformity assessment procedure whereby the manufacturer fulfils some specific obligations laid down in detail in the module and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them. It would be quite unlikely that a manufacturer would seek the intervention of a notified body for products which would be sold only in very small volumes. It should be noted that most Union harmonisation legislation, with the exception of the Low Voltage Directive, allows the manufacturer to opt for another conformity assessment procedure than modules A or C. These other modules presuppose the intervention of a notified body in the EU.

in the EU might require a prior investment in safety and environmental protection or at least a reflection by the supplier whether selling illegal products and engaging in illegal activities is sustainable and fair business model. Therefore, having a person responsible for compliance information within the EU to represent the manufacturer who sells products in the EU does not go beyond what is necessary to achieve the enforceability of market surveillance measures within the EU.

3. DETERRENCE AND SANCTIONS

3.1. The traditional deterrence approach²²⁴

Traditionally the deterrence approach assumes that enterprises will only do “the right thing” to the extent it is in their self-interest to do so. For example, critical theorists, Pearce and Tombs (1990, 1997, 1998) argue that since all corporations have profit-maximisation as their main goal, they will always be “amoral calculators” who only ever comply with regulatory requirements when the penalties are heavy enough to ensure their calculations come up with the correct answer. Law and economics theorists see compliance as the outcome of an equation of the benefits of non-compliance versus the probability of being discovered and punished, and the severity of the penalty (e.g. Becker, 1968; Cooter & Ulen, 1988, p. 533ff; Stigler, 1970; see Ogus, 1994, pp. 90-92 for a summary). On the whole the assumption is that deterrence motivates via fear of punishment or rational calculations of the potential cost of penalties or sanctions. As a consequence, efficient compliance requires making violations unattractive by increasing the cost of non-compliance (Garcia Quesada (2014), p. 336).

According to the standard economic model of rational and selfish human behaviour (i.e., *homo economicus*), people carry out dishonest acts consciously and deliberately by trading off the expected external benefits and costs of the dishonest act. People would be honest or dishonest only to the extent that the planned trade-off favours a particular action. In addition to being central to economic theory, this external cost-benefit view plays an important role in the theory of crime and punishment, which forms the basis for most policy measures aimed at preventing dishonesty and guides punishments against those who exhibit dishonest behaviour. In summary, this standard external cost-benefit perspective generates three hypotheses as to the forces that are expected to increase the frequency and magnitude of dishonesty: higher magnitude of external rewards, lower probability of being caught and lower magnitude of punishment (Mazar, Amir and Ariely (2008), pp. 4-5; Wils (2006), p. 12).

Economic theory assumes that the offender weighs the costs and the benefits in deciding whether or not to commit a crime. The rational prospective offender is assumed to be a profit maximizer who weighs the costs and the benefits of committing a crime and does not undertake illegal action unless the expected benefits of the crime exceed the expected costs. From this point of view, it can be said that the function of penalties is simply to increase the expected costs in order to deter the prospective offender (Bowles (1982), p. 54-105; Wils (2006-1), pp. 12-17).

According to the Becker's model in calculating the expected costs two important factors should be taken into account: One is the authorities' ability to catch and convict the offender (p); the other is the expected maximum punishment (S). The multiplication of these factors then constitutes the expected costs of the crime to the offender. From a different angle, economic theory indicates that the public's decision variables to combat illegal behaviour are its expenditures on police, courts, etc., which help determine the probability (p) that an offense is discovered and the offender apprehended and convicted, the size of the punishment for those convicted (f), and the form of the punishment: imprisonment, probation, fine, etc. Optimal values of these variables can be chosen subject to, among other things, the constraints imposed by three behavioural relations. One shows the damages caused by a given number of illegal actions, called offenses (0), another the cost of achieving a given p , and the third the effect of changes in p and f on 0 (Becker (1968), p. 43).

224 OECD (2000), pp. 68-70.

Based on this landmark paper, a large empirical literature has developed to test the degree to which potential offenders are deterred. The literature falls into three general categories. The first category analysed the responsiveness of crime to the probability that an individual is apprehended. This concept has typically been operationalized as the study of the sensitivity of crime to police, in particular police manpower or policing intensity. A second group examined the sensitivity of crime to changes in the severity of criminal sanctions, through an assessment of the responsiveness of crime to sentence enhancements, three strikes laws, capital punishment regimes and policy-induced discontinuities in the severity of sanctions faced by particular individuals. The third group examines the responsiveness of crime to mainly local labour market conditions, generationally operationalized using either the unemployment rate or a relevant market wage, in order to determine whether crime can be deterred through the use of positive incentives rather than punishments. The three categories measure the degree to which individuals can be deterred from participation in criminal activity. Chalfin and McCrary (2014) concluded from their literature review that there is robust evidence that crime responds to increases in police manpower and to many varieties of police redeployments. They also noted that, while the evidence in favour of a crime-sanction link is generally mixed, there does appear to be some evidence of deterrence effects induced by policies that target specific offenders with sentence enhancements..

Ultimately, the model proposed by Becker yields three main behavioural predictions: 1) the supply of offences will fall as the probability of apprehension rises, 2) the supply of offences will fall as the severity of the criminal sanction increases and 3) the supply of offences will fall as the opportunity cost of crime rises. In other words, more active enforcement occurs when monitoring to prevent rule breaking is more frequent and when more breaches are accompanied of a sanction. If enforcement is more active, the degree of compliance with EU harmonisation legislation is expected to improve, as businesses will avoid getting caught and facing sanctions.

3.2. Problems with simple deterrence theory

While the deterrence approach holds some attraction as an explanation of how regulated enterprises decide whether to comply, it is also now clear that it will only apply in very narrow circumstances. One of the leading empirical researchers of deterrence and business regulation (Scholz, 1997; see also Aalders & Wilthagen, 1997) has argued that the basic model of deterrence is only valid when the following assumptions are true:

- Corporations are fully informed utility maximizers.
- Legal statutes unambiguously define misbehaviour.
- Legal punishment provides the primary incentive for corporate compliance.
- Enforcement agents optimally detect and punish misbehaviour given available resources.

Scholz (1997), and other researchers, have concluded from empirical tests of the deterrence model that mostly these assumptions do not hold true, and that a simple model of deterrence is therefore mostly not a helpful explanation of what motivates organisations to comply with the law.

One reason for this is that regulatory agencies are often not as powerful and efficient as they would need to be in order for deterrence to work. It is well established in deterrence research that the deterrent effect of sanctions will depend on their certainty, severity, celerity, and uniformity, especially certainty (DiMento, 1989, p. 225; Friedrichs, 1996, p. 342f). Another reason is that because so many kinds of business law-breaking have high rewards and low penalties, the threatened application of sanctions is not a severe enough threat to deter non-compliance (Coffee, 1981; Ogus, 1994, p. 93).

In order to cope with these realities, researchers have abandoned the simple economic model of deterrence as an explanation for compliance in favour of a more sophisticated analysis of how deterrence works, and how it interacts with a number of other factors that also affect compliance.

3.3. Bounded rationality

The research has shown that, contrary to the assumption that corporations are fully informed utility maximizers, economic costs of non-compliance which do not draw attention to themselves by generating some kind of crisis are often overlooked by busy management (see Hopkins, 1995, pp. 88-95).

For example, Scholz and Gray's (1990; see also Weil, 1996) very comprehensive research into the effectiveness of OSHA enforcements found only a modest reduction in injury rates in all plants following an increase in enforcement activity. However individual plants that were inspected and penalised experienced a 22% decline in injuries over the next three years, despite extremely low average fines. The fact that they have been inspected and penalised in a particular year should not have affected the probability and cost-benefit calculations of those firms penalised if they had been acting purely rationally, although it might have a general deterrent effect on the whole population. Scholz and Gray conclude that imposing penalties results in improved safety for these particular firms because the imposition of a penalty focuses managerial attention on risks that would otherwise have been overlooked. Normally, the "bounded rationality" of organisations and top management – the limited capacity of people and organisations to process information in decision making (March & Simon, 1958, p. 169) - means that many do not make rational cost-benefit calculations about compliance at all. It is only when something happens to bring the risks of non-compliance to their attention, that deterrence becomes effective.

In her investigation of health and safety programmes in UK companies Genn (1993, p. 223) finds that it is "when there is a potential for a catastrophe of either an economic or political nature, and also where companies are large, well established, highly visible and thus mindful of their public image" that they are more likely to have an occupational health and safety system in place. Similarly, McCaffrey and Hart (1998, p. 87) find that in the wake of major regulatory scandals in their industry, firms will make heavier investments in compliance than they otherwise would have, suggesting that the deterrent threat of enforcement is much more effective when a major scandal draws it to people's attention.

3.4. The effects of negative publicity

The research on deterrence also shows that when individuals or management do think about the disadvantages of non-compliance, they do not make a simple calculation based on the direct economic costs of non-compliance. Rather other factors, particularly the indeterminate costs of bad publicity on the firm's reputation and morale are very significant. This

contradicts the basic premise of deterrence theory that the size of the expected financial penalty directly relates to the level of compliance.

For example, Scholz and Gray (1990) found that although workplace safety in plants inspected by OSHA improves after penalties are imposed, the size of the penalty has little impact on safety improvements (indeed most of the penalties were very low). Davidson et al (1995) measured the stock markets' reaction to OSHA announcements of sanctions on the companies receiving them (adjusting for overall stock market movement). The study found a stock market decline average of -0.46% on the days immediately before and after the announcement. However they could find no relationship at all between the size of the fine and the stock market reaction, suggesting that negative publicity was the important factor. Fisse and Braithwaite (1983) studied the impact of publicity on corporate offenders in seventeen high profile cases in great detail. They found that adverse publicity is of concern not so much by reason of its financial impacts but because of a variety of non-financial effects, the most important of which is loss of corporate prestige" and that "corporations fear the sting of adverse publicity attacks on their reputations more than they fear the law itself" (Fisse & Braithwaite, 1983, pp. 247, 249).

Indeed a series of studies have found that maintaining or advancing the corporate reputation and counteracting negative publicity is an important reason for enterprise interest in ensuring compliance (e.g. Bardach & Kagan, 1982, p. 164; Genn, 1993; Parker, 1999a, but cf Haines, 1997, pp. 188-190). It appears that, even where regulators only have small penalties at their disposal, actual, or potential bad publicity can overcome bounded rationality, put compliance issues on management agendas and improve compliance rates.

3.5. Informal sanctions and shame

The evidence also suggests that in general informal sanctions have a greater deterrent impact than formal legal sanctions (Ekland-Olson et al, 1984; Paternoster & Simpson, 1996; Tittle, 1980, p. 241), and that regardless of what kind of social control is attempted it is not its formal punitive features that make a difference, but its informal moralising features (Schwartz & Orleans, 1967).

Informal sanctions include negative publicity, public criticism, gossip, embarrassment, and shame. Formal sanctions are official sanctions such as fines, compensation, licence revocations and restrictions and prison sentences. There is however an interaction effect: formal sanctions will often trigger informal sanctions such as bad publicity. The "restorative justice" approach to dealing with corporate law-breaking relies on the effectiveness of shame and informal sanctions to reduce non-compliance (Braithwaite, 1999). [...]

3.6. The significance of maintaining legitimacy

Another body of research that is very consistent with the research on the effects of informal sanctions, negative publicity and shame shows that many enterprises are often motivated to comply with the law, or at least to appear to comply, in order to maintain their legitimacy in the eyes of government, industry peers, and the public. This body of research suggests that the possibility of fines, sanctions, and inspections acts less as a deterrent threat than as a way to focus management attention on institutional expectations that may affect the legitimacy and operation of their enterprise. This is the concern of the "new institutional" scholarship in economics, political science, and organisational theory (Scott, 1995). "New institutional" theory in economics, for example, attempts to recognise that individuals and enterprises do

not always make decisions solely on the basis of financial calculations, but a variety of other social and environmental factors including their own values and the expectations of others will affect their actions. As Suchman and Edelman (1997, p. 919) explain it, 'Institutional factors often lead organisations to conform to societal norms even when formal enforcement mechanisms are highly flawed. Frequently cited institutional influences include historical legacies, cultural mores, cognitive scripts, and structural linkages to the professions and to the state. Each, in its own way, displaces single-minded profit-maximisation with a heightened sensitivity to the organisations embeddedness within a larger social environment.'

This does not mean that financial and legal considerations are not important, but that they are not the sole explanation for organisational action. DiMaggio and Powell (1991) have described three forms of "institutional isomorphism" that explain how organisations adopt practices and structures from their social environments beyond what is strictly required by the technical and financial parameters under which they operate: "mimetic isomorphism" occurs when organisations copy the apparently successful practices of other, similar organisations; "coercive isomorphism" occurs when organisations submit to the demands of powerful external actors, such as the regulatory agencies of the state; and "normative isomorphism" occurs when organisations import the practices of professionals and other organised value carriers. Each of these mechanisms can mean that enterprises adopt compliance even when it is not strictly in their financial interest.

There is a growing body of empirical evidence that this theory does help explain corporate compliance with regulation. Edelman and various co-authors (Dobbin et al. 1988; Edelman, 1990; Edelman et al., 1993) have used neo-institutional theory to explain the growth of employee due process rights designed to protect against indiscriminate firing, safety violations, unequal discipline, sexual harassment, and discriminatory employment opportunity structures in US companies.

Hoffman's (1997) study of corporate environmentalism in the US petroleum and chemicals industry uses neo-institutional theory to explain why the growth in corporate attention to environmental issues did not follow trends in volume of new environmental laws and regulations nor growth in industrial expenditure on environmental issues as deterrence theory would predict, but rather rose and declined with public concern with environmentalism (see Hoffman, 1997, p. 144). Similarly, Rees' (1997) study of the emergence of the US Chemical Manufacturers' Association, Responsible Care, selfregulatory programme also finds that it was the imperatives of institutional legitimacy that forced chemical companies to regulate themselves after the Bhopal accident, rather than a simple model of deterrence (see also Heimer, 1996, for an application of neo-institutionalism to health care regulation).

However, a number of the scholars who have researched in this area have pointed out that often a concern with legitimacy can motivate enterprises to manage their image of compliance, without necessarily complying substantively with the requirements of the regulation (e.g. Edelman et al., 1993; Shearing, 1993, pp. 75-76).

3.7. Co-operation and trust

The basis for the theory that co-operative, persuasive regulatory enforcement strategies should be used rather than punitive ones is the assumption that most individuals/businesses are "ordinarily inclined to comply with the law, partly because of belief in the rule of law, partly as a matter of long-term self-interest" (Kagan and Scholz, 1984, p. 67; see also Bardach and Kagan, 1982, p. 66). However this claim is often based on anecdotal rather than systematic

evidence and seems to depend partially on defining being “in compliance” as being substantially in compliance, and ignoring smaller ongoing violations (cf Brown, 1994).

Nevertheless, some impressive evidence has been collected by researchers which shows that, although co-operative and persuasive strategies are not always appropriate, when they are successful they are superior to punitive sanctions in effectively and efficiently accomplishing long term compliance. A large body of empirical sociological and psychological research converges on the finding that non-coercive and informal alternatives are likely to be more effective than coercive law in achieving long term compliance with norms, and coercive law is most effective when it is in reserve as a last resort. For example, there is significant psychological evidence for a “minimal sufficiency principle” that the less powerful the technique used to secure compliance, the more likely is long term internalisation of a desire to comply. Such internalisation is discouraged by the use of rewards and punishments; reasoning and dialogue promote it (Boggiano et al., 1987; Kohn, 1993; see also Brehm & Brehm, 1981).⁶ Thus Honneland (1998) found that compliance can be secured despite weak sanctions through “discourse” persuasion and co-operation at the enforcement level among fishermen in the Svalbard restricted fishing zone. Braithwaite, Makkai, Braithwaite, and Gibson’s programme of research on nursing home regulation is probably the most systematic quantitative empirical study of regulation and compliance conducted to date. Results from this study shows that co-operative strategies of trust, restorative shaming, and praise are more effective at increasing business compliance with regulation than the application of formal sanctions (Braithwaite & Makkai, 1991, 1994, Makkai & Braithwaite, 1993, 1994a, 1994b).

A noteworthy theme of this research is the importance of trust in securing compliance. In a famous book, Francis Fukuyama (1995) argued that capitalism needs trust to work efficiently and effectively. A number of social researchers now find trust to be an essential resource in all sectors of society (e.g. Putnam 1993). This is especially important in relations between regulators and regulatees.

Trust between regulator and regulatee simultaneously builds efficiency and improves the prospect of compliance. If regulatees trust regulators as fair umpires who administer and enforce laws or regulations that have important substantive objectives, then the evidence is that compliance will be higher, and resistance and challenges to regulatory action will be low (see DiMento, 1989, p. 225). For example Scholz and Lubell (1998; see also Levi, 1988) found that tax compliance increases as trust toward the government increases and also that the sense of duty to pay taxes increases when government policies prove beneficial to the taxpayer. If regulatees feel that regulators treat them as untrustworthy, then defiance and resistance build up so that inefficiency and non-compliance both increase (see V. Braithwaite, 1995; Paternoster, et al., 1997; Sherman, 1993).

However, it should also be noted that most accounts that find people to be compliant in response to co-operation, goodwill and trust also find that deterrence is necessary as a back-up for the minority of organisations that do not voluntarily comply (see discussion of pyramids below). They also find that co-operative compliance is generally contingent upon persuading those of goodwill that their compliance will not be exploited by free riders who will get away with the benefits of noncompliance without being held to account for it (see Levi, 1988; Scholz, 1997, p. 262). Thus deterrent and punitive sanctions must still be available in the background.

More recently there has been considerable interest in another enforcement model that involves government ‘regulating at a distance’ by risk managing the risk management of individual

enterprises. This implies requiring or encouraging enterprises to put in place their own internal controls and management (via systems, plans and risk management more generally). These are then scrutinized by regulators, who take the necessary action to ensure that these mechanisms are working effectively.

3.8. Effective motivations for compliance vary among people and contexts

The strands of research summarised above give us a more complex picture of what motivates people to comply with regulation than the simple deterrence model. This picture is further complicated by the finding that effective motivations for compliance vary between persons and contexts. There are a wide variety of motivations likely to apply in different enterprises, in different parts of the same enterprises and at different times in the same enterprise.

Paternoster and Simpson (1996) looked at intentions to commit four types of corporate crime by MBA students, and found that these intentions were affected by sanction threats (formal and informal), moral evaluations and organisational factors. They find that where people do hold personal moral codes, then these will be more significant than rational calculations in predicting compliance. If moral inhibitions are high then cost-benefit calculations are virtually superfluous. But when moral inhibitions are low, then deterrence became relevant. Similarly Fisse and Braithwaite (1983, 1993) find that companies will frequently be responsive to weak sanctions including publicity and shame because there are usually a variety of actors associated with any wrongdoing. Some will be “hard targets” who cannot be deterred even by maximum penalties. But others will be “vulnerable targets” who can be deterred by penalties, and still others will be “soft targets who can be deterred by shame, by the mere exposure of the fact that they have failed to meet some responsibility they bear, even if that is not a matter of criminal responsibility.” (Fisse & Braithwaite, 1993; p. 220). Differing motivations and responses will also be partially determined by economic circumstances and place in the structure as well as by individual dispositions of particular corporate managers. A consistent research finding is that larger enterprises are more likely to implement compliance systems and to be more compliant than smaller enterprises (e.g. Ashby & Diacon, 1996; Genn, 1993; Haines, 1997).

In summary the picture of the organisation as an amoral calculator moved by appropriate deterrence to ‘do the right thing’ must be supplemented by the facts that organisations can sometimes be persuaded to do the right thing, that some influential actors within organisations will be highly motivated to be legal or socially responsible for its own sake, that the existence of deterrence threats will not necessarily be a feature of daily decision making, that many organisations will behave in ways that they feel maintain their legitimacy in the eyes of industry peers, customers or governments irrespective of individual cost and efficiency calculations, and that even where formal sanctions are applied, it is their informal ramifications (shame and negative publicity) that are more effective motivators.

3.9. Evaluation

As part of the exploration of options for the impact assessment the *investigation by the Commission (instead of member states market surveillance authorities)* and ultimately imposition of sanctions was assessed.

Similar to a coordinated approach at EU level relying on inputs from Member State authorities (through e.g. Product Compliance Network), such an option would eliminate the duplication of work linked to the need to carry out different proceedings in different Member

States. However the Commission would have to create from scratch an ad hoc investigative capacity (e.g. recruiting new staff, setting new procedures) in all the product sectors and to maintain this capacity stand-by to perform investigations, take enforcement decision and sanctions separate from and in addition to capacities in Member States authorities that would in any event continue to be needed for the bulk of product investigations. The additional costs for the Commission to avail of such a separate capacity would outweigh possible savings that could be made at national level for the cases concerned and as such the option would unlikely to be efficient. Moreover, according to the views expressed by some Member States this option brings about a negative impact on them because it would imply a transfer of national sovereignty towards the EU and so have a negative impact on subsidiarity. This option is therefore not further examined in the impact assessment.

3.10. Overview of the provisions on penalties in Union harmonisation legislation

Directive/Regulation	Provision on penalties
<p>Directive 69/493/EEC on the approximation of the laws of the Member States relating to crystal glass;</p> <p>Directive 75/107/EEC on the approximation of the laws of the Member States relating to bottles used as measuring containers;</p> <p>Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers;</p> <p>Directive 76/211/EEC on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products;</p> <p>Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC;</p> <p>Directive 92/23/EEC relating to tyres for motor vehicles and their trailers and to their fitting (valid until 31 October 2017);</p> <p>Directive 92/42/EEC on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels;</p>	<p>No provisions on penalties in the Directives.</p> <p>This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing these directives.</p>

<p>Directive 94/11/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer;</p> <p>Directive 97/68/EC on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery</p>	
<p>Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC;</p>	<p>Article 9a - Penalties</p> <p>Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive. The penalties determined must be effective, proportionate and dissuasive.</p>
<p>Directive 2000/14/EC on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors</p>	<p>No provisions on penalties in the Directive.</p> <p>This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing this directive.</p>
<p>Regulation (EC) No 2003/2003 relating to fertilisers</p>	<p>Article 36 - Penalties</p> <p>The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.</p>
<p>Directive 2004/42/CE on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC</p>	<p>Article 10 - Penalties</p> <p>Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take the necessary measures to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those rules and measures to the Commission by 30 October 2005 at the latest, and shall notify it without delay</p>

	of any subsequent amendment affecting them.
Directive 2004/52/EC on the interoperability of electronic road toll systems in the Community	No provisions on penalties in the Directive. This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing this directive.
Regulation (EC) No 552/2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation)	No provisions on penalties in the Regulation. This, however, does not necessarily mean that national law does not lay down penalties for infringing the Regulation.
Regulation (EC) No 648/2004 on detergents	Article 18 - Penalties Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. This may also include appropriate measures allowing the competent authorities of the Member States to prevent the making available on the market of detergents or surfactants for detergents that fail to comply with this Regulation. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions and any subsequent amendment affecting those provisions to the Commission without delay. Those rules shall include measures allowing the competent authorities of Member States to detain consignments of detergents that fail to comply with this Regulation.
Regulation (EC) No 850/2004 on persistent organic pollutants and amending Directive 79/117/EEC	Article 13 - Penalties Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission one year after entry into force of this Regulation at the latest and shall notify it without delay of any subsequent amendment affecting them.

<p>Directive 2005/64/EC on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability and amending Council Directive 70/156/EEC</p>	<p>No provisions on penalties in the Directives.</p> <p>This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing these directives.</p>
<p>Directive 2006/40/EC relating to emissions from air conditioning systems in motor vehicles and amending Council Directive 70/156/EEC</p>	
<p>Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery</p>	<p>Article 23 - Penalties</p> <p>Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 29 June 2008 and shall notify it without delay of any subsequent amendment affecting them.</p>
<p>Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC</p>	<p>Article 25 - Penalties</p> <p>Member States shall lay down rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and shall take all necessary measures to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those measures to the Commission by 26 September 2008 and shall inform it without delay of any subsequent amendment to them.</p>
<p>Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC,</p>	<p>Article 126 - Penalties for non-compliance</p> <p>Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than 1 December 2008 and shall notify it without delay of any subsequent amendment affecting them.</p>

93/105/EC and 2000/21/EC	
Directive 2007/45/EC laying down rules on nominal quantities for pre-packed products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC	<p>No provisions on penalties in the Directive.</p> <p>This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing this directive.</p>
Directive 2007/46/EC establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles	<p>Article 46 - Penalties</p> <p>Member States shall determine the penalties applicable for infringement of the provisions of this Directive, and in particular of the prohibitions contained in or resulting from Article 31, and of the regulatory acts listed in Part I of Annex IV and shall take all necessary measures for their implementation. The penalties determined shall be effective, proportionate and dissuasive. Member States shall notify these provisions to the Commission no later than 29 April 2009 and shall notify any subsequent modifications thereof as soon as possible.</p>
Regulation (EC) No 715/2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information	<p>Article 13 - Penalties</p> <p>1. Member States shall lay down the provisions on penalties applicable for infringement by manufacturers of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 2 January 2009 and shall notify it without delay of any subsequent amendment affecting them.</p> <p>2. The types of infringements which are subject to a penalty shall include:</p> <p>(a) making false declarations during the approval procedures or procedures leading to a recall;</p> <p>(b) falsifying test results for type approval or in-service conformity;</p> <p>(c) withholding data or technical specifications which could lead to recall or withdrawal of type approval;</p>

	<p>(d) use of defeat devices;</p> <p>and</p> <p>(e) refusal to provide access to information.</p>
<p>Directive 2008/2/EC on the field of vision and windscreen wipers for wheeled agricultural or forestry tractors (Codified version)</p>	<p>No provisions on penalties in the Directive.</p> <p>This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing this directive.</p>
<p>Directive 2008/57/EC on the interoperability of the rail system within the Community</p>	
<p>Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006</p>	<p>Article 47 - Penalties for non-compliance</p> <p>Member States shall introduce penalties for non-compliance with this Regulation and shall take all measures necessary to ensure that this Regulation is applied. The penalties must be effective, proportionate and dissuasive. Member States shall notify the Commission of the provisions for penalties by 20 June 2010 and shall notify it without delay of any subsequent amendment affecting them.</p>
<p>Directive 2009/34/EC relating to common provisions for both measuring instruments and methods of metrological control</p>	<p>No provisions on penalties in the Directive.</p> <p>This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing this directive.</p>
<p>Directive 2009/48/EC on the safety of toys</p>	<p>Article 51 - Penalties</p> <p>Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the national provisions adopted pursuant to this Directive, and shall take all measures necessary to ensure that they are implemented.</p> <p>The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of this Directive.</p> <p>The Member States shall notify the Commission of those rules by 20 July 2011, and shall notify it without delay of any subsequent amendment to</p>

	them.
Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products	<p>Article 20 - Penalties</p> <p>The Member States shall lay down the rules applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive, taking into account the extent of non-compliance and the number of units of non-complying products placed on the Community market. The Member States shall notify those provisions to the Commission by 20 November 2010 and shall notify it without delay of any subsequent amendment affecting them.</p>
Regulation (EC) No 78/2009 on the type-approval of motor vehicles with regard to the protection of pedestrians and other vulnerable road users, amending Directive 2007/46/EC and repealing Directives 2003/102/EC and 2005/66/EC	<p>Article 13 - Penalties</p> <p>1. Member States shall lay down the provisions on penalties applicable for infringement by manufacturers of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 24 August 2010 and shall notify it without delay of any subsequent amendment affecting them.</p> <p>2. The types of infringements which are subject to a penalty shall include at least the following:</p> <p>(a) making false declarations during the approval procedures or procedures leading to a recall;</p> <p>(b) falsifying test results for type-approval;</p> <p>(c) withholding data or technical specifications which could lead to recall or withdrawal of type-approval;</p> <p>(d) refusal to provide access to information.</p>
Regulation (EC) No 79/2009 on type-approval of hydrogen-powered motor vehicles, and amending Directive 2007/46/EC	<p>Article 15 - Penalties for non-compliance</p> <p>1. Member States shall lay down the provisions on penalties applicable for infringement by manufacturers of the provisions of this Regulation</p>

	<p>and its implementing measures and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. By 24 August 2010, Member States shall notify those provisions to the Commission, and shall notify it without delay of any subsequent amendment affecting them.</p> <p>2. The types of infringement which are subject to a penalty shall include at least the following:</p> <p>(a) making false declarations during an approval procedure or a procedure leading to a recall;</p> <p>(b) falsifying test results for type-approval or in-use compliance;</p> <p>(c) withholding data or technical specifications which could lead to recall or withdrawal of type-approval;</p> <p>(d) refusal to provide access to information;</p> <p>(e) use of defeat devices.</p>
<p>Regulation (EC) No 595/2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC</p>	<p>Article 11 - Penalties</p> <p>1. Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and its implementing measures and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 7 February 2011 and shall notify it without delay of any subsequent amendment affecting them.</p> <p>2. The types of infringements by manufacturers which are subject to a penalty shall include:</p> <p>(a) making false declarations during the approval procedures or procedures leading to a recall;</p> <p>(b) falsifying test results for type-approval or in-service conformity;</p> <p>(c) withholding data or technical specifications which could lead to recall or withdrawal of type-approval;</p>

	<p>(d) use of defeat strategies;</p> <p>(e) refusal to provide access to information.</p> <p>The types of infringements by manufacturers, repairers and operators of the vehicles which are subject to a penalty shall include tampering with systems which control NOx emissions. This shall include, for example, tampering with systems which use a consumable reagent.</p> <p>The types of infringements committed by operators of the vehicles which are subject to a penalty shall include driving a vehicle without a consumable reagent.</p>
<p>Regulation (EC) No 661/2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor</p>	<p>Article 16 - Penalties for non-compliance</p> <p>1. Member States shall lay down the rules on penalties applicable to infringement by manufacturers of the provisions of this Regulation and its implementing measures and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. By 20 February 2011 or, as appropriate, 18 months from the date of entry into force of the relevant implementing measure, Member States shall notify those provisions to the Commission, and shall notify it without delay of any subsequent amendment affecting them.</p> <p>2. The types of infringement which are subject to a penalty shall include at least the following:</p> <p>(a) making false declarations during an approval procedure or a procedure leading to a recall;</p> <p>(b) falsifying test results for type-approval;</p> <p>(c) withholding data or technical specifications which could lead to recall or withdrawal of type-approval.</p>
<p>Regulation (EC) No 1005/2009 on substances that deplete the ozone layer</p>	<p>Article 29 - Penalties</p> <p>Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member</p>

	States shall notify those provisions to the Commission by 30 June 2011 at the latest and shall also notify it without delay of any subsequent amendment affecting them.
Regulation (EC) No 1222/2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters	No provisions on penalties in the Regulation. This, however, does not necessarily mean that national law does not lay down penalties for infringing the Regulation.
Regulation (EC) No 1223/2009 on cosmetic products	Article 37 - Penalties Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 11 July 2013 and shall notify it without delay of any subsequent amendment affecting them.
Regulation (EC) No 66/2010 on the EU Ecolabel	Article 17 - Penalties Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission without delay and shall notify it without delay of any subsequent amendment affecting them.
Directive 2010/30/EU on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products	Article 15 - Penalties Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and its delegated acts, including unauthorised use of the label, and shall take the necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall notify these provisions to the Commission by 20 June 2011 and shall notify the Commission without delay of any subsequent

	amendment affecting those provisions.
Directive 2010/35/EU on transportable pressure equipment	<p>Article 14 - General principles of the Pi marking</p> <p>[...] 7. Member States shall ensure correct implementation of the rules governing the Pi marking and shall take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.</p> <p>Article 41 - Obligations on Member States</p> <p>Member States shall take the necessary measures to ensure that the economic operators concerned comply with the provisions set out in Chapters 2 and 5. Member States shall also ensure that the necessary implementing measures are taken in respect of Articles 12 to 15.</p>
Regulation (EU) No 1007/2011 on textile fibre names and related labelling and marking of the fibre composition of textile products and repealing Council Directive 73/44/EEC and Directives 96/73/EC and 2008/121/EC of the European Parliament and of the Council	<p>No provisions on penalties in the Regulation.</p> <p>This, however, does not necessarily mean that national law does not lay down penalties for infringing the Regulation.</p>
Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment	<p>Article 15 - Rules and conditions for affixing the CE marking</p> <p>[...] 3. Member States shall build upon existing mechanisms to ensure the correct application of the regime governing the CE marking and take appropriate action in the event of improper use of the CE marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.</p> <p>Article 23 - Penalties</p> <p>The Member States shall lay down the rules on penalties applicable to infringements of the</p>

	<p>national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 2 January 2013 and shall notify it without delay of any subsequent amendment affecting them.</p>
<p>Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products</p>	<p>No provisions on penalties in the Regulation.</p> <p>This, however, does not necessarily mean that national law does not lay down penalties for infringing the Regulation.</p>
<p>Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)</p>	<p>Article 22 - Penalties</p> <p>The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 14 February 2014 at the latest and shall notify it without delay of any subsequent amendment affecting them.</p>
<p>Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products</p>	<p>Article 87 - Penalties</p> <p>Member States shall lay down the provisions on penalties applicable to infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than 1 September 2013 and shall notify the Commission without delay of any subsequent amendment affecting them.</p>
<p>Regulation (EU) No 167/2013 on the approval and market surveillance of agricultural and forestry vehicles</p>	<p>Article 72 - Penalties</p> <p>1. Member States shall provide for penalties for infringement by economic operators of this Regulation and the delegated or implementing acts adopted pursuant to this Regulation. They shall take all measures necessary to ensure that the penalties are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those</p>

	<p>provisions to the Commission by 23 March 2015 and shall notify the Commission without delay of any subsequent amendment affecting them.</p> <p>2. The types of infringements which are subject to a penalty shall include:</p> <p>(a) making false declarations during approval procedures or procedures leading to a recall;</p> <p>(b) falsifying test results for type-approval or in-service conformity;</p> <p>(c) withholding data or technical specifications which could lead to recall, refusal or withdrawal of type-approval;</p> <p>(d) use of defeat devices;</p> <p>(e) refusal to provide access to information;</p> <p>(f) economic operators making available on the market vehicles, systems, components or separate technical units subject to approval without such approval or falsifying documents or markings with that intention.</p>
<p>Regulation (EU) No 168/2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles</p>	<p>Article 76 - Penalties</p> <p>1. Member States shall provide for penalties for infringement by economic operators of this Regulation and the delegated or implementing acts adopted pursuant to this Regulation. They shall take all measures necessary to ensure that the penalties are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 23 March 2015 and shall notify the Commission without delay of any subsequent amendment affecting them.</p> <p>2. The types of infringements which are subject to a penalty shall include:</p> <p>(a) making false declarations during approval procedures or procedures leading to a recall;</p> <p>(b) falsifying test results for type-approval;</p> <p>(c) withholding data or technical specifications which could lead to recall, refusal or withdrawal</p>

	<p>of type-approval;</p> <p>(d) use of defeat devices;</p> <p>(e) refusal to provide access to information;</p> <p>(f) economic operators making available on the market vehicles, systems, components or separate technical units subject to approval without such approval or falsifying documents or markings with that intention.</p>
<p>Directive 2013/29/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles</p>	<p>Article 45 - Penalties</p> <p>Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all the measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.</p> <p>The penalties provided for shall be effective, proportionate and dissuasive.</p>
<p>Directive 2013/53/EU on recreational craft and personal watercraft and repealing Directive 94/25/EC</p>	<p>Article 53 - Penalties</p> <p>Member States shall lay down rules on penalties which may include criminal sanctions for serious infringements, applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented.</p> <p>The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator or the private importer has previously committed a similar infringement of this Directive.</p>
<p>Directive 2014/28/EU on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses</p>	<p>Article 50 - Penalties</p> <p>Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.</p> <p>The penalties provided for shall be effective,</p>

	proportionate and dissuasive.
Directive 2014/29/EU on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels	<p>Article 40 - Penalties</p> <p>Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.</p> <p>The penalties provided for shall be effective, proportionate and dissuasive.</p>
Directive 2014/30/EU on the harmonisation of the laws of the Member States relating to electromagnetic compatibility	<p>Article 42 - Penalties</p> <p>Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.</p> <p>The penalties provided for shall be effective, proportionate and dissuasive.</p>
Directive 2014/31/EU on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments	<p>Article 42 - Penalties</p> <p>Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements</p> <p>The penalties provided for shall be effective, proportionate and dissuasive.</p>
Directive 2014/32/EU on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments	<p>Article 49 - Penalties</p> <p>Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.</p> <p>The penalties provided for shall be effective,</p>

	proportionate and dissuasive.
Directive 2014/33/EU on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts	<p>Article 43 - Penalties</p> <p>Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.</p> <p>The penalties provided for shall be effective, proportionate and dissuasive.</p>
Directive 2014/34/EU on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres	<p>Article 40 - Penalties</p> <p>Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.</p> <p>The penalties provided for shall be effective, proportionate and dissuasive.</p>
Directive 2014/35/EU on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits	<p>Article 24 - Penalties</p> <p>Member States shall lay down rules on penalties, applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.</p> <p>The penalties provided for shall be effective, proportionate and dissuasive.</p>
Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC	<p>Article 46 - Penalties</p> <p>Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.</p> <p>The penalties provided for shall be effective,</p>

	proportionate and dissuasive.
Directive 2014/68/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment	<p>Article 47 - Penalties</p> <p>Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. Such rules may include criminal penalties for serious infringements.</p> <p>The penalties referred to in the first paragraph shall be effective, proportionate and dissuasive.</p>
Directive 2014/90/EU on marine equipment and repealing Council Directive 96/98/EC	<p>No provisions on penalties in the Directive.</p> <p>This, however, does not necessarily mean that national law does not lay down penalties for infringing national rules transposing this directive.</p>
Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006	<p>Article 25 - Penalties</p> <p>1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.</p> <p>Member States shall notify those provisions to the Commission by 1 January 2017 at the latest and shall notify it without delay of any subsequent amendment affecting them.</p> <p>2. In addition to the penalties referred to in paragraph 1, undertakings that have exceeded their quota for placing hydrofluorocarbons on the market, allocated in accordance with Article 16(5) or transferred to them in accordance with Article 18, may only be allocated a reduced quota allocation for the allocation period after the excess has been detected.</p> <p>The amount of reduction shall be calculated as 200 % of the amount by which the quota was exceeded. If the amount of the reduction is higher than the amount to be allocated in accordance with Article 16(5) as a quota for the allocation period after the excess has been detected, no quota shall be allocated for that allocation period and the</p>

	<p>quota for the following allocation periods shall be reduced likewise until the full amount has been deducted.</p>
<p>Regulation (EU) No 540/2014 on the sound level of motor vehicles and of replacement silencing systems, and amending Directive 2007/46/EC and repealing Directive 70/157/EEC</p>	<p>No provisions on penalties in the Regulation.</p> <p>This, however, does not necessarily mean that national law does not lay down penalties for infringing the Regulation.</p>
<p>Regulation (EU) 2016/424 on cableway installations and repealing Directive 2000/9/EC</p>	<p>Article 45 - Penalties</p> <p>1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation and of national law adopted pursuant to this Regulation. Such rules may include criminal penalties for serious infringements. The penalties provided for shall be effective, proportionate and dissuasive and may be increased where the relevant economic operator has previously committed a similar infringement of this Regulation. Member States shall notify those rules to the Commission by 21 March 2018, and shall notify it without delay of any subsequent amendment affecting them.</p> <p>2. Member States shall take all measures necessary to ensure that their rules on penalties applicable to infringements by economic operators of the provisions of this Regulation are enforced.</p>
<p>Regulation (EU) 2016/425 on personal protective equipment and repealing Council Directive 89/686/EEC</p>	<p>Article 45 - Penalties</p> <p>1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation. Such rules may include criminal penalties for serious infringements.</p> <p>The penalties provided for shall be effective, proportionate and dissuasive.</p> <p>Member States shall notify those rules to the Commission by 21 March 2018, and shall notify it without delay of any subsequent amendment affecting them.</p> <p>2. Member States shall take all measures necessary to ensure that their rules on penalties applicable to infringements by economic operators</p>

	of the provisions of this Regulation are enforced.
Regulation (EU) 2016/426 on appliances burning gaseous fuels and repealing Directive 2009/142/EC	<p>Article 43 - Penalties</p> <p>1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation. Such rules may include criminal penalties for serious infringements.</p> <p>The penalties provided for shall be effective, proportionate and dissuasive.</p> <p>Member States shall notify those rules to the Commission by 21 March 2018 and shall notify it without delay of any subsequent amendment affecting them.</p> <p>2. Member States shall take all measures necessary to ensure that their rules on penalties applicable to infringements by economic operators of the provisions of this Regulation are enforced.</p>
Directive (EU) 2016/802 relating to a reduction in the sulphur content of certain liquid fuels	<p>Article 18 - Penalties</p> <p>Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive.</p> <p>The penalties determined shall be effective, proportionate and dissuasive and may include fines calculated in such a way as to ensure that the fines at least deprive those responsible of the economic benefits derived from the infringement of the national provisions as referred to in the first paragraph and that those fines gradually increase for repeated infringements.</p>

3.11. EU mechanisms already in place regarding recognition and enforcement of financial penalties

This section contains an explanation of the EU mechanisms already in place regarding recognition and enforcement of financial penalties.

a) Council framework decision 2005/214/JHA

The recognition and enforcement of financial penalties imposed by judicial or administrative authorities is subject to Council framework decision 2005/214/JHA (hereafter 'The Decision'). The Decision applies the principle of mutual recognition to financial penalties, enabling a judicial or administrative authority to transmit a financial penalty directly to an authority in another EU country and to have that penalty recognised and executed without any further

formality. The Decision had to be implemented by Member States by 22 March 2007 (article 20).²²⁵ The Decision has been implemented by most Member States, including the United Kingdom and Denmark.²²⁶ As far as records show, it has not been implemented in Italy and Ireland yet, but should be implemented in the near future.²²⁷ Implementation in Greece has not taken place and is unclear when this will change.²²⁸

The Decision has been amended in 2009 by Council Framework Decision 2009/299/JHA of 26 February 2009 amending Framework Decisions 2002/584/JHA, 2005/214/JHA, 2006/783/JHA, 2008/909/JHA and 2008/947/JHA, thereby enhancing the procedural rights of persons and fostering the application of the principle of mutual recognition to decisions rendered in the absence of the person concerned at the trial, which had to be implemented 28 March 2011.

The measures as included in the Decision make it possible that, for example, fines imposed in Member State A for a violation of EU product legislation committed in Member State A by an economic operator with its registered seat in Member State B, have to be recognised and enforced by Member State B if Member State A makes a request for enforcement with Member state B.

b) Which financial penalties are subject to mutual recognition?

The mechanisms as imposed by this decision apply also to '*offences established by the issuing State and serving the purpose of implementing obligations arising from instruments adopted under the EC Treaty or under Title VI of the EU Treaty*' (art. 5 (1) sub 39). Since EU product safety regulations qualify as such instruments and require Member States to lay down rules on penalties for economic operators,²²⁹ this framework decision applies to decisions of Member State (authorities or judiciaries) on financial penalties for violations of European product legislation.

In most Member States the penalties on violation of EU product legislations have been regulated via administrative legislation (i.e. civil penalties) and/or criminal legislation (i.e. criminal penalties). The framework decision is not limited to criminal fines but also includes administrative fines: The principle of mutual recognition applies to all offences in relation to which financial penalties can be imposed.²³⁰ The penalties must be imposed by the judicial or

225 The decision has been evaluated in 2008: COM/2008/0888 final - Report from the Commission based on Article 20 of the Council Framework Decision 2005/214/JHA of 24 February 2005 on the application of the principle of mutual recognition to financial penalties.

226 a.o. PIFP, Implementation of the Framework Decision of the Council of the European Union of 24 February 2005 (2005/214/JHA) of the application of the principle of mutual recognition to financial penalties. 2010. Publication date: 03/06/2011. <http://www.ejn-crimjust.europa.eu/ejn/libdocumentproperties.aspx?Id=225> and Answers received by the General Secretariat in reply to the Questionnaire on "Implementation of the Framework Decision of the Council of the European Union of 24 February 2005 (2005/214/JHA) of the application of the principle of mutual recognition to financial penalties". March 2012. Publication Date 10/12/2012. <http://www.ejn-crimjust.europa.eu/ejn/libdocumentproperties.aspx?Id=1044>

227 In the latest answers to the questionnaire on the implementation Ireland indicated that a draft bill that is apparently still pending. Answers received by the General Secretariat in reply to the Questionnaire on "Implementation of the Framework Decision of the Council of the European Union of 24 February 2005 (2005/214/JHA) of the application of the principle of mutual recognition to financial penalties". March 2012. Publication Date 10/12/2012. <http://www.ejn-crimjust.europa.eu/ejn/libdocumentproperties.aspx?Id=1044> And furthermore: http://www.ejn-crimjust.europa.eu/ejn/EJN_Library_StatusOfImpByCou.aspx?CountryId=293

228 http://www.ejn-crimjust.europa.eu/ejn/EJN_Library_StatusOfImpByCou.aspx?CountryId=293

229 According to article 41 of Regulation (EC) 2008/765 Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the provisions of this regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of the provisions of this Regulation. Sector specific regulations and/or directives include similar provisions.

230 Paragraph 2 of the preambles and article I(a) (ii) and (iii) of the Decision. See also: http://ec.europa.eu/justice/criminal/recognition-decision/financial-penalties/index_en.htm, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:l16003>, https://e-justice.europa.eu/content_mutual_recognition_of_financial_penalties-388-en.do.

administrative authorities of the Member States and this decision must be final, i.e. there is no longer any possibility to appeal the decision.

Some Member States do not (always) impose fines for violations of EU product safety legislation, but (instead) recover the costs for the enforcement measures taken. The definition of financial penalty includes '*a sum of money in respect of the costs of court or administrative proceedings leading to the decision*' (art. 1 (b) (iii))²³¹ but excludes '*orders for the confiscation of instrumentalities or proceeds of a crime*' (which could be the product itself or the profits earned therewith) or '*orders that have a civil nature and arise out of a claim for damages and restitution and which are enforceable under [Brussel Ibis]*' (civil and commercial matters) (article 1 (b) second paragraph, second bullet). Depending on how restitution is regulated in the Member State, there could be a possibility that such costs may also qualify as financial penalty and may be recognised (for example if it is not regulated as compensation but has a penalty element in it). This is a matter of interpretation of the Member States national laws as well as the definitions of the Regulation.

c) How does mutual recognition and enforcement work?

If Member State A (the issuing state) wants to enforce one of its decisions in Member State B (the receiving state), the decision, together with a certificate as provided for in the Framework Decision (Annex 1), may be transmitted to the competent authorities in Member State B. A decision may be transmitted to the competent authorities of a Member State in which the natural or legal person against whom a decision has been passed has property or income, is normally resident or has its registered seat (article 4(1)) Therefore, a request may also be made if there are only assets of the Economic Operator present in a Member State.

Each Member State has designated one or more authorities that are competent under its national law for the management of the transmission of decisions on issuing financial penalties in cross-border cases. The competent authorities and details on the national procedures may be found here: <http://www.ejn-crimjust.europa.eu/ejn/libcategories.aspx?Id=25>. Please note that the actual enforcement procedures may differ per Member State. Standardised c.q. translated forms may also be found here (see article 16 on the language of the form and translation of the decision required). Please note that the documents on the aforementioned website show that some authorities except translations in languages other than their own like English.

In principle, Member State B may not refuse the enforcement and has to take **forthwith** all the necessary measures for its execution in Member state B (article 6).

Only in limited cases (article 7) the recognition and/or enforcement may be refused. One of these circumstances is when the acts have been committed outside of the territory of the issuing State and the law of the executing state does not allow prosecution for the same offences when committed outside its territory (article 7 (2) (d) (ii)). Other grounds for refusal may be if the certificate provided for is not produced or is incomplete (article 7 (1), the offence in Member State A does not constitute an offence under the laws of Member State B (article 7 (2) (b)), the person concerned was put with limits for a legal remedy (article 7 (2) (g) (i), the financial penalty is below EUR 70 (article 7 (2) (h)) etc.

231 Germany has asked questions in the Council in 2012, stating that there appears no legal basis for isolated enforcement of the costs of criminal proceedings in a foreign country by means of mutual assistance in enforcement. Note of the German Delegation of 26 September 2012, <http://www.ejn-crimjust.europa.eu/ejn/libdocumentproperties.aspx?Id=990>.

The amount to be paid may be reduced by the Member State, if the acts were not carried out in the issuing state's territory, to the maximum amount provided for acts of the same kind under national law of the executing state (article 8).

The execution of the decision is governed by the law of the executing state (article 9). It can impose imprisonment or other penalties provided for by national law in the event of non-recovery of the financial penalty (article 10). Monies obtained from the enforcement of decisions will accrue to the executing state, unless otherwise agreed by the respective Member States (article 13). Member states may not claim from each other the refund of costs from application of this framework decision (article 17).

d) Other useful instruments regarding mutual recognition in criminal matters

In case of suspected serious infringements of EU product legislation that have a cross border character or element to it, other cross-border cooperation mechanisms in criminal matters could apply. Most of these mechanisms and instruments regard cooperation between judges and/or prosecutors in different Member States and regard, for example:

- the European Arrest Warrant,²³²
- the European Evidence Warrant,²³³
- Freezing of assets and evidence,²³⁴
- Confiscation orders,²³⁵
- Exchange of information on convictions/criminal records,²³⁶
- Decisions on (non-custodial) pre-trial supervision measures,²³⁷
- Mutual recognition and execution of convictions, both custodial and non-custodial,²³⁸
- Mutual recognition of protection measures.²³⁹

232 Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States - Statements made by certain Member States on the adoption of the Framework Decision

233 Council Framework Decision 2008/978/JHA of 18 December 2008 on the European evidence warrant for the purpose of obtaining objects, documents and data for use in proceedings in criminal matters

234 Council Framework Decision 2003/577/JHA of 22 July 2003 on the execution in the European Union of orders freezing property or evidence.

235 Council Framework Decision 2001/500/JHA of 26 June 2001 on money laundering, the identification, tracing, freezing, seizing and confiscation of instrumentalities and the proceeds of crime. COUNCIL FRAMEWORK DECISION 2005/212/JHA of 24 February 2005 on Confiscation of Crime-Related Proceeds, Instrumentalities and Property. COUNCIL FRAMEWORK DECISION 2006/783/JHA of 6 October 2006 on the application of the principle of mutual recognition to confiscation orders. COUNCIL DECISION 2007/845/JHA of 6 December 2007 concerning cooperation between Asset Recovery Offices of the Member States in the field of tracing and identification of proceeds from, or other property related to, crime. DIRECTIVE 2014/42/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 April 2014 on the freezing and confiscation of instrumentalities and proceeds of crime in the European Union.

236 Council Framework Decision 2009/315/JHA of 26 February 2009 on the organisation and content of the exchange of information extracted from the criminal record between Member States. Council Decision 2009/316/JHA of 6 April 2009 on the establishment of the European Criminal Records Information System (ECRIS) in application of Article 11 of Framework Decision 2009/315/JHA.

237 Council Framework Decision 2009/829/JHA of 23 October 2009 on the application, between Member States of the European Union, of the principle of mutual recognition to decisions on supervision measures as an alternative to provisional detention

238 Council Framework Decision 2008/947/JHA of 27 November 2008 on the application of the principle of mutual recognition to judgments and probation decisions with a view to the supervision of probation measures and alternative sanctions

239 Directive 2011/99/EU on the European Protection Order (EPO). Regulation (EU) No. 606/2013 on mutual recognition of protection measures in civil matters.

Although such cooperation often cannot be forced by Market Surveillance Authorities themselves, it does not prevent Market Surveillance Authorities from filing informal requests with judges and/or public prosecutors in their own Member State for cooperation with their colleagues in other Member States when necessary. Market Surveillance Authorities have the best overview regarding the whole distribution chain, product locations and parties involved. Their information and files may be useful in the investigation phase and/or for the completion of a case regarding criminal prosecution in other Member States. At the same time, the help of judges and/or prosecutors in other Member States might be necessary for successful Market Surveillance in the Market Surveillance Authorities home country in the investigation as well as the prosecution phase. Cooperation at those levels is therefore highly encouraged.

3.12. Overview of the recent Jurisprudence of the Court of Justice on penalties

Judgement	Extract
<p>Judgment of the Court of 26 November 2015.</p> <p>SC Total Waste Recycling SRL v Országos Környezetvédelmi és Természetvédelmi Főfelügyelőség.</p> <p>Case C-487/14.</p> <p>ECLI identifier: ECLI:EU:C:2015:780</p>	<p>[...] 51. In that regard, it is appropriate to state that Article 50(1) of Regulation No 1013/2006 requires the Member States to lay down ‘the rules on penalties applicable for infringement of the provisions of [that] regulation The penalties provided for must be effective, proportionate and dissuasive’. It is clear that that regulation does not contain more precise rules with regard to the establishment of those national penalties and, in particular, that it does not establish any express criterion for the assessment of the proportionality of such penalties.</p> <p>52. According to settled case-law, in the absence of harmonisation of EU legislation in the field of penalties applicable where conditions laid down by arrangements under that legislation are not complied with, Member States are empowered to choose the penalties which seem to them to be appropriate. They must, however, exercise that power in accordance with EU law and its general principles, and, consequently, in accordance with the principle of proportionality (see, inter alia, judgment in Urbán, C-210/10, EU:C:2012:64, paragraph 23 and the case-law cited).</p> <p>53. In that regard, it should be borne in mind that, in order to assess whether the penalty in question is consistent with the principle of proportionality, account must be taken inter alia of the nature and the degree of seriousness of the infringement which the penalty seeks to sanction and of the means of establishing the amount of the penalty (see, inter alia, judgment in Rodopi-M 91, C-259/12, EU:C:2013:414, paragraph 38 and the case-law cited). The Member States are thus required to comply with the principle of proportionality also as regards the assessment of the factors which may be taken into account in the fixing of a fine (judgment in Urbán, C-210/10, EU:C:2012:64, paragraph 54).</p> <p>54. However, it is ultimately for the national court, by taking into account all the factual and legal circumstances of the case</p>

before it, to assess whether the amount of the penalty does not go beyond what is necessary to attain the objectives pursued by the legislation in question. As regards the specific application of that principle of proportionality, it is for the national court to determine whether the national measures are compatible with EU law, the competence of the Court of Justice being limited to providing the national court with all the criteria for the interpretation of EU law which may enable it to make such a determination as to compatibility (see, inter alia, to that effect, judgment in Profaktor Kulesza, Frankowski, Józwiak, Orłowski, C-188/09, EU:C:2010:454, paragraph 30 and the case-law cited).

55. As regards the penalties imposed for infringement of the provisions of Regulation No 1013/2006, which aims to ensure a high level of protection of the environment and human health, the national court is required, in the context of the review of the proportionality of such penalty, to take particular account of the risks which may be caused by that infringement in the field of protection of the environment and human health.

56. Accordingly, the imposition of a fine penalising the illegal shipment of waste, such as that referred to in Annex IV to that regulation, in the country of transit at a border crossing point which differs from that provided in the notification document, having been consented to by the competent authorities, of which the basic amount is the same as the fine imposed for a breach of the requirement to obtain consent and to give prior notification in writing, is to be considered to be proportionate only if the circumstances of the infringement make it possible to find that they involve equally serious infringements.

57. In the light of the foregoing considerations, the answer to the fourth question referred is that Article 50(1) of Regulation No 1013/2006, according to which the penalties applied by the Member States for infringement of the provisions of that regulation must be proportionate, must be interpreted as meaning that the imposition of a fine penalising the illegal shipment of waste, such as that referred to in Annex IV to that regulation, in the country of transit at a border crossing point which differs from that provided in the notification document which had been consented to by the competent authorities, of which the basic amount is the same as the fine imposed for a breach of the requirement to obtain consent and to give prior notification in writing, is to be considered to be proportionate only if the circumstances of the infringement make it possible to find that they involve equally serious infringements. It is for the national court to determine, by taking into account all the factual and legal circumstances of the case before it, and, in particular, the risks which may be created by that infringement in the field of the protection of the environment and human

	<p>health, whether the amount of the penalty does not go beyond what is necessary to attain the objectives of ensuring a high level of protection of the environment and human health. [...]</p>
<p>Judgment of the Court of 16 July 2015.</p> <p>Robert Michal Chmielewski v Nemzeti Adó- és Vámhivatal Dél-alföldi Regionális Vám- és Pénzügyőri Főigazgatósága.</p> <p>Case C-255/14.</p> <p>ECLI identifier: ECLI:EU:C:2015:475</p>	<p>[...] 16. As Regulation No 1889/2005 lays down harmonised rules for the control of movements of cash entering or leaving the European Union, it is necessary to examine the legislation at issue in the main proceedings first of all in the light of the provisions of that regulation.</p> <p>17. As is apparent from Article 1(1) of Regulation No 1889/2005, read in conjunction with recitals 1 to 3 in the preamble thereto, in the context of promoting harmonious, balanced and sustainable economic development throughout the European Union, that regulation seeks to supplement the provisions of Directive 91/308 by laying down harmonised rules for the control of cash entering or leaving the European Union.</p> <p>18. In accordance with recitals 2, 5 and 6 in the preamble to Regulation No 1889/2005, the regulation seeks to prevent, discourage and avoid the introduction of the proceeds of illegal activities into the financial system and their investment after laundering by the establishment, inter alia, of a principle of obligatory declaration of such movements allowing information to be gathered concerning them.</p> <p>19. To that end, Article 3(1) of that regulation lays down an obligation, for any natural person entering or leaving the European Union and carrying an amount of cash equal to or more than EUR 10 000, to declare that amount.</p> <p>20. Under Article 9(1) of that regulation, each Member State is to introduce penalties to apply in the event of failure to comply with the obligation to declare. According to that provision, the penalties are to be effective, proportionate and dissuasive.</p> <p>21. In that regard, it should be noted that, according to the Court's settled case-law, in the absence of harmonisation of EU legislation in the field of penalties applicable where conditions laid down by arrangements under such legislation are not complied with, Member States are empowered to choose the penalties which seem to them to be appropriate. They must, however, exercise that power in accordance with EU law and its general principles, and consequently in accordance with the principle of proportionality (see judgments in Ntioni and Pikoulas, C-430/05, EU:C:2007:410, paragraph 53, and Urbán, C-210/10, EU:C:2012:64, paragraph 23).</p> <p>22. In particular, the administrative or punitive measures permitted under national legislation must not go beyond what is necessary in order to attain the objectives legitimately pursued</p>

by that legislation (see judgments in Ntioni and Pikoulas, C-430/05, EU:C:2007:410, paragraph 54, and Urbán, C-210/10, EU:C:2012:64, paragraphs 24 and 53).

23. In that context, the Court has stated that the severity of penalties must be commensurate with the seriousness of the infringements for which they are imposed, in particular by ensuring a genuinely dissuasive effect, while respecting the general principle of proportionality (see judgments in Asociația Accept, C-81/12, EU:C:2013:275, paragraph 63, and LCL Le Crédit Lyonnais, C-565/12, EU:C:2014:190, paragraph 45).

24. In respect of the dispute in the main proceedings, it should be noted that the effectiveness and dissuasiveness of the penalties provided for in Paragraph 5/A of Law No XLVIII have been contested neither before the referring court nor before this Court.

25. In that context, it suffices to note that penalties such as those at issue in the main proceedings seem to be an appropriate means of attaining the objectives pursued by Regulation No 1889/2005 and of ensuring effective enforcement of the obligation to declare laid down in Article 3 of that regulation, since they are likely to dissuade the persons concerned from breaching that obligation.

26. Moreover, a system under which the amount of the penalties imposed in Article 9 of that regulation varies in accordance with the amount of undeclared cash does not seem, in principle, to be disproportionate in itself.

27. As regards the proportionality of penalties imposed by the legislation at issue in the main proceedings, it should be noted that the amount of the fines is graduated according to the amount of undeclared cash.

28. In contrast to what is maintained by the European Commission, the requirement that the penalties introduced by the Member States under Article 9 of Regulation No 1889/2005 must be proportionate does not mean the competent authorities must take account of the specific individual circumstances of each case.

29. As noted by the Advocate General in points 79 to 81 of his Opinion, under Article 9(1) of that regulation, Member States enjoy a margin of discretion concerning the choice of penalties which they adopt in order to ensure compliance with the obligation to declare laid down in Article 3 of that regulation, provided that a breach of that obligation can be penalised in a simple, effective and efficient way, and without the competent authorities necessarily having to take account of other

circumstances, such as intention or recidivism.

30. However, in the light of the nature of the infringement concerned, namely a breach of the obligation to declare laid down in Article 3 of Regulation No 1889/2005, a fine equivalent to 60% of the amount of undeclared cash, where that amount is more than EUR 50 000, does not seem to be proportionate. Such a fine goes beyond what is necessary in order to ensure compliance with that obligation and the fulfilment of the objectives pursued by that regulation.

31. In that regard, it must be noted that the penalty provided for in Article 9 of Regulation No 1889/2005 does not seek to penalise possible fraudulent or unlawful activities, but solely a breach of that obligation.

32. In that context, it should be noted that, as stated in recitals 3 and 15 in the preamble to that regulation, the latter seeks to ensure more effective control of movements of cash entering or leaving the European Union, in order to prevent the introduction of the proceeds of unlawful activities in the financial system, whilst respecting the principles recognised by the Charter of Fundamental Rights of the European Union.

33. It should also be noted that Article 4(2) of Regulation No 1889/2005 provides for the possibility to detain, by administrative decision in accordance with the conditions laid down under national legislation, cash which has not been declared in accordance with Article 3 of that regulation, in order, *inter alia*, to allow the competent authorities to carry out the necessary controls and checks relating to the provenance of that cash, its intended use and destination. Therefore, a penalty which consists of a fine of a lower amount, together with a measure to detain cash that has not been declared in accordance with Article 3 thereof, is capable of attaining the objectives pursued by that regulation without going beyond what is necessary for that purpose. In this case, it is apparent from the file submitted to the Court that the legislation at issue in the main proceedings does not make provision for such a possibility.

34. In light of the foregoing considerations, it is not necessary to examine whether there exists a restriction within the meaning of Article 65(3) TFEU.

35. In those circumstances, the answer to the questions referred is that Article 9(1) of Regulation No 1889/2005 must be interpreted as precluding national legislation, such as that at issue in the main proceedings, which, in order to penalise a failure to comply with the obligation to declare laid down in Article 3 of that regulation, imposes payment of an administrative fine, the amount of which corresponds to 60% of

	the amount of undeclared cash, where that sum is more than EUR 50 000. [...]
<p>Judgment of the Court of 13 November 2014.</p> <p>Ute Reindl v Bezirkshauptmannschaft Innsbruck.</p> <p>Case C-443/13.</p> <p>ECLI identifier: ECLI:EU:C:2014:2370</p>	<p>[...] 32. It must be observed that Article 3(1) of Regulation No 2073/2005 states that the food business operators must ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I at each stage of food production, processing and distribution, including the retail sale stage.</p> <p>33. However, although Regulation No 2073/2005 sets the microbiological criteria with which foodstuffs must comply at all stages in the food chain, that regulation does not contain any provisions relating to the rules on the liability of food business operators.</p> <p>34. In that connection, it is appropriate to refer to Regulation No 178/2002. Article 17(1) thereof provides that food business operators at all stages of production, processing and distribution within the businesses under their control must ensure that foods satisfy the requirements of food law relevant to their activities.</p> <p>35. Article 17(2) of Regulation No 178/2002 provides that Member States must lay down the rules on measures and penalties applicable to infringements of food law. The measures and penalties provided for must be effective, proportionate and dissuasive.</p> <p>36. It follows that EU law and, in particular, Regulations No 178/2002 and No 2073/2005 must be interpreted as meaning that, in principle, they do not preclude national legislation, such as that at issue in the main proceedings, which penalises food business operators active only at the distribution stage for placing on the market foodstuffs which fail to comply with the microbiological criteria mentioned in Annex I, Chapter 1, Row 1.28, to Regulation No 2073/2005.</p> <p>37. However, by laying down rules on the sanctions applicable in the event of failure to comply with the microbiological criterion, the Member States are bound to observe conditions and limits laid down by EU law, including that laid down, in the present case, by Article 17(2) of Regulation No 178/2002, which requires penalties to be effective, proportionate and dissuasive.</p> <p>38. According to settled case-law, whilst the choice of penalties remains within their discretion, Member States must ensure that infringements of EU law are penalised under conditions, both procedural and substantive, which are analogous to those applicable to infringements of national law of a similar nature and importance and which, in any event, make the penalty effective, proportionate and dissuasive (see to that effect, judgment in Lidl Italia, C-315/05, EU:C:2006:736, paragraph</p>

58, and Berlusconi and Others, C-387/02, C-391/02 and C-403/02, EU:C:2005:270, paragraphs 65 and the case-law cited).

39. In the present case, the measures imposing penalties permitted under the national legislation at issue in the main proceedings must not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by that legislation; when there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see, judgment in Urbán, Case C-210/10, EU:C:2012:64, paragraph 24 and the case-law cited).

40. In order to assess whether a penalty is consistent with the principle of proportionality, account must be taken of, inter alia, the nature and the degree of seriousness of the infringement which the penalty seeks to sanction and of the means of establishing the amount of the penalty (see judgment in Equoland, C-272/13, EU:2014:2091, paragraph 35).

41. Legislation, such as that at issue in the main proceedings, providing for a fine if food stuffs unfit for human consumption are placed on the market, may help to attain the fundamental objective of food law, that is, a high level of protection of human health, as set out in paragraph 28 of the present judgment.

42. Even if the system of penalties in the case in the main proceedings is a system of strict liability, it must be recalled that, according to the case-law of the Court, such a system is not, in itself, disproportionate to the objectives pursued, if that system is such as to encourage the persons concerned to comply with the provisions of a regulation and where the objective pursued is a matter of public interest which may justify the introduction of such a system (see judgment in Urbán, EU:C:2012:64, paragraph 48 and the case-law cited).

43. It is for the national court to determine, in the light of that information, whether the penalty at issue in the main proceedings observes the principle of proportionality referred to in Article 17(2) of Regulation No 178/2002.

44. Having regard to all the foregoing, the answer to the second and third questions is that EU law, in particular Regulations No 178/2002 and 2073/2005, must be interpreted as meaning that, in principle, it does not preclude national law, such as that at issue in the main proceedings, which imposes a penalty on a food business operator active only at the distribution stage for placing a foodstuff on the market, on account of the failure to comply with the microbiological criterion laid down in Annex

	<p>I, Chapter 1, Row 1.28, to Regulation No 2073/2005. It is for the national court to determine whether the penalty at issue in the main proceedings observes the principle of proportionality referred to in Article 17(2) of Regulation No 178/2002. [...]</p>
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3.13. Application of penalties by market surveillance authorities in the 2010-2013 period

Sectors	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SL	SK	FI	SE	UK
Sector 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)		7.75	62.00				0.00						0.00				0.75			0.00	9.25	7.25		0.25	0.00	0.00		
Sector 2 - Cosmetics			70.75	2.00			0.25			38.50				1			62.75					27			0.75	0		8.00
Sector 3 - Toys		64.25	384.00	1.50		0.00		6.50		43.25	80.00		1.00	32.75		0.00	154.25				24.50	21.25	1,356	77.00	80.00	0.00	0.25	27.50
Sector 4 - Personal Protective Equipment		15.50	177.25	0.00				1.00		6.00				10.00			59.50			0.00	1.50	5.00	16.25	48.75	39.00	0.00	1.00	
Sector 5 - Construction Products	1.00	76.25	96.75			0.25		4.00		63.75			2.5	24.5			154			0.75	22	4.25	7.5	42.25	25	6		
Sector 6 - Aerosol dispensers		10.25	574.50	0.00				3.00					0.00				0.00			0.00	0.00	3.50	1.00	1.00		0.00		
Sector 7 - Simple pressure vessels and Pressure Equipment		2.00	4.00	0.00				2.25		0.00				2.50			0.00				0.25	4.25	3.00			0.00		
Sector 8 - Transportable pressure equipment		4.33	1.50	0.00				1.00		0.00				9.00			0.00				0.00		0.25	20.00		0.00		
Sector 9 - Machinery		9.50	64.50	0.00			1.00	12.25		14.00				0.75			22.75			0.50	0.25	6.75	35.25	9.00		0.00	5.00	
Sector 10 - Lifts		1.00	2.25	0.00													1.00			0.00	0.00		0.25	2.75		0.00		
Sector 11 - Cableways		2.00	2.00	0.00						0.00				0.00				0.00		0.00	0.00		0.25	8.50		0.00		
Sector 12 - Noise emissions for outdoor equipment			11.50	0.00										0.75			14.25			0.00	0.00	6.25	14.50	2.75		0.00		
Sector 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres			1.00	0.00						0.25							0.00				0.25		5.50	0.00		0.00		

Sectors	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SL	SK	FI	SE	UK
Sector 14 - Pyrotechnics		15.33	62.00	0.00		0.25	0.00			0.00		0.00	0.00				0.00				0.00		3.75		22.00	0.00		
Sector 15 - Explosives for civil uses			2.67				0.00			0.00		0.00	0.00				0.25				0.00		0.50		0.00	0.00		
Sector 16 - Appliances burning gaseous fuels		4.00	9.00	3.00				4.25		0.00				4.00			0.25			0.00	0.25	4.00	1.50	5.00	35.00	0.00	6.00	
Sector 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products		5.75	75.50	2.00		0.00	0.00	11.00		85.25	62.00			2.25		0.00	20.50			153.25	0.00	54.25	25.50	0.00	28.00	0.00		
Sector 18 - Electrical equipment under EMC		19.00	105.75	9.25	574.50					8.75			15.67	9.75		0.00	7.25			0.00	0.25	6.75	6.00	2.75		0.00		
Sector 19 - Radio and telecom equipment under RTTE		23.00	103.75	9.25	574.50	0.25		101.25		0.00		158.50	0.25	1.00		0.00	43.25			2.75	1.50	22.25	23.00	4.75		0.00		
Sector 20 - Electrical appliances and equipment under LVD	28.00	135.00	272.50							48.50			15.67	12.75		0.00	297.25			0.00	11.50	19.25	329.50	31.00	130.00	0.00		
Sector 21 - Electrical and electronic equipment under RoHS, WEEE and batteries			2.00	2.00			0.00							9.75			2.75					29.25	16.25	0.00		0.00		
Sector 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)		0.50	3.00	1.25			0.00	35.00		7.75				15.50			45.50							1.50	10.75	0.00		
Sector 23 - Ecodesign and Energy labelling		4.50	55.00	3.67			0.00			4.75		6.67	24.50	9.75		0.00	4.25			0.00	0.75		110.50	1.25	0.00	0.00		
Sector 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels							0.00	2.50									0.00						0.00			0.00		
Sector 25 - Recreational craft			1.67	0.00				2.00		0.00				0.00						0.00	0.00			0.25	0.00	0.25	5.00	
Sector 26 - Marine Equipment				0.00						0.00		0.00								0.00	0.00	1.25	0.00			0.00	0.00	
Sector 27 - Motor vehicles and tyres		33.50		0.25						4.00				3.33			0.00			0.00			546.25	4.00	0.00	0.00		

Sectors	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SL	SK	FI	SE	UK
Sector 28 - Non-road mobile machinery														2.00			0.25						9.50	2.50				
Sector 29 - Fertilisers	0.75	3.25	1.25		2.00		0.00			0.50	5.00						6.75				17.5	6	9	14	10.75	0		
Sector 30 - Other consumer products under GPSD		446.50	1.67					54.75		5.50				6.00		0.00	390.00					34.75	7.25			0.00	1.00	

3.14. Overview of the penalties in the field of toy safety

Introduction

In view of gathering information on the enforcement of Union harmonisation legislation in the Member States and the extent of any differences that may exist, the Commission drew up a questionnaire for Member States on penalties for infringements of the national provisions adopted pursuant to Directive 2009/48/EC on the safety of toys. In particular, this questionnaire concerned the implementation of article 51 of Directive 2009/48/EC.

Twenty-seven Member States responded to the questionnaire. Also, two EEA countries – Norway and Iceland - submitted responses.

The following general conclusions may be drawn from the replies provided:

- At national level, the focus is clearly on ensuring that non-compliant toys are not available on the market. Whenever a non-compliant toy is found, action by national authorities is directed at withdrawing/recalling the toy as appropriate, sometimes by issuing warnings. However, national authorities do not necessarily follow these actions with infringement proceedings which would lead to the imposition of a penalty on the responsible economic operator.
- It is not clear whether the measures reported as penalties by national authorities do have a punitive element and thus should be in practice classified as such (i.e. withdrawing a product from the market).
- Whilst in most countries a certain choice of penalties is available, these are not really imposed in practice in many countries. The information provided on the penalties imposed per year is not sufficiently comparable, since the time periods are not the same in all the replies and in some cases they are provided in absolute numbers while in others they are provided only as a percentage of non-compliances found. However, it can be seen that there are a number of countries with a stronger focus on enforcement and where penalties, and in particular economic sanctions, are often imposed whilst in some other countries the focus of the authorities is not in the imposition of penalties. Similarly, the maximum economic penalty that can be imposed in theory varies greatly across the EU.

Distinction by the legislation between the different ‘types’ of infringements - formal non-compliance vs. non-compliance with essential requirements

- More than half of the countries that replied– 17 out of 29- reported that their legislation makes a distinction between these different types of infringements (BG, CZ, EL, ES, HR, IT, LV, LT, LU, NL, AT, PT, RO, SI, SK, FI and IS).
- Other countries indicated that the legislation did not make such distinction (BE, DE, FR, PL, MT, CY, IE, EE, DK, SE, UK and NO).

For the following situations, several actions may be taken by the national authorities. It is not clear whether many of these may be defined as a penalty. The degree of discretion for national authorities varies across the EU. In some cases, the legal provisions on the applicable penalties are graduated depending on whether the infringement at hand was a formal non-compliance or a non-compliance with the essential requirements. In other cases, it is the up to the authorities to make these adjustments depending on the circumstances of the case. In particular, the actions taken due to a formal non-compliance will likely be less stringent at first, with more serious measures being taken if the formal non-compliance is not remedied.

a. Formal non-compliance

- i. The CE marking has been affixed in violation of Article 16 or 17 of the TSD
 - A warning may be sent to the economic operator – BE, NL, SI
 - Measures taken against the product: product recall or withdrawal– EL, IT, NL, IE, RO, UK NO, IS
 - A fine may be imposed – BG, CZ, EE, EL, HR, FR, CY, LU, PT, RO, SK, UK, MT, ES, IE
 - Imprisonment – UK, MT
- ii. The EC declaration of conformity has not been drawn up correctly
 - A warning may be sent to the economic operator- BE, NL, SI
 - Measures taken against the product: product recall or withdrawal - EL, IT, IE, NL, RO, SE, UK, IS, NO
 - A fine may be imposed - BG CZ, EE, EL, HR, FR, IT, CY, LU PT, RO, SK, UK, MT, SE, ES, IE
 - Imprisonment – UK, MT
- iii. The EC declaration of conformity has not been drawn up
 - A warning may be sent to the economic operator- BE, NL, SI
 - Measures taken against the product: product recall or withdrawal – BE, EE, EL, IE, IT, NL, RO, SE, UK, IS, NO
 - A fine may be imposed – BG, CZ, EE, EL, ES, IE, HR, CY, LU, LV, FR, PT, RO, SK, MT, SE, UK
 - Imprisonment – UK, MT
- iv. The CE marking has not been affixed

- A warning may be sent to the economic operator BE, NL, SI
- Measures taken against the product: product recall or withdrawal – BE, BG, EL, LV (confiscation), HR, IT, RO, FI, SE, IS, NO
- A fine may be imposed – BG, CZ, EE, EL, FR, IT, HR, MT, CY, LU, PT, RO, SK, UK, ES, IE, LV, SE
- Imprisonment – UK, MT

v. The technical documentation is either not available or not complete

- A warning may be sent to the economic operator - BE, NL, SI
- Measures taken against the product: product recall or withdrawal – BE, EL, IE, HR, IT, IS, NL, RO, SE, UK, NO, LV (confiscation)
- A fine may be imposed – BG, CZ, EE, FR, IT, CY, LU, PT, RO, SK, UK, HR, ES, EL, LV, MT, SI, SE
- Imprisonment – UK, MT

b. Failure to meet one or more essential requirements set out in the TSD

- A warning may be sent to the economic operator BE, NL
- Measures taken against the product: product recall or withdrawal BE, EL, HR, IT, NL, UK, BG, IE, RO, FI, SE, IS, NO. Confiscation/destruction: LV, LU, IS
- A fine may be imposed – BG, CZ, EE, EL, FR, HR, IT, LU, PT, RO, SK, UK, ES, IE, LV, MT, NL, AT, SI, SE
- Publication of penalties/public warning – NO, ES
- Criminal prosecution possible- IE, CY, LU, PL, ES
- Imprisonment – UK, FR, IT, LV, MT, IS

c. Failure to comply with the applicable conformity assessment procedures

- A warning may be sent to the economic operator - BE, NL
- Measures taken against the product: product recall or withdrawal - BE, EL, HR, IT, NL, ES, IE, RO, FI, SE, UK, IS, NO. Confiscation LV, LU
- A fine may be imposed – BG, CZ, EE, EL, HR, FR, PT, RO, SK, UK, ES, IE, LV, MT, NL, AT, SE
- Criminal prosecution possible – LU, PL

- Imprisonment – UK, LU, MT

Most common types of toy safety related infringements

The most common TSD-related infringements were reported to be the following:

- Administrative deficiencies
 - Lack of or incomplete technical file – BE, NL
 - Formal non-compliance in general- EL, CY, SE, NO
 - Problems with the warnings (absence or incorrect languages), safety information or labelling errors – BE, BG, EE, CZ, IE, ES, FR, LV, LT, AT, PL, PT, SI, SK, UK, IS
 - Problems with EU Declaration of conformity- PL, SK
 - Problems with the contact details of manufacturers/importers – BE, BG, CZ, LV, PL, SK
 - CE marking – IE, ES, FR, HR, IT, MT, PT, IS
- Non-compliance with essential requirements
 - In general – FR, ES, HR, CY, NL, AT, RO, FI, UK
 - Requirements for children under 3 – BE, BG, IE, LT, IS
 - Chemical properties – EE
 - Sound levels - EE

Cases of infringement (as a percentage on a yearly basis) actually pursued all the way to imposition of an economic penalty

Member States have not been able to provide information on a yearly basis in many cases and the information provided is unfortunately difficult to compare. In some cases, the information is provided in absolute numbers (without referring to the actual number of overall non-compliance cases found) and in others it is provided as a percentage. From the information provided, it can be observed that in most Member States the enforcement of the Toy Safety Directive is focused on ensuring that non-compliant toys are not available on the market.

In cases where an infringement of the Directive is observed, no economic penalties are imposed in many MS (LU, NO, SE, MT, IE or PT). Some other MS have not been able to provide any estimation on percentages or absolute numbers for penalties imposed in past periods (BE, DE, FR, IT, CY, RO, FI, SK, UK).

In cases where this information is provided, it ranges between a handful of cases (2 since the entry into force of the Directive in DK, 3 to 10 per year in IS) to a much higher number per year (314 cases in a given year (2013) in ES or 600 per year in CZ).

Finally, even in those cases where Member States have declared to have taken measures, it is not clear that the measure should be considered as such as a penalty or just a corrective measure to remove the product from the market.

Detailed information:

- Unknown / No information– BE, DE, FR, IT, CY, RO, FI, SK, UK
- No cases where penalties were imposed – LU, NO, SE, MT (10 per year with measure, ban or withdrawal but no penalty) IE (no penalties but toys withdrawn), PT

Reporting in absolute numbers

- DK: 2 cases since the entry into force of the Toy Safety Directive
- IS: 3-10 per year
- BG: 213 between 2011 and May 2014
- CZ: 600 per year
- ES: 314 in 2013 with imposition of penalty
- NL: 29 in 2013
- HR: 31 penalties between 2011 and 2014 –
- LT: 54 administrative penalties and 12 economic sanctions out of 145 infringements in 2013
- PL: 23 out of 132 in 2013 but not clear it is a penalty
- SI: 99 out of 1540 inspections in 2013

Reporting in percentage figures

- EL: from 1% to 10% per year
- AT: 20% - 25% - administrative penalties or corrections to products being made (not clear these are classified as penalties)
- 30% - 40% per year EE (between 2010 and July 2014) and LV in 2013

- 50% - 60% per year for LV in 2014.

Nature of the penalties that are in force to fulfil the criteria of article 51 TSD of "effective proportionate and dissuasive" penalties

Regarding whether the penalties imposed are of an administrative or criminal nature, the following answers were provided in the different countries:

- Only administrative penalties – BG, CZ, LT, PT, RO, SK, SE
- Only criminal penalties – DK, MT, NO, PL
- Both criminal and administrative penalties. – BE, EE (criminal only in case of danger to human life or health), EL, ES, FR, IT, CY, LV, LU, NL, AT, SI, FI, IS

Penalties or sanctions that can be imposed

Twenty-six Member States as well as IS and NO reported to have the possibility of imposing economic sanctions.

Twenty-four Member States and IS and NO reported to also have the possibility of imposing other than economic sanctions.

In particular:

- Economic sanctions – BG, BE, CZ, DK, EE, IE, EL, ES, FR, HR, IT, CY, LV, LT, LU, MT, NL, AT, PL, PT, RO, SI, SK, FI, SE, UK, IS, NO
- Imprisonment – EE, IE, EL, IT, CY, LV, LU, MT, NL, SI, UK, IS, NO
- Seizure or destruction of the product – BG, CZ, DK, EE, IE, EL, ES, FR, HR, IT, CY, LV, LU, NL, AT, PT, RO, FI, SE, UK, IS, NO
- Publication of the fines imposed or of the judgment – BE, IE, EL, ES, CY, NL, AT, SK, UK, IS
- Temporary or permanent disqualification from the practice of industrial or commercial activities, including stopping production – BE, ES, FR, HR, LV, LU, MT, NL, AT, RO, SE, IS
- Others:
 - Measures on the product (withdrawal) BE, BG, EL, FR, FI
 - Community service: LV

Highest level of economic penalty foreseen

The highest level of economic penalty is:

- a) **Below €10.000:** in BG (€7673), RO (€2229) and UK (€6896).
- b) **Between €10.000 and €50.000:** in HR (€13.097), LV (€14.000), NL (€20.250), LT (€23.169), MT (€23.293), EL (€40.000), CY (€40.000), PT (€ 44. 891) and IT (€50.000).
- c) **Above €50.000:** in IS (€70.793), BE (€150.000), IE (€500.000), LU (€500.000), ES (€660.000), CZ (€ 1.850.365) and EE (€16.000.000).

No specific amount was indicated for DK, SI, SK, FI, SE, NO.

Aggravating or mitigating circumstances taken into account when setting a penalty

- Several countries (IE, MT, PL, UK and NO) indicated that such circumstances are not foreseen in the law, but they are for the Court to appreciate when determining the level of a fine.
- Five MS indicated that neither aggravating nor mitigating factors are taken into account (HR, IT, RO, FI, SE) when setting the penalty.
- CY, EL, NL and SI take into account mitigating factors and the rest of the countries indicated to take into account both aggravating and mitigating circumstances (BG, CZ, DK, EE, ES, FR, LV, LT, IS, LV, AT, PT, SK).

As aggravating circumstances, the following are taken into account:

- Having previously committed an offense in BG, CZ, ES, FR, LV or SK.
- The seriousness of the damage caused in EE, ES, LV, PT, SK.
- The intent or degree of fault in ES, AT, PT or FR.

As mitigating factors, the following are taken into account:

- Negligence in NL or PT
- Voluntary compensation for any damage or efforts by the economic operator to provide redress in EE, SI, SK, LT, LV
- Willingness to cooperate with the relevant authorities in SL, LT, LV and CY.

Effect of the recidivism on the level of the penalty

The majority of the respondents reported that the recidivism affected the level of penalty imposed (BE, BG, CZ, DK, EE, EL, ES, FR, HR, CY, LV, LT, LU, MT, NL, AT, PT, RO, SK, IS). Some of the respondents explicitly specified that the imposition of penalties is within the jurisdiction of a national criminal court (IE, PL, UK, NO). In four cases (FI, SI, SE, IT), it was indicated that recidivism is not taken into account.

Enforcement of penalties imposed on economic operators based in another MS for infringements committed in the national Member State

The majority of the countries reported that they enforce penalties only to economic operators established in their respective country (BG, CZ, DK, DE, EE, IE, ES, FR, HR, CY, LV, LT, PL, RO, SK, FI, SE, UK, IS, NO). However, in some cases they ask for assistance from, or send a notification to the authorities in other countries (CZ, DE, IE, MT, SI, NL, PL, and RO)

Several Member States specified they the measures apply to the economic operator responsible for making the product available on the national market (EL, LU, PT) irrespectively of where the economic operator is based. Once the penalty is imposed the respective Member State informs the Member State where the economic operator is based (BE, IT, LV, LU, PT).

Problems in enforcing penalties imposed on economic operators based in another Member States

- The majority of the respondents reported that they have no precedent in this regard or that this is not applicable due to the national legislative system (BG, CZ, DK, DE, EE, IE, EL, FR, HR, IT, CY, LT, LU, NL, PL, RO, SI, SK, FI, SE, NO)
- Two Member States (MT, UK) reported they didn't have any problems to report.

The problems reported in enforcing penalties imposed on economic operators based in different Member States for infringements committed in another Member State were:

- Economic operators do not respond to registered letters (BE)
- No means for enforcing such penalties (ES, LV, NO)
- communicating the procedural documents, given the language barrier was considered problematic (PT)
- Economic costs (PT)
- Information flow in between the MS and EEA in terms of imposition of penalties was considered problematic (IS)

Prosecution of infringements committed by online retailers located outside the EU

The majority of the MS and NO reported that they do not have precedent in pursuing infringements committed by online retailers located outside the EU (BE, BG, CZ, DK, DE, EE, IE, EL, ES, FR, HR, IT, CY, LV, LT, NL, PL, RO, SI, SK, FI, UK, NO).

BE indicated that action is taken under the E-commerce Directive but that retailers outside the EU rarely cooperate. DE mentioned that action against non-compliant products from online retailers established outside the EU is taken indirectly under the customs procedures by

imposing an import ban. ES, SI, SE, IS and LU indicated that these situations fall within the scope of EU legislation, however they highlight that compliance is difficult to enforce. LU acts, in cooperation with customs authorities, against the product present in the national territory. Other States report to only inform the country of origin about infringements (AT, FI).

3.15. Penalties for non-compliance with the legislation on toys safety

Country	National legislation (transpositions of Article 51 of Directive 2009/48/EC)
Austria	<p>Federal Act against Unfair Competition 1984</p> <p>§ 32: up to 2900 € Food Safety and Consumer Protection Act</p> <p>§ 90: up to € 20,000, in case of recurrence 40,000 € or Imprisonment up to 6 weeks</p>
Belgium	<p>Art. XV.69. 1 Les dispositions du Livre Ier du Code pénal sont applicables aux infractions visées par le présent Code sous réserve de l'application des dispositions spécifiques mentionnées ci-après.</p> <p>Art. XV.70. Les infractions aux dispositions du présent Code sont punies d'une sanction pouvant aller du niveau 1 au niveau 6.</p> <ul style="list-style-type: none"> - La sanction de niveau 1 est constituée d'une amende pénale de 26 à 5 .000 euros. - La sanction de niveau 2 est constituée d'une amende pénale de 26 à 10.000 euros. - La sanction de niveau 3 est constituée d'une amende pénale de 26 à 25 .000 euros. - La sanction de niveau 4 est constituée d'une amende pénale de 26 à 50 .000 euros. - La sanction de niveau 5 est constituée d'une amende pénale de 250 à 100.000 euros et d'un emprisonnement d'un mois à un an ou d'une de ces peines seulement. - La sanction de niveau 6 est constituée d'une amende pénale de 500 à 100.000 euros et d'un emprisonnement d'un an à cinq ans ou d'une de ces peines seulement. <p>Art. XV.71. Lorsque les faits soumis au tribunal font l'objet d'une action en cessation, il ne peut être statué sur l'action pénale qu'après qu'une décision coulée en force de chose jugée a été rendue relativement à l'action en cessation.</p>

Art. XV.72. En cas de récidive dans les cinq ans à dater d'une condamnation coulée en force de chose jugée du chef de la même infraction, le maximum des amendes et des peines d'emprisonnement est porté au double.

Art. XV.73. Les sociétés et associations ayant la personnalité civile sont civilement responsables des condamnations aux dommages-intérêts, amendes, frais, confiscations, restitutions et sanctions pécuniaires quelconques, prononcées pour infraction aux dispositions du présent Code contre leurs organes ou préposés.

Il en est de même des membres de toutes associations commerciales dépourvues de la personnalité civile, lorsque l'infraction a été commise par un associé, gérant ou préposé à l'occasion d'une opération entrant dans le cadre de l'activité de l'association. L'associé civilement responsable n'est toutefois personnellement tenu qu'à concurrence des sommes ou valeurs qu'il a retirées de l'opération.

Ces sociétés, associations et membres peuvent être cités directement devant la juridiction répressive par le ministère public ou la partie civile.

Art. XV.74. A l'expiration d'un délai de dix jours à compter du prononcé, le greffier du tribunal ou la cour est tenu de porter gratuitement à la connaissance du ministre, par lettre ordinaire ou par voie électronique, tout jugement ou arrêt faisant application d'une disposition du présent livre.

CHAPITRE 2. - Les infractions sanctionnées pénalement

Section 2. - Les peines relatives aux infractions au Livre IV

Art. XV.80. Toute infraction aux articles IV.13 et IV.14 est punie d'une sanction de niveau 2. Toute infraction à l'arrêté visé à l'article IV.15 est punie d'une sanction de niveau 5.

L'utilisation ou la divulgation, à d'autres fins que l'application du Livre IV et des articles 101 et 102 du TFEU, des documents ou renseignements obtenus en application des dispositions du Livre IV, est punie d'une sanction de niveau 5.

Toute infraction aux articles IV.34 et IV.35 est également punie d'une sanction de niveau 5.

Section 3. - Les peines relatives aux infractions au Livre V

Art. XV.81. Sont punis d'une sanction du niveau 5, ceux qui, étant tenus de fournir les renseignements en vertu du Livre V, titre 2 du présent Code, ne remplissent pas les obligations qui leur sont imposées.

Art. XV.82. Sont punis d'une sanction du niveau 6, ceux qui commettent une infraction à l'article V.8 ou ne se conforment pas ou refusent leur

collaboration à l'exécution de ce que dispose une décision prise en application des articles V.4, V.5, V.11 et V.12 et V.14, § 3, du présent Code.

Section 6. - Les peines relatives aux infractions au Livre VIII

Art. XV.99. Sont punis d'une sanction du niveau 2 :

1° ceux qui, en employant des manoeuvres frauduleuses, obtiennent ou tentent d'obtenir d'un organisme accrédité en vertu du Livre VIII, titre 2, un certificat ou un rapport d'évaluation de la conformité;

2° ceux qui accordent un certificat ou un rapport d'évaluation de la conformité en infraction aux dispositions du Livre VIII, titre 2, ou de ses arrêtés d'exécution;

3° ceux qui utilisent ou tentent d'utiliser un certificat ou un rapport d'évaluation de la conformité en infraction aux dispositions du Livre VIII, titre 2, ou de ses arrêtés d'exécution;

4° ceux qui, en employant des manoeuvres frauduleuses, notamment par des agissements qui peuvent prêter à confusion, donnent faussement l'impression qu'un produit, un service ou un processus bénéficie d'un certificat ou un rapport d'évaluation de la conformité délivré par un organisme accrédité en vertu du Livre VIII, titre 2.

Art. XV.100. Sans préjudice de l'application, s'il y a lieu, des peines prévues par le Code pénal, notamment par l'article 184 en matière de contrefaçon de marques, sont punis d'une sanction du niveau 2 :

1° ceux qui ont contrevenu aux dispositions du Livre VIII, titre 3, ou à ses arrêtés d'exécution ou aux règlements pris en vue de son exécution, ainsi qu'aux conditions accompagnant les dérogations accordées en vertu de l'article VIII.56;

2° ceux qui détiennent ou emploient des instruments de mesure manifestement inexacts, dans les lieux précisés à l'article VIII.45;

3° ceux dont les activités comportent une référence abusive au Réseau visé à l'article VIII.55, § 4, 2°.

Art. XV.101. Sans préjudice de l'application des règles relatives à la saisie et la confiscation, les instruments de mesure dont la détention ou l'usage constituent des infractions aux dispositions du Livre VIII, titre 3, ou à ses arrêtés d'exécution ou aux règlements pris en vue de son exécution peuvent être détruits.

Section 7. - Les peines relatives aux infractions au Livre IX

Art. XV.102. § 1er. Sont punis d'une sanction du niveau 2, ceux qui

	<p>enfreignent l'article IX.9.</p> <p>§ 2. Sont punis d'une sanction du niveau 3 :</p> <p>1° ceux qui mettent sur le marché des produits dont ils savent ou dont ils auraient dû savoir, sur la base de normes européennes ou belges, qu'ils ne présentent pas les garanties visées à l'article XI.2 en ce qui concerne la sécurité et la protection de la santé;</p> <p>2° ceux qui enfreignent l'article IX.8;</p> <p>3° ceux qui enfreignent les articles IX.4, IX.5, IX.6 et IX.7 ou un arrêté pris en exécution des articles IX. 4, §§ 1er à 3 et IX.5, §§ 1er et 2;</p> <p>4° ceux qui ne donnent pas suite aux avertissements visés à l'article XV.31.</p> <p>5° ceux qui commettent des infractions aux règlements de l'Union européenne qui ont trait à des matières relevant, en vertu du Livre IX, du pouvoir réglementaire du Roi.</p> <p>Section 12. - Entrave au contrôle</p> <p>Art. XV.126. Tout empêchement ou entrave volontaire à l'exercice des fonctions des agents visés à l'article XV.2 ou des fonctionnaires de police de la police locale et fédérale est, en application des dispositions du présent Code, puni d'une sanction du niveau 4.</p> <p>Toute nouvelle infraction telle que visée à l'alinéa 1er commise avant que cinq années ne se soient écoulées depuis l'accomplissement de la peine ou de la prescription de celle-ci pour la même infraction, est punie d'une sanction du niveau 5.</p> <p>CHAPITRE 3. - Les peines complémentaires [...]</p> <p>Section 2. – Confiscation</p> <p>Art. XV.130. Sans préjudice de l'application des articles 42 à 43quater inclus du Code pénal, en cas de condamnation pour une infraction aux Livres VIII et IX les Cours et Tribunaux sont autorisés à prononcer la confiscation, même lorsque le propriétaire de l'objet de l'infraction est une tierce personne.</p> <p>Sans préjudice de l'application des articles 42 à 43quater du Code pénal, ils ont également la faculté de prononcer, même s'ils sont la propriété d'un tiers, la confiscation des moyens de production, de transformation, de distribution, de transport et d'autres objets quelconques destinés ou ayant servi à produire, fabriquer, transformer, distribuer ou transporter les biens faisant l'objet de l'infraction ainsi que des moyens nécessaires pour prester les services.</p> <p>Lorsque l'objet de l'action en confiscation est la propriété d'un tiers, ce tiers</p>
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	<p>est appelé à la cause et, si aucune preuve de sa mauvaise foi n'est apportée, la confiscation n'est pas prononcée ou est annulée.</p> <p>Les cours et tribunaux peuvent en outre ordonner la confiscation des bénéfices illicites réalisés à la faveur de l'infraction.</p> <p>Section 3. - L'affichage du jugement ou de l'arrêt</p> <p>Art. XV.131. En cas de condamnation pour une infraction aux Livres VIII et IX les cours et tribunaux peuvent ordonner l'affichage du jugement, de l'arrêt ou du résumé qu'ils en rédigent pendant le délai qu'ils déterminent, aussi bien à l'extérieur qu'à l'intérieur des établissements du contrevenant et aux frais de celui-ci, de même que la publication du jugement, de l'arrêt ou du résumé aux frais du contrevenant dans des journaux ou de toute autre manière.</p>
<p>Bulgaria</p>	<p>Chapter Six ADMINISTRATIVE PENAL PROVISIONS (Bulgarian Law on Technical Requirements to Products)</p> <p>Art. 50. (amended — SG No 93 of 2002, SG No 45 of 2005, SG No 86 of 2007) any person that violates the provisions of Articles 3 or 4 shall be punishable by a fine of BGN 1000 to 5000 or a financial penalty of BGN 5000 to BGN 15 000.</p> <p>Art. 51. (amended — SG No 93 of 2002, SG No 86 of 2007) a person who draws up and/or used a declaration of compliance with content which does not comply with the content defined in the Regulations referred to in Articles 7 and/or the implementing measures referred to in Article 26a or with new approach Directives shall be punishable by a fine of BGN 300 to 1000 or a financial penalty of BGN 1000 to 5000 if the act is not an offence.</p> <p>Article 51a. (New — SG No 93 of 2002, amended in SG No 45 of 2005) any person who places on the market and/or puts into service products with conformity marking in breach of the Regulation referred to in Article 24 shall be punishable by a fine of BGN 300 to 800 or a financial penalty of BGN 500 to BGN 1000.</p> <p>Article 51b. (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, supplemented in SG No 86 of 2007) any person who places on the market and/or puts into service products with conformity marking and supplementary marking or declaration of conformity without having assessed their compliance with the essential requirements laid down in the Regulations referred to in Articles 7 and/or with the eco-design requirements laid down in implementing measures under Article 26a, shall be liable to a fine of BGN 3000 to 8000 or a financial penalty of BGN 5000 to BGN 10 000.</p> <p>Article 51c. (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, supplemented in SG No 86 of 2007) any person who places on the market and/or puts into service products without marking, without</p>

additional markings or without declaration of conformity, when requested, under the provisions of Article 7 and/or with the eco-design requirements laid down in implementing measures under Article 26a, shall be liable to a fine of BGN 500 to 800 or a financial penalty of BGN 1500 to BGN 3000.

Article 51d. (New — SG No 86 of 2007, amended in SG No 38 of 2011) any person who places on the market and/or puts into service products marked contrary to the requirements of Regulation (EC) No 106/2008 of the European Parliament and of the Council of 15 January 2008 on a Community programme for labelling the energy efficiency of office equipment (OJ L 39/1 of 13 February 2008) shall be punishable by a fine of BGN 3000 to 8000 or a financial penalty of BGN 5000 to BGN 10 000.

Art. 52. (amended — SG No 93 of 2002, SG No 45 of 2005, SG No 86 of 2007) any person that fails to fulfil its obligations under Articles 25 or 26, paragraph 1 or 2 shall be punishable by a fine of BGN 500 to 1000 or a financial penalty of BGN 5000 to BGN 10 000.

Article 52a. (New — SG No 93 of 2002, amended in SG No 45 of 2005, SG No 86 of 2007) any person who places on the market and/or puts into service products without indicated on them the name and/or its head office or without instruction and/or instruction for use in Bulgarian shall be punishable by a fine of BGN 200 to 500 or a financial penalty of BGN 500 to BGN 2000.

Article 52b. (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, amended in SG No 86 of 2007) a trader who makes products without conformity marking or without additional marking, when such marking is required in the Regulations referred to in Articles 7 and/or the implementing measures referred to in Article 26a, shall be liable to a fine or penalty payment of BGN 250-1000

Article 52c. (New — SG No 93 of 2002, amended in SG No 45 of 2005, amended and supplemented in SG No 86 of 2007) a trader who makes products without declaration of conformity, when requested, under the provisions of Article 7 and/or implementing measures under Article 26a, shall be liable to a fine or penalty payment of BGN 250-1000

Article 52d. (New — SG No 93 of 2002, amended in SG No 45 of 2005, SG No 86 of 2007) a trader who makes products without indication of name or address of management to the person who places on the market and/or put into service is punishable by a fine or penalty payment of BGN 250-1000

Article 52e. (New — SG No 93 of 2002, amended in SG No 45 of 2005, SG No 86 of 2007) a trader who makes products without instruction and/or instruction for use in Bulgarian, shall be liable to a fine or penalty payment of BGN 250-1000

Article 52f. (New — SG No 86 of 2007, amended in SG No 38 of 2011) a

trader who makes products marked contrary to the requirements of Regulation (EC) No 106/2008 of the European Parliament and of the Council of 15 January 2008 on a Community programme for labelling the energy efficiency of office equipment, shall be punishable by a fine of BGN 250 or confiscation of property worth BGN 1000.

Art. 53. (amended — SG No 93 of 2002, supplemented in SG No 45 of 2005, amended in SG No 86 of 2007, SG No 38 of 2011) for non-compliance or infringement of the compulsory rules referred to in Article 30a, paragraph 1, 2, 4 and 5 and Art. 30c, paragraph 1 shall be fined BGN 300 to 1000 or a financial penalty of BGN 1000 to BGN 5000.

Article 53a. (New — SG No 86 of 2007) for other infringements of the provisions of Article 7 and/or implementing measures under Article 26a shall be punishable by a fine of BGN 300 to 1000 or a financial penalty of BGN 1000 to BGN 5000.

Art. 54. Article 219. (1) (Amended — SG. — SG No 93 of 2002, SG No 45 of 2005, SG No 95 of 2005, amended and supplemented in SG No 86 of 2007) Statements establishing infringements under Articles 50, 51, 51a to 51d, 52, 52a to 52f, 53, 53a and 56 shall be drawn up by officials designated by the President of the State Agency for Metrological and Technical Surveillance.

(2) (supplemented, — SG No 45 of 2005, amended in SG No 95 of 2005) the penalty decrees shall be issued by the State Agency for Metrological and Technical Surveillance or officials authorised by him.

(3) (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, repealed in SG No 77 of 2012, in force since 9.10.2012).

Art. 55. (1) (amended and supplemented. — SG No 93 of 2002) in breach of the provisions of Articles 36, 44, 46 paragraph 1, 1, 6 and 7 or paragraph 2 and of the coercive administrative measure referred to in Article 49, paragraph 1, natural persons are liable to a fine of BGL 500-10 000, and legal persons and sole traders, financial penalty in the same order.

(2) (supplemented, — SG No 93 of 2002) for other breaches of Chapter Five of the law and its implementing regulations, the penalty shall be a fine or penalty payment of BGN 100 to BGN 2000.

Art. 56. (Supplemented — SG No 86 of 2007) that prevents or does not provide the documents referred to in Art. 30 g (1) (4 market surveillance authorities and technical surveillance authorities to perform their duties is punishable by a fine of BGN 200 to 2000.

Art. 57. Where breaches of this Law or its implementing regulations are committed by those serving equipment with increased risk, infringers may be

deprived from the acquired competence for a period of one month to two years.

Art. 58. (1) (supplemented, — SG No 45 of 2005) the infringements chapter 5 of law and its implementing provisions and infringements under Article 56 shall be established by an official report drawn up by the staff of the Directorate-General for Inspection for government technical supervision”.

Article 219. (2) (Amended — SG. — SG No 95 of 2005) the penalty decrees shall be issued by the State Agency for Metrological and Technical Surveillance or officials authorised by him.

(3) (New — SG No 93 of 2002, repealed in SG No 77 of 2012, in force since 9.10.2012).

Article 58a. (New — SG No 45 of 2005) (1) (amended, — SG No 86 of 2007) for the breach is ascertained in accordance with Article 14a or 14b be penalised by a financial penalty of BGN 600.

(2) (New — SG No 86 of 2007) in the event of a repeated infringement under paragraph 1 shall be liable to a penalty or a fine of BGN 1000.

Article 219. (3) (Amended — SG. — SG No 95 of 2005, former subparagraph 2, No 86 of 2007, amended in SG No 66 of 2013, in force as of 26.07.2013, SG No 66 of 2013, in force as of 26.07.2013) Statements establishing infringements under paragraphs 1 shall be drawn up by determined by the President of the State Agency for Metrological and Technical Supervision of the Minister of Investment Design, officials of the relevant administration. Penalty enactments shall be issued by the State Agency for Metrological and Technical Supervision of the Minister of investment design.

Art. 59. The procedure for establishing infringements, issuing, appealing and implementing penalty enactments shall be as set out in the Administrative Infringements and Penalties Act.

Article 59a. (New — SG No 86 of 2007) (1) Where the infringer does not arrive to drafting the Act on administrative violation by the control authorities, the act shall be sent immediately for service by the municipality or mayoralty of the registered office of the legal person or sole proprietor. They are obliged to notify the infringer with communication with acknowledgement of deposited Act and within 14 days from the date of receipt to be served. No show of the infringer this statement should be signed by an authorised officer of the municipality or mayoralty and will be forfeited. Upon return of the Act within two months is issued and shall enter into force from the date of issue.

(2) The penal orders indicate that the fine or financial penalty imposed, as well as the costs for taking and testing of samples of products shall be payable to the bank account of the State Agency for Metrological and Technical

	<p>Surveillance and serve as a formal reminder after their entry into force.</p> <p>(3) Where the infringer is not found at the address indicated in the service of infringement notices, or has left the country, or has indicated address only abroad, an order will be forfeited. It shall be considered effective two months as of its issue.</p> <p>(4) (Repealed. — SG No 38 of 2012, in force since 1.07.2012).</p>
<p>Croatia</p>	<p>Directive on safety of toys are prescribed in Article 42 and 44 of the Act on Common Use Items which is published in the Official Gazette of the Republic of Croatia No 39/2013. (found in http://narodne-novine.nn.hr/clanci/sluzbeni/2013_04_39_719.html - Google translate)</p> <p>V. PENAL PROVISIONS</p> <p>Article 42</p> <p>(1) A fine of the amount of HRK 50,000.00 to 100,000.00 shall be imposed on a legal person as a business operator in general use if :</p> <ol style="list-style-type: none"> 1. Puts on the market defective or incompatible consumer goods contrary to the Article 4 of this Act; 2. Puts on the market consumer goods that have no information on the product in accordance with Article 6 of this Act; 3. Puts on the market consumer goods contrary to Article 7 of this Act; 4. Advertises smoking accessories contrary to the provisions of Paragraph 3 of Article 9 of this Act; 5. Acts contrary to the Article 10 of this Act; 6. Performs internal control in accordance with Article 13 of this Act; 7. Acts contrary to the Article 15 of this Act; 8. Provides to the consumer goods which serve as a carrier for the transport of food used for other purposes in contravention of Article 16 Paragraph 2 of this Act; 9. Does not perform laboratory testing products and keep records of the testing performed, or does not examine the microbiological purity of production in accordance with Article 18 paragraphs 1 and 2 of this Act; 10. As competent inspector does not make available the required quantity of samples for laboratory testing in accordance with Article 22

	<p>Paragraph 2 of this Act;</p> <p>11. Produces and markets detergents, cosmetic products and materials and articles intended to come into direct contact with food, contrary to the specific requirements of Articles 25, 26 and 27 of this Act;</p> <p>12. Imports items of general use, contrary to Article 30 of this Act.</p> <p>(2) For the offense referred to in paragraph 1 of this Article a fine of 5,000.00 to 10,000.00 shall be imposed on the responsible person or the legal person.</p> <p>(3) For the offense referred to in paragraph 1 of this Article any natural person - craftsman shall be punished as business operator with general use as business operator with general use by a fine of HRK 5,000.00 to 15,000.00.</p> <p>(4) For the offense referred to in paragraph 1 of this Article any natural person shall be punished by a fine of HRK 3,000.00 to 10,000.00.</p> <p>Article 43</p> <p>(1) A fine in the amount of 5,000.00 to 10,000.00 shall be imposed on the operator dealing with general use if he does not provide or does not use the prescribed protective clothing and footwear (Article 17 , paragraph 1) .</p> <p>(2) For the offense referred to in paragraph 1 this Article a fine in the amount of 2,000.00 to 5,000.00 shall be imposed on the responsible person of the legal person.</p> <p>Article 44</p> <p>(1) A fine in the amount of HRK 1,000.00 shall be imposed on the responsible person in a legal entity or a natural person engaged in economic activities for non-compliance with hygiene requirements and other conditions set forth in the regulations of the governing sanitary control.</p> <p>(2) If a person repeats an offense under paragraph 1 of this Article within six months, he/she shall be fined with an amount of HRK 3,000.00 .</p>
Cyprus	<p>Article 48 Penalties</p> <p>The competent authority shall lay down penalties for economic operators, which may include criminal sanctions for serious infringements pursuant to Articles 52 and 53 of the Law. The competent authority shall notify the Commission of those rules by 20 July 2011, and shall notify it without delay of any subsequent amendment to them.</p>
Czech	<p>Article 19 Administrative Offences</p>

<p>Republic</p>	<p>A natural person shall commit a misdemeanour by misusing the CE marking or another established marking, certificate or other document under this Act, or by counterfeiting or altering a certificate or other document under this Act. A fine of up to CZK 20 000 000 may be imposed for a misdemeanour under paragraph (1)(a), and a fine of up to CZK 1 000 000 for a misdemeanour under paragraph (1)(b) or (c).</p> <p>A legal person or a natural person engaged in business shall commit an administrative offence by misusing the CE marking or another established marking, certificate or other document under this Act, or by counterfeiting or altering a certificate or other document under this Act, by carrying out conformity assessment activities reserved for the purposes of this Act for an authorised person without authorisation pursuant to Section 11(1), or by carrying out conformity assessment activities reserved for the purposes of this Act for an authorised person without certification pursuant to Section 16(1).</p> <p>A manufacturer, importer, authorised representative or distributor shall commit an administrative offence by placing on the market, putting into service, or distributing specified products without the CE marking or another established marking or document provided for by a government regulation, or with a marking or document in conflict with Section 13, failing to comply with a safeguard measure issued in accordance with Section 18a(1), (3) or (4), or failing to comply with an obligation set by a surveillance body under Section 18(2)(c) or (d).</p> <p>A legal person or a natural person engaged in business shall commit an administrative offence by, as an importer, failing to fulfil the obligation under the second sentence of Section 13(1), a distributor, failing to fulfil any of the obligations under Section 13(9), a manufacturer or importer, failing to fulfil any of the obligations under Section 13(10), a manufacturer, importer or distributor, failing to fulfil any of the obligations under Section 13(11), a manufacturer, importer, distributor or authorised representative, failing to fulfil the obligation under Section 13(12), or an importer or distributor, failing to fulfil the obligation under Section 13(13).</p> <p>The following fines shall be imposed for administrative offences:</p> <ul style="list-style-type: none"> • up to CZK 50 000 000 for an administrative offence under paragraph (3), • up to CZK 20,000,000 for an administrative offence under paragraph (1)(a), (d) or (e), • up to CZK 500 000 for an administrative offence under paragraph (4). <p>Common Provisions on Administrative Offences</p> <p>A legal person shall not be held liable for an administrative offence if it proves that it made all efforts that could reasonably be expected of it to</p>
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	<p>prevent the infringement of the legal obligation. When assessing the amount of a fine to be levied, factors to be taken into account shall be the seriousness of the administrative offence, in particular the manner in which it was perpetrated, its consequences, and the circumstances under which it was perpetrated. A legal person shall not be held liable for an administrative offence if the administrative body fails to initiate proceedings within three years of the date on which it learned of the administrative offence, but no later than five years from the date on which the administrative offence was committed. Administrative offences under Section 19(1)(b) and (c), Section 19a(1)(b), (c), (d) and (e), and Section 19a(2) shall be heard in the first instance by the Office; administrative offences under Section 19(1)(a) and Section 19a(1)(a) and Section 19a(3) and (4) shall be heard in the first instance by the surveillance body. Provisions of this Act applying to a legal person's responsibility and sanctions shall apply to the responsibility for any action that occurs during the business activities of an undertaking who is a natural person, or in direct relation to such activities.</p>
<p>Denmark</p>	<p>Article 68.</p> <p>1. Any person who,</p> <p>1) in contravention of § 4, cf. § 27(1) or (2), or § 28(1), (2) or (3), or § 13, cf. § 27(1) or (2), or § 28 (1), (2) or (3), deliberately places a toy on the market,</p> <p>2) deliberately fails to provide a toy with identification, cf. § 8 (1),(2) or (3), or § 16(1) or (2),</p> <p>3) in contravention of § 20, cf. § 27(1) or (2), or § 28(1), (2) or (3), deliberately makes a toy available on the market,</p> <p>4) deliberately fails to provide a toy with warnings, cf. § 9(1) cf. § 29(1), (2) or (3), or § 30(1), (2), (3), (4) or (5),</p> <p>5) deliberately fails to ensure that a toy, where relevant, is accompanied by instructions and safety information in Danish, cf. § 9(2),</p> <p>6) deliberately fails to ensure that the requirements concerning warnings, instructions and safety information are met, cf. § 14(1) No 3, cf. § 9(1) cf. § 29(1), (2) or (3), or § 30(1), (2), (3), (4) or (5), or § 9(2),</p> <p>7) deliberately fails to comply with the essential safety requirements laid down in § 27(1) or (2), § 28(1), (2) or (3),</p> <p>8) deliberately or through gross negligence fails to provide the surveillance authority with the information referred to in § 59(1),</p> <p>9) fails to keep documentation in accordance with § 6, cf. § 5(1), (2) or (3), or § 42(1), (2), (3) or (4), § 18 or § 26(1) or (2),</p>

	<p>10) fails to inform the surveillance authorities in accordance with § 10(2), § 15(2) or § 19, cf. § 10(2)</p> <p>shall be liable to a fine, unless a more severe penalty is incurred under other legislation,.</p> <p>2. The unauthorised use of the CE mark, either deliberately or through gross negligence, and where the infringement led to or was intended to lead to a financial advantage for the party concerned or a third party, shall be punishable by a fine, unless a more severe penalty is incurred under other legislation.</p> <p>3. Companies etc. (legal persons) may be held criminally liable under the rules set out in Chapter V of the Criminal Code.</p>
Estonia	<p>§ 58. Specifics for issue of precept and penalty payment rate</p> <p>(1) Before a precept is issued for withdrawal of a product from the market or recall thereof from consumers or before a relevant act is performed, economic operators shall be notified of the possibility to lodge objections. Economic operators need not be provided with the possibility to lodge objections if a market surveillance authority is obliged to apply measures immediately.</p> <p>(2) If the possibility to lodge objections was not provided to an economic operator before the issue of a precept for withdrawal of a product from the market or recall thereof from consumers or before the performance of a relevant act for the reason that the market surveillance authority was obliged to apply measures immediately, the opinion of the economic operator shall be asked for within reasonable time after the issue of the precept or the performance of the act.</p> <p>(3) When applying measures in a precept laying down the requirement for recalling a product from consumers or withdrawing the product from the market and in the case of performing an act, the participation of the distributors, users and consumers shall be fostered.</p> <p>(4) Filing a challenge against a precept or an act shall not exempt an economic operator from the obligation to comply with the precept.</p> <p>(5) If the precept is not complied with, the maximum penalty payment applied in accordance with the procedure laid down in the Substitutive Enforcement and Penalty Payment Act shall be EUR 10 000.</p>
Finland	<p>The toys sold in Finland must meet the requirements set in the Toy Safety Act. The Act (1154 /2011) entered into force on 1st of January 2012, and its chemical requirements came into force on 20th of July 2013. The requirements laid down in the Toy Safety Directive (2009/48/EY) are brought into force in Finland by the Toy Safety Act. The Toy Safety Act lays down</p>

requirements for operators (manufacturers, importers and distributors) as well as the structural and chemical safety of toys. The Government Decree (1218/2011) issued under the Toy Safety Act contains more detailed requirements for toy structure and composition as well as the warnings which should accompany the toy. Also issued under the Toy Safety Act is the Ministry of Employment and the Economy Decree on the requirements concerning certain chemicals in toys (1352/2011). According to the Toy Safety Act, (Chapter 6, Sections 56 and 57), the market surveillance authorities of the Toy Safety Act are the authorities of the Consumer Safety Act (Finnish Statute book 920/2011) and the Consumer Safety Act applies to the market surveillance of toys safety. The Consumer Safety Act (920/2011) repealed the Act on the Safety of Consumer Products and Services (75/2004)). Please see the unofficial translation of the Consumer Safety Act (920/2011) http://www.tem.fi/files/31314/Kuluttajaturvallisuuslaki_en.pdf.

There are only a few provisions under the Consumer Safety Act which somehow deal with or refers to the penalties (Sections 45 and 50). The criminal sanctions for serious infringements are regulated in the Criminal Code of Finland (in Chapter 44, Section 1). In practise the criminal sanctions have never been applied in a question of toys safety.

Consumer Safety Act, Chapter 7, Section 50 states the following:

“Section 50 Penal provisions

Penalties for a health offence committed in violation of the provisions of this Act or provisions or regulations issued by virtue of it are included in Chapter 44, Section 1, of the Criminal Code. Anyone who deliberately or through gross negligence violates a prohibition or order referred to in Sections 34–44 shall be issued with a fine for a consumer safety offence, unless a more severe punishment is provided for the offence elsewhere under law. Anyone who violates a prohibition or an order, imposed under Sections 34–44, that has been intensified by a conditional fine need not be sentenced to a penalty for the same act.”

“Criminal Code of Finland, Chapter 44 – Offences endangering health and safety (400/2002): Section 1 – Health offence (921/2011) - (1) A person who intentionally or through gross negligence in violation of

1. the Plant Protection Act (1563/2011) or Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, referred to in the following as the plant protection regulation,
2. the Consumer Safety Act (920/2011),
3. the Chemical Act (744/1989), Regulation (EC) No 1907/2006 of the

European Parliament and of the Council concerning the registration, evaluation, authorization and restriction of chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/ED and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, hereinafter the REACH Regulation, or Regulation (EC) No. 1272/2008 of the European Parliament and of the

4. Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EEC, and amending Regulation (EC) No. 1907/2006, referred to in the following as the CLP regulation,

5. the Health Protection Act (763/1994), or

6. the Foodstuffs Act (23/2006)

or of a provision or general order or order concerning an individual case issued on their basis produces, handles, imports or intentionally attempts to import, keeps in his or her possession, stores, transports, keeps for sale, conveys or gives goods or substance, product or object so that the act is conducive to endangering the life or health of another, shall be sentenced, unless a more severe penalty for the act has been provided elsewhere in the law, for a health offence to a fine or to imprisonment for at most six months. (565/2011)

(2) Unless a more severe penalty for the act has been provided elsewhere in the law, also a person who intentionally or through gross negligence, in violation of the Product Safety Act or a provision given on its basis or of an order given in general or in an individual case provides, keeps for sale or otherwise in connection with his or her commercial activity provides a consumer service so that the act is conducive to endangering the life or health of another, shall be sentenced for a health offence.”

Also Section 45 of the Consumer Safety Act can be understood as a kind of penalty if the payment of a conditional fine imposed is ordered by a decision of the Administrative Court.

Section 45: Conditional fine, threat against default and threat of suspension of operations

The surveillance authority may intensify the effect of an order or prohibition by imposing a conditional fine, or by having measures taken at the expense of the defaulting respondent (‘threat against default’), or by imposing a threat of suspension of operations. Provisions on conditional fine, threat against default and threat of suspension of operations are laid down in the Act on Conditional

	<p>Imposition of Fines (1113/1990).</p> <p>The surveillance authority is authorized to reinforce the obligation to provide information referred to in Section 9, the obligation to notify and to provide information referred to in Section 26, the obligation to provide information and present the documents referred to in Section 27, and the obligation to comply with an order referred to in Section 34(2) by imposing a conditional fine. The payment of a conditional fine imposed under paragraph 1 or 2 is ordered by a decision of the Administrative Court.</p>
France	<p>Art. 17. – Est puni de l’amende prévue pour les contraventions de la cinquième classe le fait :</p> <p>1o De fabriquer en vue de la mise sur le marché de l’Union, importer, détenir en vue de la vente ou de la distribution à titre gratuit, mettre en vente, vendre, mettre à disposition sur le marché à titre gratuit ou onéreux des jouets ne respectant pas les obligations prévues aux 2o et 3o de l’article 3 ;</p> <p>2o De ne pas être en mesure de présenter aux agents chargés du contrôle les documents prévus au chapitre IV. La récidive est réprimée conformément aux dispositions des articles 132-11 et 132-15 du code pénal. Est puni de l’amende prévue pour les contraventions de la troisième classe le fait :</p> <p>1o De fabriquer en vue de la mise sur le marché de l’Union, importer, détenir en vue de la vente ou de la distribution à titre gratuit, mettre en vente, vendre, mettre à disposition sur le marché à titre gratuit ou onéreux des jouets ne respectant pas l’obligation prévue au 4o de l’article 3;</p> <p>2o D’apposer sur un jouet, sur son emballage ou sur les documents, notices d’information du fabricant qui l’accompagnent des inscriptions de nature à créer des confusions avec le marquage « CE » ou à en compromettre la visibilité ou la lisibilité ;</p> <p>3o D’exposer, lors de salons professionnels et expositions, des jouets qui ne respectent pas les dispositions de l’article 6.</p>
Germany	<p>§ 22 Regulatory offences</p> <p>Anyone who, contrary to § 4(2) first sentence, also in conjunction with § 6(5) second sentence, deliberately or negligently fails to provide information, fails to provide correct information, fails to provide complete information or fails to provide information on time shall be guilty of a regulatory offence within the meaning of § 19(1)1.b) of the Equipment and Product Safety Act.</p>
Greece	<p>1. Persons who manufacture, import, sell or resell and, in general, place on the market toys which come within the scope of the provisions herein in breach of the said provisions or who obstruct the relevant inspections shall be subject to</p>

	<p>a fine of between EUR 1 000 and EUR 40 000.</p> <p>2. The fines listed in the table below have been calculated on the basis of the severity of the infringement, taking account of the degree of non-compliance, the risk factor associated with the toy at issue and the number of non-compliant toys placed on the market.</p> <p>Infringement of provisions of this decision</p> <p>Penalties</p> <table border="0"> <tr> <td data-bbox="379 616 813 728">Infringement of Articles 5, 6, 7, 8 or 10</td> <td data-bbox="813 616 1404 728">Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 1 000 and EUR 40 000</td> </tr> <tr> <td data-bbox="379 728 813 840">Infringement of Article 11 & Annex II</td> <td data-bbox="813 728 1404 840">Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 5 000 and EUR 40 000</td> </tr> <tr> <td data-bbox="379 840 813 952">Infringement of Article 12 & Annex V</td> <td data-bbox="813 840 1404 952">Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 1 000 and EUR 8 000</td> </tr> <tr> <td data-bbox="379 952 813 1288">Infringement of Article 16 & Annex III, Articles 17, 18, 19, 20 & Annex VII, Article 21 & Annex VII or Article 22 & Annex IV, as summarised in Article 42</td> <td data-bbox="813 952 1404 1288">Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 1 000 and EUR 40 000</td> </tr> </table> <p>3. In the event of a repeat offence, offenders shall be punished with a fine of at least double the initial fine, capped at EUR 40 000.</p> <p>4. In the event that the placing of a toy on the market poses a serious risk to the health and safety and protection of consumers/children, in addition to the above, the case file shall be forwarded to the competent prosecuting authorities.</p> <p>5. The economic operators responsible must: a) allow the authorised officers of the competent services provided for in Article 4 herein entry to manufacturing, sales or storage premises, provide them with any information requested in connection with the manufacture or origin of the toy at issue and facilitate the work of the said inspectors, and b) provide the competent toy-inspection bodies with free samples and, on request, send stamped samples of the toy at issue to a laboratory specified by the competent services provided for in Article 4 herein for testing. The said samples shall be returned on the responsibility of the interested party, once it has been ascertained that they comply with the provisions herein and provided that they were not altered</p>	Infringement of Articles 5, 6, 7, 8 or 10	Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 1 000 and EUR 40 000	Infringement of Article 11 & Annex II	Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 5 000 and EUR 40 000	Infringement of Article 12 & Annex V	Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 1 000 and EUR 8 000	Infringement of Article 16 & Annex III, Articles 17, 18, 19, 20 & Annex VII, Article 21 & Annex VII or Article 22 & Annex IV, as summarised in Article 42	Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 1 000 and EUR 40 000
Infringement of Articles 5, 6, 7, 8 or 10	Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 1 000 and EUR 40 000								
Infringement of Article 11 & Annex II	Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 5 000 and EUR 40 000								
Infringement of Article 12 & Annex V	Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 1 000 and EUR 8 000								
Infringement of Article 16 & Annex III, Articles 17, 18, 19, 20 & Annex VII, Article 21 & Annex VII or Article 22 & Annex IV, as summarised in Article 42	Ban on manufacturing/distribution & withdrawal from the market and fine of between EUR 1 000 and EUR 40 000								

	<p>during testing, such that they are unsuitable for use.</p> <p>6. The fine shall be imposed by decision of the Minister for Economic Affairs, Competitiveness and Shipping, at the proposal of the competent authority, once the liable party has been summoned to a hearing in accordance with the provisions of Article 6 of Law 2690/1999 (Government Gazette 45A). The said decision may also ban further placing on the market and sales of the said toys and/or may impose withdrawal thereof from the market. The economic operator shall be responsible for and shall bear the costs of such withdrawal.</p> <p>7. Any decision issued in accordance with the present article imposing a fine and/or a ban on the placing on the market or sale of a product and/or the withdrawal thereof must be fully reasoned and notified directly to the interested party by registered mail and/or fax.</p> <p>8. Fines imposed pursuant hereto, the amount of which shall at least cover the costs incurred in ascertaining the unsuitability of the toy, shall be payable within sixty (60) days into special account no. 234218/6, which has been opened at the Bank of Greece in order to cover the costs of all manner of laboratory or other testing of electrical material in circulation, in accordance with decision no 37101/1146/18.04.85 by the Minister for Finance. On expiry of the above deadline, fines shall be assessed and collected in accordance with current provisions on collection of public revenue.</p> <p>9. The competent authority shall notify the European Commission in accordance with the provisions of Article 40(4).</p> <p>10. Interested parties may file an appeal with the Minister against the above decision within thirty (30) days of notification thereof.</p>
Hungary	<p>Act CLV of 1997 on consumer protection (hereinafter: Consumer Protection Act) 47. § (1) (a), (b), (c), (d), (e), (f) and (i):</p> <p>‘47. § (1) If the consumer protection authority finds that the new § 45/A. (1)-(3) Specific consumer protection provisions of the case, all the circumstances (in particular the severity, duration, and recurrence of the infringement and the benefit from it) and proportionality, may:</p> <p>a) order that the situation constituting a violation of law,</p> <p>b) prohibit the continuation of the behaviour constituting an infringement;</p> <p>c) oblige the enterprise to correct any faults or deficiencies by a set date, stipulating that the enterprise of these corrective measures, should inform the consumer protection authority,</p> <p>d) impose conditions until the infringement is terminated or prohibit the sale of goods, or Sale,</p>

	<p>e) the consumer may order life, health and physical integrity dangerous product, withdrawal and recall</p> <p>f) may order the consumer's life, health and physical integrity of the product to be destroyed</p> <p>Consideration of environmental aspects,</p> <p>g) the lawful situation until the infringement period may order the temporary closure of the business concerned, if the consumers' lives, physical integrity and health protection and the prevention of injury to a wide range of consumers is necessary in order to prevent threats,</p> <p>h) the Article 16/A. (1h 3) in the event of a breach of the provisions the infringement may prohibit a period of up to one year from the date of the determination of alcoholic beverages and the tobacco and sexual product, those provisions may, in the case of repeated infringements of the business involved in the infringement for a period of not more than thirty days and, in the case of temporary closure</p> <p>i) consumer protection fine (hereinafter Impose fines).</p> <p>The Consumer Protection Act. Section 47/C. (5) (a) and (b):</p> <p>“The consumer protection authority shall impose fines if appropriate, a) the consumer protection authority of a final decision finding an infringement is provided for the undertaking to give the expiry of the closing date, or within six months following the expiry of the period of the undertaking, where the infringement has been committed on the same site, repeated infringements of the same legal provision, (b) the life and health of consumers, endangers or affects a wide range of consumers, and...”</p> <p>The safety of goods and services and the relating market surveillance procedure 79/1998.</p> <p>(IV. 29.) 6. § (1):</p> <p>‘Where the market surveillance authorities establish the course of the market surveillance process, that a product does not meet the requirements, they are entitled to</p> <p>(a) the danger arising from the use of the product, information on alerts</p> <p>(b) impose comprehensive information, so that the threat inherent in the use of the product in time and appropriate means, if necessary, the radio and television broadcasts or in the press consumers</p> <p>(c) its placing on the market and its advertising and to limit or prohibit the</p>
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	<p>measures necessary to enforce the ban,</p> <p>(d) the withdrawal of products already placed on the market and information to the effect in point (b) as set out,</p> <p>(e) order recall of the product — if appropriate, in cooperation with the producers and distributors to recall the product from consideration of environmental aspects and destruction and control their implementation.”</p>
Ireland	<p>Penalties</p> <p>49. (1) A person guilty of an offence under Regulation 48 shall be liable—</p> <p>(a) on summary conviction, to a class A fine or imprisonment for a term not exceeding 6 months or both, or</p> <p>(b) on conviction on indictment, to a fine not exceeding €500,000 or imprisonment for a term not exceeding 2 years or both.</p> <p>(2) (a) Where a person is convicted of an offence under these Regulations in proceedings brought by the Agency, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Agency the costs and expenses, measured by the court, incurred by the Agency in relation to the investigation, detection and prosecution of the offence, including the costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of authorised officers, employees, consultants and advisers engaged by the Agency.</p> <p>(b) An order for costs and expenses under subparagraph (a) is in addition to and not instead of any fine or penalty the court may impose.</p> <p>Offences by bodies corporate</p> <p>50. Where an offence under these Regulations has been committed by a body corporate and is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a person being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person, as well as the body corporate, commits an offence and shall be liable to be proceeded against and punished as if he or she had committed the first-mentioned offence.</p>
Italy	<p>ARTICLE 31 (Penalties)</p> <p>1. Unless the fact constitutes a more serious offence, a manufacturer or importer placing on the market products in breach of Article 3(1) and Article 5(2) shall be punishable by a term of imprisonment of up to one</p>

	<p>year and by a fine from EUR 10 000 to EUR 50 000.</p> <ol style="list-style-type: none"> 2. Unless the fact constitutes a more serious offence, a manufacturer or importer failing to comply with the measures issued under Article 30(2) shall be punishable by a term of imprisonment from six months to one year and by a fine from EUR 10 000 to EUR 50 000. 3. Unless the fact constitutes an offence, a manufacturer or importer placing on the market a toy not provided with the technical documentation referred to in Annex IV to this Decree shall receive an administrative penalty from EUR 2 500 to EUR 40 000. 4. Unless the fact constitutes an offence, a manufacturer or importer placing on the market a toy not provided with the CE marking shall receive an administrative penalty from EUR 2 500 to EUR 30 000. 5. Unless the fact constitutes an offence, the administrative penalty under paragraph 4 of this Article shall also apply to a manufacturer or importer placing on the market a toy not provided with the warnings referred to in Article 10 of this Decree. 6. Unless the fact constitutes an offence, a manufacturer or importer failing to comply with the prohibition issued under Article 30(6) shall receive an administrative penalty from EUR 2 500 to EUR 10 000. 7. Unless the fact constitutes an offence, a manufacturer or importer placing on the market a toy not provided with the CE marking or the warnings under Article 10 of this Decree shall receive an administrative penalty from EUR 1 500 to EUR 10 000. 8. Unless the fact constitutes an offence, a manufacturer or importer failing to comply with its obligations under Article 8 of this Decree shall receive an administrative penalty from EUR 2 500 to EUR 10 000. 9. Unless the fact constitutes an offence, the administrative penalty under paragraph 8 of this Article shall also apply to any authorised representative failing to comply with his/her obligations under Article 4(3) of this Decree. 10. The administrative penalties referred to in this Article shall be issued by the Chamber of Commerce, Industry, Craft and Agriculture having territorial competence.
Latvia	<p>Supplying an unsafe product can result in a fine of up to LVL 5,000 for each offence, and/or a term of imprisonment of up to three months. (http://www.ptac.gov.lv/page/265&mode=print - Consumer Rights Protection Centre).</p>

<p>Lithuania</p>	<p>Law No IX-1702 of the Republic of Lithuania amending the Administrative Infringements Code (Official Gazette 2003, No 74-3421)</p> <p>Article 50. Amendment of Article 163(13) Article 163(13) shall be amended to read as follows:</p> <p>"Article 163(13). Sales of Goods that Are Unmarked in the Statutory Procedure in the Domestic Market and Providing Incorrect Information about Goods</p> <p>Sales of goods that are unmarked in the statutory procedure in the domestic market of the Republic of Lithuania – shall result in a warning or fine for natural persons pursuing individual activities from LTL 20 up to LTL 100, a fine for corporate employees from LTL 100 up to LTL 500 and a fine for officers from LTL 500 up to LTL 1 000.</p> <p>The same actions committed by a person who has already been imposed an administrative penalty for the infringement referred to in paragraph 1 of this Article – shall result in a fine from LTL 50 up to LTL 200 for natural persons pursuing individual activities, from LTL 200 up to LTL 1 000 for corporate employees and from LTL 1 000 up to LTL 2 000 for officers.</p> <p>Provision of incorrect information on a label of goods – shall result in a warning or fine for natural persons pursuing individual activities from LTL 20 up to LTL 100, a fine for corporate employees from LTL 100 up to LTL 500 and a fine for officers from LTL 500 up to LTL 1 000.</p> <p>The same actions committed by a person who has already been imposed an administrative penalty for the infringement referred to in paragraph 3 of this Article – shall result in a fine from LTL 50 up to LTL 200 for natural persons pursuing individual activities, from LTL 200 up to LTL 1 000 for corporate employees and from LTL 1 000 up to LTL 2 000 for officers."</p> <p>Law No IX-1988 of the Republic of Lithuania amending Articles 1, 3, 4, 7, 8, 9, 10, 11, 13, 14, 15, 16, 16, 19, 21, 23, 24, 25, the title of Chapter Four of the Law on Product Safety and adding an Annex to the Law (Official Gazette 2004, No 25-757)</p> <p>Article 17. Amendment of Article 23</p> <p>In paragraphs 1, 2, 3, 4, 5, 6, 7 of Article 23 all the words ‘unsafe’ shall be replaced by the word ‘dangerous’ and this Article shall read as follows:</p> <p>‘Article 23. Fines for infringements of this Law</p> <ol style="list-style-type: none"> 1. The producer or distributor who has placed dangerous products on the market shall be fined from LTL 500 to 5 000. 2. The producer or distributor who has placed dangerous products on the
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	<p>market following the order to discontinue their sale shall be fined from LTL 3 000 to 15 000.</p> <p>3. The supplier of a service who has provided or is providing dangerous services shall be fined from LTL 500 to 2 500.</p> <p>4. The supplier of a service who has provided or keeps providing a dangerous service following the order to discontinue it shall be fined from LTL 2 000 to 10 000.</p> <p>5. The persons indicated in Article 22 of this Law who fail to comply with the requirements of the Board or the control authorities to withdraw dangerous products from the market or to destroy them shall be fined from LTL 5 000 to 20 000.</p> <p>6. If the person referred to in Article 22 of this Law placed dangerous products on the market which have caused a health impairment to the consumer shall be fined from LTL 5 000 to 40 000.</p> <p>7. If the person referred to in Article 22 of this Law placed dangerous products on the market which have caused the consumer's death shall be fined from LTL 20 000 to 80 000.</p> <p>8. Imposition of fines does not exempt from the duty to compensate damages caused to consumers.'</p> <p>There is no need to transpose and implement this article of the Directive.</p>
Luxembourg	<p>Art. 18. – Dispositions pénales dans le cadre de la surveillance du marché (http://www.ilnas.public.lu/fr/legislation/ilnas/ilnas/loi-ilnas.pdf)</p> <p>(1) Est punie d'une amende de 251 euros à 25.000 euros et d'une peine d'emprisonnement de 8 jours à un an ou d'une de ces peines seulement, toute personne qui a mis sur le marché ou qui a mis à disposition sur le marché un produit dont il sait ou dont il aurait dû savoir que celui-ci n'est pas conforme aux prescriptions de la présente loi ou aux dispositions légales ou réglementaires transposant les directives visées par la présente loi.</p> <p>(2) Est punie des mêmes peines, le maximum de l'amende prévue étant porté à 125.000 euros, toute personne qui ne s'est pas conformée aux décisions prises en application de l'article 17.</p> <p>(3) Est puni d'une amende de 25 euros à 250 euros, le distributeur qui a mis à disposition sur le marché un produit qui n'est pas conforme aux prescriptions de la présente loi ou aux dispositions légales et réglementaires transposant les directives visées par la présente loi. La confiscation du produit peut être ordonnée.</p> <p>(4) Est puni des peines prévues au paragraphe 1er, le distributeur qui a commis</p>

	<p>de nouveau la contravention spécifiée au paragraphe 3 avant l'expiration d'un délai d'un an à partir du jour où une précédente condamnation du chef d'une telle contravention ou d'un des délits spécifiés aux paragraphes 1er et 2 du présent article sera devenue irrévocable.</p>
<p>Malta</p>	<p>PART IV PROCEEDINGS (Product Safety Act V of 2001, as amended by Legal Notice 426 of 2007 and Act XXIX of 2007)</p> <p>Proceedings.</p> <p>30. Proceedings in relation to any offence under this Act may only be instituted at the instance of the Director, who may conduct the prosecution before the Court. Prescription.</p> <p>31. Criminal actions for offences under this Act shall be prescribed by the lapse of two years.</p> <p>Fines.</p> <p>32. (1) A person found guilty of an offence under article 23 shall, on conviction, be liable to a fine (multa) of not less than four hundred and sixty-five euro and eighty-seven cents (465.87) and not exceeding two thousand and three hundred and twenty-nine euro and thirty-seven cents (2,329.37), or to imprisonment for a term not exceeding six months or to both such fine and imprisonment.</p> <p>(2) A person found guilty of any other offence under this Act shall be liable, on conviction, to a fine (multa) of not less than one thousand and one hundred and sixty-four euro and sixty-nine cents (1,164.69) but not exceeding eleven thousand and six hundred and f o r t y - s i x euro and e ighty-seven cents (11,646.87) or to imprisonment for a term not exceeding three years or to both such fine and imprisonment.</p> <p>(3) A person found guilty of a second or subsequent offence shall, on conviction, be liable to a fine (multa) of not less than one thousand and seven hundred and forty-seven euro and three cents (1,747.03) but not exceeding twenty-three thousand and two hundred and ninety-three euro and seventy-three cents (23,293.73) or to imprisonment not exceeding four years or to both such fine and imprisonment.</p> <p>(4) The Court may, upon conviction for any offence committed under this Act, with the exception of offences committed under article 23, if it feels that circumstances so warrant, additionally order the suspension or cancellation of any licence or licences issued in favour of the person charged or in respect of the premises involved in the proceedings.</p> <p>(5) Without prejudice to the generality of the foregoing, any person convicted in relation to an offence under articles 26 or 29 shall additionally be liable to</p>

	<p>the additional fine (multa) of not more than four hundred and sixty-five euro and eighty-seven cents (465.87) for each day that a notice or undertaking has not been complied with.</p> <p>Reimbursement to the Director.</p> <p>33. Where a person has been convicted of an offence under this Act, the Court shall order that person to reimburse to the Director, within such period as it shall stipulate, any costs incurred in connection with the proceedings instituted against him. Such costs shall include expenses incurred in the seizure, lifting, detention, testing, analysis, inspection and examination of products, or samples thereof, involved in the said proceedings.</p> <p>Right to appeal.</p> <p>34. The Attorney General shall have the right to appeal from any judgement given in proceedings instituted under this Act or in connection with regulations made thereunder.</p>		
Netherlands	Description of the infringement	Fine	Per category
	C-30 Toys (Commodities Act) Decree 2011	I	II
	C-30.1.1 Article 2(1) [It shall be forbidden to manufacture or trade in toys which do not satisfy the provisions of this Decree] in conjunction with Article 3(1) [When designing and manufacturing toys and placing them on the market, manufacturers shall comply with the provisions of: a. Article 4; b. Article 9; c. Article 10; d. Article 11; e. Article 15; f. Article 18; g. Article 21(3) and (4); and h. Annex II to Directive 2009/48/EC.]	€ 525	€ 1050
	C-30.1.2 Article 2(1) [It shall be forbidden to manufacture or trade in toys which do not satisfy the provisions of this Decree] in conjunction with Article 4(1) [A manufacturer who appoints an authorised representative shall comply with and ensure compliance with Article 5 of Directive 2009/48/EC]	€ 525	€ 1050
	C-30.1.3 Article 2(1) [It shall be forbidden to manufacture or trade in toys which do not satisfy the provisions of this Decree] in	€ 525	€ 1050

	conjunction with Article 4(2) [The authorised representative referred to in paragraph 1 shall comply with Articles 5(3) and 9 of Directive 2009/48/EC]		
C-30.1.4	Article 2(1) [It shall be forbidden to manufacture or trade in toys which do not satisfy the provisions of this Decree] in conjunction with Article 5(1) [When placing toys on the market, importers shall satisfy the requirements of: a. Article 6; b. Article 8; and c. Article 9; of Directive 2009/48/EC]	€ 525	€ 1050
C-30.1.5	Article 2(1) [It shall be forbidden to manufacture or trade in toys which do not satisfy the provisions of this Decree] in conjunction with Article 6 [When making toys available on the market, distributors shall comply with the provisions of: a. Article 7; b. Article 8; and c. Article 9; of Directive 2009/48/EC]	€ 525	€ 1050
C-30.2.1	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 3(1) [When designing and manufacturing toys and placing them on the market, manufacturers shall comply with the provisions of: a. Article 4; b. Article 9; c. Article 10; d. Article 11; e. Article 15; f. Article 18; g. Article 21(3) and (4); and h. Annex II to Directive 2009/48/EC]	€ 525	€ 1050
C-30.2.2	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 3(2) [Instructions and safety information referred to in Article 4(7) of Directive 2009/48/EC shall be written in the Dutch	€ 525	€ 1050

	language at least]		
C-30.2.3	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 3(3) [The EC declaration of conformity referred to in Article 15(2) of Directive 2009/48/EC shall be written in Dutch or English at least]	€ 525	€ 1050
C-30.2.4	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 5(1) [When placing toys on the market, importers shall satisfy the requirements of: a. Article 6; b. Article 8; and c. Article 9; of Directive 2009/48/EC]	€ 525	€ 1050
C-30.2.5	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 5(2) [Instructions and safety information as referred to in Article 6(4) of Directive 2009/48/EC shall be written in the Dutch language at least]	€ 525	€ 1050
C-30.2.6	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 6 [When making toys available on the market, distributors shall comply with the provisions of: a. Article 7; b. Article 8; and	€ 525	€ 1050

	c. Article 9; of Directive 2009/48/EC]		
C-30.2.7	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 7(1) [Warnings and safety information concerning toys shall be in accordance with Article 11(1) and (2) of Directive 2009/48/EC]	€ 525	€ 1050
C-30.2.8	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 7(2) [The warnings and safety information referred to in paragraph 1 shall be written in the Dutch language at least]	€ 525	€ 1050
C-30.2.9	Article 2(2) [It shall be forbidden to trade in toys other than in accordance with the provisions of this Decree with regard to the use of statements on or depictions of the nature, composition, construction, quality, properties, purpose or dimensions of the goods] in conjunction with Article 9(1) [In accordance with Article 16(1) and (2) and Article 17 of Directive 2009/48/EC, toys which are made available on the market shall be provided with the CE marking]	€ 525	€ 1050
C-30.3.1	Article 2(3) [It shall be forbidden to bring toys into the territory of the Netherlands other than in accordance with the provisions of this Decree] in conjunction with Article 5(1) [When placing toys on the market, importers shall satisfy the requirements of: a. Article 6; b. Article 8; and c. Article 9; of Directive 2009/48/EC]	€ 525	€ 1050
Poland	Chapter 7 criminal Liability (Law on Conformity Assessment) – Google		

	<p>translate</p> <p>Article 45: Anyone who is on the market or puts into service the product inconsistent with the essential requirements is subject to a fine.</p> <p>Article 46: Anyone who puts the conformity marking on the product, which does not meet the basic or detailed requirements, or for which the manufacturer or his authorized representative issued a declaration of conformity, is subject to a fine.</p> <p>Article 47: Anyone who puts on the product a sign similar to a conformity marking, which could mislead the user, the consumer or distributor of the product, is subject to a fine.</p> <p>Article 47a: Anyone who is on the market or puts into service the product under the label of conformity and without such marking is subject to a fine.</p> <p>Article 47b: Anyone who puts the conformity marking on the product, which is not subject to the labelling or marketed such a device, is subject to a fine.</p> <p>Article 47c: Anyone who, being obliged to store the control, destroys, removes or prevents the security from the examination of the sample, is subject to a fine.</p>
Portugal	<p>CHAPTER VII Supervision and system of penalties</p> <p>Article 35 Power of supervision</p> <p>1. The market surveillance and control of toys which enter the Community market in compliance with this Decree-law shall be governed by the provisions of Chapter III of Decree-law No 23/2011 of 11 February 2011 implementing in national law Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008.</p> <p>2. The Directorate General for Consumers shall be responsible for supervision in respect of the provisions of the preceding paragraph.</p> <p>Article 36 Offences</p> <p>1. The following shall constitute offences punishable by a fine of EUR 1 000 to EUR 2 500 in the case of a natural person and EUR 3 000 to EUR 20 000 in the case of a legal person: (a) infringement of the obligations of economic operators provided for in Article 5(5) and (6), Article 8(5) and (7), Article 9(2) and Article 10(2) to (7); (b) infringement of the information obligation provided for in Article 12; (c) infringement of the obligations relating to technical documentation provided for in Article 24(2) and (3).</p> <p>2. The following shall constitute offences punishable by a fine of EUR 1 500 to EUR 3 740.98 in the case of a natural person and EUR 5 000 to EUR 44</p>

891.81 in the case of a legal person: (a) infringement of the obligations of economic operators provided for in Article 5(2), (3) and (7) to (10), Article 6(1) and (2), Article 8(2) to (4), (6), (8) and (9), and Article 9(1) and (3); (b) infringement of the essential safety requirements provided for in Article 13(1) and (2); (c) infringement of the obligations relating to warnings provided for in Articles 14, 15 and 16; (d) infringement of the requirements relating to the EC declaration of conformity provided for in Article 18; (e) infringement of the rules and conditions for affixing the EC marking provided for in Article 20; (f) infringement of the obligation to carry out the safety assessment provided for in Article 21; (g) failure to comply with the conformity assessment procedures provided for in Article 22(1); (h) failure to comply with the technical documentation requirements provided for in Article 24(1); (i) failure to comply with the rules relating to advertising provided for in Article 34(1) and (3).

3. The offences provided for Article 19(2)(a) and (b) of this Decree-law shall apply to the provisions of Article 6 of Decree-law No 23/2011 of 11 February 2011 implementing in national law Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008.

4. Negligence and attempt shall be punishable, the minimum and maximum amounts of the applicable fines being reduced by half.

Article 37 Supplementary penalties

Where the seriousness of the offence and the fault of the perpetrator so justify, the competent authority may, together with the fine, order the imposition of the supplementary penalties provided for under the general system for offences.

Article 38 Power to impose penalties

1. The ASAE and the Directorate General for Consumers shall be responsible for bringing offence proceedings in connection with unlawful advertising.

2. The Comissão de Aplicação de Coimas em Matéria Económica e de Publicidade (Commission for the Application of Economic and Advertising Fines) (CACMEP) shall be responsible for imposing the fines and supplementary penalties provided for in this Decree-law.

Article 39 Distribution of the proceeds of fines

1. The proceeds of the fines shall be distributed as follows:

(a) 15% to the body which drew up the notice of infringement;

(b) 15% to the body which carried out the investigation;

	<p>(c) 10% to the decision-making body;</p> <p>(d) 60% to the State.</p> <p>2. The distribution of the proceeds of the fines referred to in Article 36(3) shall be governed by Article 10 of Decree-law No 23/2011 of 11 February 2011 implementing in national law Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008.</p>
Romania	<p>Article 48 Sanctions</p> <p>(1) Breach of this decision leads to heritage status, disciplinary, administrative or criminal case of the culprits.</p> <p>(2) The contravention and is punishable as follows: a) Failure to art. 4-7 with a fine of 4,000 to 7,500 lei and, if necessary, withdrawal from the market and / or recalled from consumers or prohibiting the placing on the market and / or the availability of non-compliant toys on the market; b) Failure to art. 10 and 11, with a fine of 6,500 to 10,000 lei and, if necessary, withdrawal from the market and / or recalled from consumers or prohibiting the placing on the market and / or the availability of non-compliant toys on the market; c) Failure to art. 15-17, a fine of 1,500 to 5,000 lei and, if necessary, withdrawal from the market and / or recalled from consumers or prohibiting the placing on the market and / or the availability of non-compliant toys on the market; d) Failure to art. 9, a fine of 2,000 to 6,000 lei, if necessary, withdrawal from the market and / or recalled from consumers or prohibiting the placing on the market and / or the availability of non-compliant toys on the market, to provide the required identification data.</p> <p>(3) Establishing offense and applying sanctions are made by representatives of the National Authority for Consumer Protection.</p> <p>(4) The contraventions provided in paragraph (2) Applicant them to the Government Ordinance no. 2/2001 on the legal regime of contraventions, approved with amendments and completions by Law no. 180/2002, with subsequent modifications,.</p> <p>(5) The Ministry of Economy, Trade and Business Environment notify the Commission without delay of any subsequent paragraph.</p>
Slovakia	<p>(1) The Authority Office attributes to the manufacturer, importer, authorized representative or distributor a fine of</p> <p>a) 1,500 to 50,000 euros if they breach the obligation of § 4 paragraph. 1 point. a) and k), § 6 par. 1 point. b), § 6 par. 2 point. c), § 7. 1 point. d) or § 7. 2 point. b)</p> <p>b) 500 to 30,000 euros if they breach the obligation of § 4 paragraph. 1 point.</p>

	<p>b) to f) , I) , j) , l) to n) and p) , § 5 section . 2, § 6 par. 1 point. a), c) and d), § 6 par. 2 point. a) to d) , g) , I) and j) , § 7 . 1 point. a) to c), § 7. 2 point. a), c) to f), § 8, § 10 or § 16. 11</p> <p>c) 200 to 15,000 euros if they breach the obligation of §4. 1 point g) , h) and o) , § 6 par 2 point e) and h) or § 12</p> <p>(2) The Office shall impose a fine of 150 to 35,000 euros to a person who a) unlawfully acting beyond the activities listed in notification, b) illegally issues, alters or falsifies a document for the purposes of conformity assessment.</p> <p>(3) The Office shall impose a fine of 100 to 10,000 euros to the person who breached the duty.</p> <p>(4) The upper limit of the fine rates shall be increased or doubled if the manufacturer, importer, acting representative or distributor repeatedly violate the same obligation, for breach of which had already been fined by the authorities within 12 months from the date of the first decision .</p> <p>(5) The specifications of the fines should take into particular account the severity, the duration, the consequences of the offense and the repeated breach of obligations under this Act.</p> <p>(6) The fines go to the state budget.</p> <p>(7) A fine may be imposed within one year from the date that the office authority or the supervision office found a violation of obligations under this Act, and not later than three years from the date that the violation obligation occurred.</p>
Slovenia	<p>Article 42 (Offences)</p> <p>(1) A fine between EUR 3 000 to 40 000 shall be issued to a legal entity concerning its pursuit of activities as a manufacturer, importer or representative in the Republic of Slovenia where:</p> <ul style="list-style-type: none"> - it does not perform obligations in accordance with Article 15 of this Decree; - it does not perform tasks under Article 16(3) of this Decree; - it does not perform obligations in accordance with Article 17 of this Decree; - upon the request of the ZIRS it does not provide identification information of economic operators in accordance with Article 20 of this Decree; - marks toys contrary to the general rules for EC marking or on placing the

	<p>EC marking in accordance with Articles 9 and 10 of this Decree;</p> <ul style="list-style-type: none"> - it does not perform safety assessment in accordance with Article 11 of this Decree; <p>(2) A fine of EUR 2 000 to 15 000 shall be issued to an independent entrepreneur or an individual independently pursuing an activity who concerning the performance of activities as a manufacturer, importer or authorised representative in the Republic of Slovenia has committed an offence listed in the preceding Paragraph.</p> <p>(3) A fine of EUR 1 200 to 4 000 shall be issued to a responsible person of a legal person or independent entrepreneur who as a manufacturer, importer or representative in the Republic of Slovenia commits an offence referred to in Paragraph 1 of this Article.</p> <p>(4) A fine of EUR 1 200 to 3 000 shall be issued to a legal person as a distributor for an offence where:</p> <ul style="list-style-type: none"> - it does not perform obligations in accordance with Article 17 of this Decree; - upon the request of the ZIRS it does not provide identification information of economic operators in accordance with Article 20 of this Decree. <p>(5) A fine of EUR 800 to 3 000 shall be issued to an independent entrepreneur or individual independently pursuing an activity who as a distributor commits the offence referred to in the preceding Paragraph.</p> <p>(6) A fine of EUR 200 to 400 shall be issued to a responsible person of a legal person or independent entrepreneur who as a distributor of the product commits an offence referred to in Paragraph 4 of this Article.</p>
Spain	<p>Article 47. Rules governing penalties</p> <p>1. The rules governing the offences and penalties for infringement of this Royal Decree shall be those established in Legislative Royal Decree No 1/2007 of 16 November 2007, approving the consolidated text of the General Law for the Protection of Consumers and Users and other supplementing legislation, and the regional implementing provisions.</p> <p>2. Offences shall be categorised as minor, serious or very serious. Insofar as this Royal Decree is concerned:</p> <ul style="list-style-type: none"> a) minor infringements shall be: formal labelling deficiencies which do not affect the safety conditions of the toy; formal deficiencies in the EC marking. b) serious infringements shall be: deficiencies in the labelling of the toy which affect safety, and deficiencies relating to warnings, instructions for use or

	<p>recommendations for the appropriate age of children; absence of the identifying particulars of the person responsible for placing the toy on the market; using the EC marking incorrectly; failing to provide the documentation referred to in Annexes III and IV to the Royal Decree, at the request of the authorities.</p> <p>c) very serious infringements shall be: failure to comply with the safety requirements referred to in Article 11 of and Annex II to the Royal Decree.</p> <p>3. The infringements referred to shall be penalised in accordance with the types and levels of penalties established in Articles 51 and 52 of Legislative Royal Decree No 1/2007 of 16 November 2007.</p> <p>4. The authorities competent to determine and impose the corresponding penalties shall be the authorities established under Article 3 of this Royal Decree.</p> <p>Where the power to impose penalties lies with the State, the competent authority shall be the Ministry for Health, Social Policy and Equality, through the National Consumer Institute.</p>
Sweden	<p>In Swedish legislation, article 51 of the Toy Safety Directive is transposed through sections 28 and 32 of the Swedish Act on the safety of toys (lagen [2011:579] om leksakers säkerhet). According to section 28, an order or prohibition from a market surveillance authority required in an individual case to ensure compliance with the Act on the safety of toys, or with regulations made in accordance with the Act, shall be made subject to a default fine (“vite” in Swedish), unless it is deemed unnecessary for special reasons.</p> <p>Section 32 prescribes sanction charges (“sanktionsavgift” in Swedish) for economic operators if they intentionally or by neglect fail to comply with certain obligations laid down in the Act on the safety of toys and regulations made in accordance with the Act.</p>
United Kingdom	<p>Offences may result in fines of up to £5,000, or a maximum prison term of six months, or both. Where a supplier does not comply with a request to have toys tested within a reasonable time the penalties are a term of imprisonment up to three months or a fine of up to £5,000. (found in https://www.gov.uk/toy-manufacturers-and-their-responsibilities)</p>

3.16. Penalties for non-compliance with the legislation on pyrotechnic articles

Country	National transpositions of Article 45 of Directive 2013/29/EU
Austria	(1) Unless forms a behaviour to constitute a subject to the jurisdiction of the ordinary courts offense, commits an administrative offense who violates this

	<p>federal law, regulations or decisions issued pursuant to this Federal Law. He is in the event of an infringement</p> <ol style="list-style-type: none"> 1. the provisions of the second main piece with a fine of up to € 10 000 or imprisonment for up to six weeks 2. the use prohibition according to § 39 para. 2 with a fine not exceeding € 4,360 or imprisonment for up to four weeks 3. other provisions with a fine not exceeding € 3,600 or imprisonment for up to three weeks to punish. <p>(2) The attempt is punishable.</p>
Belgium	<p>The sanctions are laid down in the basic law, i.e. The 'Code de droit économique' (http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2013022819&table_name=loi)</p> <p>Rule XV.102.</p> <p>Section 1. Is punishable by a penalty of level 2, those who infringe Article IX.9.</p> <p>§ 2. Is punishable by a penalty of level 3:</p> <ol style="list-style-type: none"> 1° those placing on the market products which they know or ought to know, on the basis of European standards or Belgian do not have the guarantees referred to in Article XI.2 concerning safety and health protection; 2° those in breach of Article IX.8; <p>Those who violate the articles 3° IX.4, IX.5, IX.6 and IX.7 or a decree adopted pursuant to Articles IX. 4, § § 1 to 3, IX.5, § § 1 and 2;</p> <ol style="list-style-type: none"> 4° which do not respond to warnings to Rule XV.31. 5° those committing infringements of the rules of the European Union which concern matters under Book IX of the regulatory power of the King. <p>[Article IX.9:</p> <p>For products intended for consumers, labelling and information required by this book and its implementing decrees, instructions for use and the guarantee shall at least be expressed in a language which is comprehensible to the average consumer, in view of the linguistic region in which the products or services are placed on the market. This obligation also applies to other products, unless orders adopted under Article IX.4 and IX.5 provides for</p>

derogation conditions.]

The sanctions referred to in Article XV.102 are the following:

Art. XV.69.

The provisions of Book I of the Criminal Code, including Chapter VII and Article 85, shall apply to infringements covered by the present Code subject to the application of the specific provisions mentioned below.

Art. XV.70.

Breaches of this Code shall be punishable by a penalty ranging from level 1 to level 6.

- the level-1 penalty shall consist of a fine of EUR 26 to EUR 5,000.
- the level-2 penalty shall consist of a fine of EUR 26 to EUR 10,000.
- the level-3 penalty shall consist of a fine of EUR 26 to EUR 25,000.
- the level-4 penalty shall consist of a fine of EUR 26 to EUR 50,000.
- the level-5 penalty shall consist of a fine of EUR 250 to EUR 100,000 and imprisonment of one month to one year or one of these penalties only.
- the level-6 penalty shall consist of a fine of EUR 500 to EUR 100,000 and imprisonment of one to five years, or one of these penalties only.

Art. XV.71.

When the facts as submitted to the Court are the subject of an injunction, it may not qualify for adjudication in the criminal proceedings only after a decision *res judicata* was made in relation to the injunction.

Art. XV.72.

In the event of a repeated infringement within five years of a conviction *res judicata* in respect of the same infringement, the maximum fines and imprisonment is credited in duplicate.

Art. XV.73.

Companies and associations having legal personality shall be held civilly liable for damages, fines, convictions, confiscations, refunds and any pecuniary sanctions imposed for breaches of this Code against their bodies or its agents.

The same is true of the members of all trade associations without legal

	<p>personality, where the infringement was committed by a partner, manager or employee on a transaction falling within the scope of the Association's activities. The shareholder liable is, however, personally bound up to the limit of the amounts of money or securities that it has withdrawn from the operation.</p> <p>These companies, associations and members may be summoned directly before the criminal court by the public prosecutor or plaintiff.</p> <p>Art. XV.74.</p> <p>Upon expiry of a period of ten days from delivery, the Registrar of the Court or the Court must be free of charge to the Minister, by ordinary letter or electronically, a judgment applying a provision of this book.</p>
Bulgaria	<p>Chapter Six ADMINISTRATIVE PENAL PROVISIONS (Bulgarian Law on Technical Requirements to Products)</p> <p>Art. 50. (amended — SG No 93 of 2002, SG No 45 of 2005, SG No 86 of 2007) any person that violates the provisions of Articles 3 or 4 shall be punishable by a fine of BGN 1000 to 5000 or a financial penalty of BGN 5000 to BGN 15 000.</p> <p>Art. 51. (amended — SG No 93 of 2002, SG No 86 of 2007) a person who draws up and/or used a declaration of compliance with content which does not comply with the content defined in the Regulations referred to in Articles 7 and/or the implementing measures referred to in Article 26a or with new approach Directives shall be punishable by a fine of BGN 300 to 1000 or a financial penalty of BGN 1000 to 5000 if the act is not an offence.</p> <p>Article 51a. (New — SG No 93 of 2002, amended in SG No 45 of 2005) any person who places on the market and/or puts into service products with conformity marking in breach of the Regulation referred to in Article 24 shall be punishable by a fine of BGN 300 to 800 or a financial penalty of BGN 500 to BGN 1000.</p> <p>Article 51b. (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, supplemented in SG No 86 of 2007) any person who places on the market and/or puts into service products with conformity marking and supplementary marking or declaration of conformity without having assessed their compliance with the essential requirements laid down in the Regulations referred to in Articles 7 and/or with the eco-design requirements laid down in implementing measures under Article 26a, shall be liable to a fine of BGN 3000 to 8000 or a financial penalty of BGN 5000 to BGN 10 000.</p> <p>Article 51c. (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, supplemented in SG No 86 of 2007) any person who places on the market and/or puts into service products without marking, without</p>

additional markings or without declaration of conformity, when requested, under the provisions of Article 7 and/or with the eco-design requirements laid down in implementing measures under Article 26a, shall be liable to a fine of BGN 500 to 800 or a financial penalty of BGN 1500 to BGN 3000.

Article 51d. (New — SG No 86 of 2007, amended in SG No 38 of 2011) any person who places on the market and/or puts into service products marked contrary to the requirements of Regulation (EC) No 106/2008 of the European Parliament and of the Council of 15 January 2008 on a Community programme for labelling the energy efficiency of office equipment (OJ L 39/1 of 13 February 2008) shall be punishable by a fine of BGN 3000 to 8000 or a financial penalty of BGN 5000 to BGN 10 000.

Art. 52. (amended — SG No 93 of 2002, SG No 45 of 2005, SG No 86 of 2007) any person that fails to fulfil its obligations under Articles 25 or 26, paragraph 1 or 2 shall be punishable by a fine of BGN 500 to 1000 or a financial penalty of BGN 5000 to BGN 10 000.

Article 52a. (New — SG No 93 of 2002, amended in SG No 45 of 2005, SG No 86 of 2007) any person who places on the market and/or puts into service products without indicated on them the name and/or its head office or without instruction and/or instruction for use in Bulgarian shall be punishable by a fine of BGN 200 to 500 or a financial penalty of BGN 500 to BGN 2000.

Article 52b. (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, amended in SG No 86 of 2007) a trader who makes products without conformity marking or without additional marking, when such marking is required in the Regulations referred to in Articles 7 and/or the implementing measures referred to in Article 26a, shall be liable to a fine or penalty payment of BGN 250-1000

Article 52c. (New — SG No 93 of 2002, amended in SG No 45 of 2005, amended and supplemented in SG No 86 of 2007) a trader who makes products without declaration of conformity, when requested, under the provisions of Article 7 and/or implementing measures under Article 26a, shall be liable to a fine or penalty payment of BGN 250-1000

Article 52d. (New — SG No 93 of 2002, amended in SG No 45 of 2005, SG No 86 of 2007) a trader who makes products without indication of name or address of management to the person who places on the market and/or put into service is punishable by a fine or penalty payment of BGN 250-1000

Article 52e. (New — SG No 93 of 2002, amended in SG No 45 of 2005, SG No 86 of 2007) a trader who makes products without instruction and/or instruction for use in Bulgarian, shall be liable to a fine or penalty payment of BGN 250-1000

Article 52f. (New — SG No 86 of 2007, amended in SG No 38 of 2011) a

trader who makes products marked contrary to the requirements of Regulation (EC) No 106/2008 of the European Parliament and of the Council of 15 January 2008 on a Community programme for labelling the energy efficiency of office equipment, shall be punishable by a fine of BGN 250 or confiscation of property worth BGN 1000.

Art. 53. (amended — SG No 93 of 2002, supplemented in SG No 45 of 2005, amended in SG No 86 of 2007, SG No 38 of 2011) for non-compliance or infringement of the compulsory rules referred to in Article 30a, paragraph 1, 2, 4 and 5 and Art. 30c, paragraph 1 shall be fined BGN 300 to 1000 or a financial penalty of BGN 1000 to BGN 5000.

Article 53a. (New — SG No 86 of 2007) for other infringements of the provisions of Article 7 and/or implementing measures under Article 26a shall be punishable by a fine of BGN 300 to 1000 or a financial penalty of BGN 1000 to BGN 5000.

Art. 54. Article 219. (1) (Amended — SG. — SG No 93 of 2002, SG No 45 of 2005, SG No 95 of 2005, amended and supplemented in SG No 86 of 2007) Statements establishing infringements under Articles 50, 51, 51a to 51d, 52, 52a to 52f, 53, 53a and 56 shall be drawn up by officials designated by the President of the State Agency for Metrological and Technical Surveillance.

(2) (supplemented, — SG No 45 of 2005, amended in SG No 95 of 2005) the penalty decrees shall be issued by the State Agency for Metrological and Technical Surveillance or officials authorised by him.

(3) (New — SG No 93 of 2002, amended and supplemented in SG No 45 of 2005, repealed in SG No 77 of 2012, in force since 9.10.2012).

Art. 55. (1) (amended and supplemented. — SG No 93 of 2002) in breach of the provisions of Articles 36, 44, 46 paragraph 1, 1, 6 and 7 or paragraph 2 and of the coercive administrative measure referred to in Article 49, paragraph 1, natural persons are liable to a fine of BGL 500-10 000, and legal persons and sole traders, financial penalty in the same order.

(2) (supplemented, — SG No 93 of 2002) for other breaches of Chapter Five of the law and its implementing regulations, the penalty shall be a fine or penalty payment of BGN 100 to BGN 2000.

Art. 56. (Supplemented — SG No 86 of 2007) that prevents or does not provide the documents referred to in Art. 30 g (1) (4 market surveillance authorities and technical surveillance authorities to perform their duties is punishable by a fine of BGN 200 to 2000.

Art. 57. Where breaches of this Law or its implementing regulations are committed by those serving equipment with increased risk, infringers may be deprived from the acquired competence for a period of one month to two

years.

Art. 58. (1) (supplemented, — SG No 45 of 2005) the infringements chapter 5 of law and its implementing provisions and infringements under Article 56 shall be established by an official report drawn up by the staff of the Directorate-General for Inspection for government technical supervision”.

Article 219. (2) (Amended — SG. — SG No 95 of 2005) the penalty decrees shall be issued by the State Agency for Metrological and Technical Surveillance or officials authorised by him.

(3) (New — SG No 93 of 2002, repealed in SG No 77 of 2012, in force since 9.10.2012).

Article 58a. (New — SG No 45 of 2005) (1) (amended, — SG No 86 of 2007) for the breach is ascertained in accordance with Article 14a or 14b be penalised by a financial penalty of BGN 600.

(2) (New — SG No 86 of 2007) in the event of a repeated infringement under paragraph 1 shall be liable to a penalty or a fine of BGN 1000.

Article 219. (3) (Amended — SG. — SG No 95 of 2005, former subparagraph 2, No 86 of 2007, amended in SG No 66 of 2013, in force as of 26.07.2013, SG No 66 of 2013, in force as of 26.07.2013) Statements establishing infringements under paragraphs 1 shall be drawn up by determined by the President of the State Agency for Metrological and Technical Supervision of the Minister of Investment Design, officials of the relevant administration. Penalty enactments shall be issued by the State Agency for Metrological and Technical Supervision of the Minister of investment design.

Art. 59. The procedure for establishing infringements, issuing, appealing and implementing penalty enactments shall be as set out in the Administrative Infringements and Penalties Act.

Article 59a. (New — SG No 86 of 2007) (1) Where the infringer does not arrive to drafting the Act on administrative violation by the control authorities, the act shall be sent immediately for service by the municipality or mayoralty of the registered office of the legal person or sole proprietor. They are obliged to notify the infringer with communication with acknowledgement of deposited Act and within 14 days from the date of receipt to be served. No show of the infringer this statement should be signed by an authorised officer of the municipality or mayoralty and will be forfeited. Upon return of the Act within two months is issued and shall enter into force from the date of issue.

(2) The penal orders indicate that the fine or financial penalty imposed, as well as the costs for taking and testing of samples of products shall be payable to the bank account of the State Agency for Metrological and Technical

	<p>Surveillance and serve as a formal reminder after their entry into force.</p> <p>(3) Where the infringer is not found at the address indicated in the service of infringement notices, or has left the country, or has indicated address only abroad, an order will be forfeited. It shall be considered effective two months as of its issue.</p> <p>(4) (Repealed. — SG No 38 of 2012, in force since 1.07.2012).</p>
Croatia	<p>1) A fine in the amount of 40,000 to 100,000 kunas shall be imposed on a legal person if:</p> <ol style="list-style-type: none"> 1. In the production, transport, use, storage, and handling explosive substances do not take measures to protect the life and health of people, their property and the environment (Article 5, paragraph 1) 2. Do not bring the general act, does not draw up a plan of treatment or fails to comply with the plan and with the regulations (Article 5, paragraph 2 and 3) 3. Do not know all the people in her performing activities with respect to explosive substances with the measures specified in the bylaws or does not enable them to act in the event of an accident (Article 5, paragraph 4) 4. Do not provide a permanent physical or technical protection of facilities that provide services in production, transport and storage of explosive substances (Article 5, paragraph 5) 5. the loss or theft of explosives does not inform the nearest police station (Article 5, paragraph 7) 6. placed on the market and use of explosive substances for which no authorization was granted marketing authorization (Article 6) 7. perform professional tasks in the conformity assessment procedure without authority (Article 8), 8. let explosive substances by persons who do not meet the requirements for handling explosive substances (Article 11, paragraph 1) 9. start production of explosives without the approval of the Ministry and continues to perform production and the Ministry of her decision revoked approval for the production of explosives (Article 14, paragraph 1 and Article 17, paragraph 1) 10. produces explosives at the site without the permission of the Ministry (Article 16, paragraph 1) 11. explore new types of explosive materials without the authorization of the

	<p>Ministry (Article 18)</p> <p>12. deals with traffic of explosives without a permit from the Ministry (Article 21, paragraph 1)</p> <p>13. if he sold explosives legal entity or tradesman without purchasing a license (Article 21, paragraph 3)</p> <p>14. procure explosives without the permission of the police department (Article 22, paragraph 1)</p> <p>15. running of public fireworks without the approval of the Ministry (Article 31, paragraph 2)</p> <p>16. perform tasks blasting without the approval of the Ministry (Article 34, paragraph 1)</p> <p>17. in the performance of mining does not take security measures to protect the life and health of people, their property and the environment (Article 35, paragraph 1)</p> <p>18. running loud cracking without the permission of the Ministry (Article 41, paragraph 1)</p> <p>19. improper and unprofessional destruction of explosive substances endangering the lives and health of people, their property and the environment (Article 43, paragraph 2)</p> <p>20. without the approval of the Ministry or the police department set up a portable tank in a place where performs blasting (article 44, paragraph 3).</p> <p>(2) For the offenses referred to in paragraph 1 of this Article shall be punished with a fine of 5000 to 10,000 kuna and responsible persons in the legal person.</p> <p>(3) For the offenses referred to in paragraph 1 of this Article shall be punished with a fine of 40,000 to 100,000 kuna craftsman or other natural person.</p> <p>(4) For the offenses referred to in paragraph 1 of this Article made in the Magistrates Court will return with a fine legal entity or tradesman imposed a protective measure of prohibition of activity for up to a year.</p> <p>Article 53rd</p> <p>(1) A fine in the amount of 20,000 to 40,000 kunas shall be imposed on a legal person if:</p> <p>1st Explosive Substances by persons who are not professionally trained but not controlled by trained personnel, or if not previously familiar with the hazards</p>
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	<p>and safe method of work (Article 12, paragraph 2)</p> <p>2. within eight days to notify the Ministry of the start or termination of approved activities with explosive substances or on status changes (Article 13)</p> <p>Third within eight days from the finality of the decision to revoke the authorization for the production of explosives does not submit to the Ministry all the records that must be governed by this Law (Article 17, paragraph 2)</p> <p>4. Put on the market, transport or use of explosives that are not packaged in the original packaging tested and marked in the manner determined by the regulations on the transport of dangerous goods (Article 20, paragraph 1) and / or if the packaging does not contain the information referred to in Article 20, paragraph 2 of this Act,</p> <p>5. Within eight days from the finality of the decision on the withdrawal of marketing authorizations of explosives does not submit to the Ministry all the records that must be governed by this Law (Article 21, paragraph 4)</p> <p>6. procurement of explosive substances in quantities greater than currently available storage capacity (Article 23, paragraph 1)</p> <p>7. sells explosives and not stay permit or authorization does not specify sales volumes of explosive substances (Article 24, paragraph 1)</p> <p>8. at the latest 24 hours before the start of the use of explosives does not notify the local competent police department, where she used explosives outside the area police department that issued the approval for the acquisition (Article 24, paragraph 3)</p> <p>9. Do not return unused explosive materials in the original wrapper in a warehouse or container or destroyed according to the manufacturer's instructions and destroys them so that endangers the life, health and safety of people and material goods and the environment (Article 25)</p> <p>10. Use purchased explosive substances contrary to the provisions of Article 26, paragraph 1 of this Act,</p> <p>11. holding larger amounts of pyrotechnic devices for entertainment class I and II. of prescribed in stores, kiosks, warehouses or other containers or mobile stores or sale of pyrotechnic devices for entertainment class I, contrary to the provisions of this Act (Article 29 and Article 30, paragraph 2), or if pyrotechnic articles holds in store windows (Article 30 . paragraph 3)</p> <p>12. sale of pyrotechnical devices for entertainment class II. outside the approved store or stores of weapons and ammunition, selling these assets in the period from 2 January to 1 December and this means sales to persons under 18 years of age (Article 30, paragraph 1)</p>
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	<p>13. within eight days from the finality of the decision to revoke the authorization to perform the public fireworks do not submit to the Ministry all the records that must be governed by this Law (Article 31, paragraph 5);</p> <p>14. running public fireworks without the approval of the runtime issued by the police department or if you performed a public fireworks display fireworks that are not approved or do not comply with the prescribed conditions (Article 32, paragraphs 1, 2 and 3)</p> <p>15. within eight days from the finality of the decision to revoke the authorization for the performance of mining does not submit to the Ministry all the records that must be governed by this Law (Article 34, paragraph 5)</p> <p>16. does not make any plan for mining or if you allow the use of explosives contrary blasting plan (Article 35, paragraph 2)</p> <p>17. perform blasting in a populated area or in the vicinity of the settlement of a previously not inform the competent police department or to inform the public through local mass media or legal persons that manage communal infrastructure (Article 35, paragraph 3)</p> <p>18. business overhead blasting, blasting in demining, special mining or underground mining is done by persons who do not have permission for mining or for a particular type of mining (Article 36, 37 and 38)</p> <p>19. Following the preparation of mining or ancillary tasks performed by a person who does not meet the prescribed conditions (Article 40 paragraph 1 and 2)</p> <p>20. within eight days from the finality of the decision to revoke the authorization to perform loud shooting does not submit to the Ministry all the records that must be governed by this Law (Article 41, paragraph 4)</p> <p>21. loud cracking performs more operators who are not capable of handling explosive substances (Article 42, paragraph 1)</p> <p>22. without the permission of the police department running out shooting in a place where gather a larger number of persons (Article 42, paragraph 3)</p> <p>23. unused explosive substances for which there are no conditions for storage is not returned to the supplier or destroyed or fails to report to the police department that issued the approval for the acquisition (Article 43, paragraph 1)</p> <p>24. destroys explosives and does not inform the competent police department or if you through local media not inform the local population in cases when it is foreseen the emergence of strong detonations (Article 43, paragraph 3 and 4)</p>
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	<p>25. does not keep proper registers (Article 46, paragraph 2 and 3)</p> <p>26 does not implement the Inspector's decision (Article 50, paragraph 1 5, 6 and 7)</p> <p>27. not keep registers referred to in Article 46, paragraph 2 of ten years and registers referred to in Article 46, paragraph 3 five years,</p> <p>28. inspectors prevents the performance of the inspection supervision or does not provide the necessary data and information (Article 50, paragraph 3)</p> <p>29.acts contrary to the security measures laid down in the regulations that the Minister of the Interior passes under the authority of this Act.</p> <p>(2) For the offenses referred to in paragraph 1 of this Article shall be punished with a fine of 4000 to 8000 kuna and responsible persons in the legal person.</p> <p>(3) For the offenses referred to in paragraph 1 of this Article shall be punished with a fine of 20,000 to 40,000 kunas craftsman or other natural person.</p> <p>(4) For the offenses referred to in paragraph 1 of this Article made in the Magistrates Court will return with a fine legal entity or tradesman imposed a protective measure of prohibition of activity for up to six months.</p>
Cyprus	<p>Any person who in any way -</p> <p>a) possesses, sells or attempts to sell or acquire pyrotechnic article in violation of the provisions of these Regulations</p> <p>b) affixes or has affixed to pyrotechnic any false marking or labelling or</p> <p>c) falsifies any documents or certificates are provided for in these Regulations</p> <p>commits an offense and, on conviction, is liable to imprisonment not exceeding five (5) years or to a fine not exceeding seventeen thousand euros (17,000 €) or to both such penalties.</p>
Czech Republic	<p>(8) An administrative offense shall be fined up</p> <p>a) 5,000,000 CZK, for an administrative offense under paragraph 1 point. b), c) or r), pursuant to paragraph 2 point. g) pursuant to paragraph 3. d) or to paragraph 4. and),</p> <p>b) 1,000,000 CZK, for an administrative offense under paragraph 1 point. d), i), j), s) and t)</p> <p>c) 500,000 CZK, for an administrative offense under paragraph 1 point. a), e), g), h), k), l), o), p) or q) pursuant to paragraph 2. b) i) j) k) l) m) n) o) or p),</p>

	<p>pursuant to paragraph 3. e), f), g), h), j) or k), pursuant to paragraph 4. b) or c) pursuant to paragraph 5. a), d) or f),</p> <p>d) 100 000 CZK, for an administrative offense under paragraph 1 point. f), m) or n), pursuant to paragraph 2 point. a), c), e), f) or h), according to paragraph 3 point. a), c) or i) or paragraph 5 point. b), c), e) or g)</p> <p>e) 50 000 CZK, for an administrative offense under paragraph 2 point. d) pursuant to paragraph 3. b) pursuant to paragraph 6 or paragraph 7.</p>
Denmark	<p>Penalty that:</p> <ol style="list-style-type: none"> 1) contrary to § 6 paragraph. 1, § 7, paragraph. 1 pt. 1, 2 or 3, § 8 or § 9, no. 1, 2 or 3, making fireworks or other pyrotechnic articles available on the market 2) brings fireworks covered by § 10 paragraph. 1, no. 1-8 on the market or otherwise make available on the market, 3) fails to store documentation in accordance with § 20, 4) violates the prohibition issued pursuant to § 32 paragraph. 1 5) under leaves to comply with orders issued pursuant to § 32 paragraph. 2, on the withdrawal, recall or destruction of articles or 6) fails to comply with orders issued pursuant to § 32 paragraph. 3, to eliminate improper CE marking. <p>PCS. 2. The penalty may, in aggravating circumstances, increase to imprisonment for up to 2 years if the infringement was committed intentionally or through gross negligence when the violation is:</p> <ol style="list-style-type: none"> 1) caused significant damage to persons, property or the environment or the risk thereof, or 2) achieved or intended financial gain for himself or others, including savings. <p>PCS. 3. If improper use of CE marking see. § 21 paragraph. 5 or § 22 paragraph. 1 is intentional or due to gross negligence and if the violation is achieved or was intended to achieve financial gain for himself or others, punished the CE marking to a fine, unless more severe punishment is prescribed under other legislation.</p> <p>PCS. 4. There can be imposed on companies. (Legal persons) under the rules of the Penal Code Chapter 5.</p>
Estonia	<p>Penalty payment rates: Failure to comply with the appropriate state official exercising supervision may apply substitutive enforcement or Substitute Enforcement and Penalty Payment Penalty Payment Act. The maximum</p>

	<p>penalty payment is generally 640 euros, the explosives sector operator for 2600 euros.</p> <p>Explosives and pyrotechnic products storage and use of non-compliance [RT I 2010, 31, 158- entered into force. 01.10.2010]</p> <p>(1) of the explosive or pyrotechnic product use or storage of non-compliance, as well as explosive or pyrotechnic product use the restrictions imposed for non-compliance - is punishable by a fine of up to 300 fine units. [RT I 2010, 31, 158- entered into force. 01.10.2010]</p> <p>(2) The same act, if committed by a legal person - is punishable by a fine of up to 3,200 euros.</p> <p>The use of explosive substances store and plants</p> <p>(1) explosive substances store or plants for the operation of the operating license is required - is punishable by a fine of up to 300 fine units.</p> <p>(2) The same act, if committed by a legal person - is punishable by a fine of up to 3,200 euros.</p> <p>Violation of requirements:</p> <p>(1) The project concerned the blasting for carrying out the blasting project is required - is punishable by a fine of up to 300 fine units.</p> <p>(2) The same act, if committed by a legal person - is punishable by a fine of up to 3,200 euros.</p> <p>For the non-compliance of the pyrotechnic article to Estonia for the Technical Surveillance Authority without prior notice, if such, notification is required, as well as explosive substances into the authorization to Estonia for a fine not exceeding 200 penalty units. [RT I, 07.12.2014, 1 entered into force. 01/01/2015] (2) The same act, if committed by a legal person - is punishable by a fine of up to 2,000 euros. [RT I 2010, 22, 108- entered into force. 01.01.2011]</p> <p>Failure to comply with the appropriate state official exercising supervision may apply substitutive enforcement or Substitute Enforcement and Penalty Payment Penalty Payment Act. The maximum penalty payment is generally 640 euros, the explosives sector operator for 2600 euros.</p>
Finland	<p>In addition to the penalty provisions of § 125 chemicals safety law the provisions of Chapter 44. § 11 Penal Code (FFS 39/1889) on penalties for violations of the rules on explosives goods are applied in the landscape. Although the provisions of Chapter 44. § 12 of the Criminal Code The penalty for careless handling of a dangerous chemicals or explosive or such product</p>

referred to in Chapter 5. Chemical Safety Act shall apply in the province.

The penalty for the explosive offense of the Criminal Code provides for Chapter 44, § 11. Anyone who wilfully or negligently violates the obligation laid down in, § 5 of this Act § 7-12: the manufacturer laid down in obligations, § 13: the importer provided for in obligations, § 14: distributor stipulated in obligations § 42-44, or by virtue of prohibition or order issued, shall be sentenced, unless the act is provided elsewhere more severe punishment, pyrotechnic articles for breaching the provisions of a fine.

Administrative coercive measures: The Authority may reinforce a prohibition under this Act or a warrant under penalty of fine or commissioned by, or cessation, such as a periodic penalty payment on the law (1113/1990) provides.

Violation of the Explosives Legislation: Anyone who wilfully or negligently contrary to this Act or pursuant to a provision violates 1) the operator 7 to 20, 26 or a 133, § general duties laid down in, 2) 23, 37, 58, 58 a or 58 b § authorization requirement laid down in this Act or the storage area provided for in, 3), 23, 24, 63, 79, 81, 91, 93, 94, 97, 101, 133 or § 134: 33 § reporting obligations laid down in, 4), 28, 30-32, 41-44 or 62 §: accidents laid down in the containment and prevention of obligation, or 98 §: set out in the notification of accidents, 5) § 46-49: the manufacture of the product referred to in, import or marketing of the obligation laid down in Chapter 5, or similar explosives on the 67-69 or The obligation laid down in, 6) 71 §: a § 69 regarding the use of fireworks obligations laid down in, 93 §: 91 § laid down in the quality control obligation in the manufacture and importation of fireworks to the operator responsible for the set obligations, or 94 or 94 a § provided the fireworks show organizer responsibilities and obligations, 7) 73 § concerning the import of explosives authorization requirement laid down in 74 § of the transfer of the obligation laid down in, 75 § transit of the obligation laid down in 77 § of the labelling obligation laid down in, for the use of 78 § provided for in the obligation, for the supply of 82, a 82, 83 or 83 a § the obligation laid down in, § 84 for the holding of the obligation laid down in 86 § of accounts: the obligation laid down in or on the disposal of § 88-90: the obligation laid down in, 8) § 38: audit obligation laid down in, § 53: installation laid down in or maintenance obligation, § 54: audit provided for in, repair or decommissioning obligation, § 55: in the installation, maintenance or operation of the inspection requirement laid down in § 103 or together provided the performance of the inspection tasks obliged, 9), 29, 39, 56, 61, 65, 81, 93, 94 or 112 § the appointment of the person responsible for the obligation or the person in charge of 29, 39, 56, 61, 65, 81 or 95 provided for in § Journal the obligations laid down, 10), 35 or 36 § concerning the storage of dangerous chemicals on or in storage 87 §: the obligation laid down in, 11), 25, 34, 36, 37, 55, 59, 63 66 § of the obligations laid down in or explosives storage , 70, 73, 79, 81, 91, 93, 94, 97 or 100 §: condition or restriction imposed under or 79, 81, 91 or 97 §: the prohibition imposed under 12) 83 §:

	the prohibition issued under or 92 §: order issued under or prohibition, 13), 106, 109 or § 111 of the prohibition imposed under or 105-108 or 110 § the obligation imposed under or 14) 117 or § 121 of the disclosure obligation laid down in shall be sentenced, unless a more severe penalty is provided for violation of the provisions of the explosive to a fine.
France	<p>Is punishable by a fine for 5th class offenses fact of:</p> <ul style="list-style-type: none"> - Hold or knowingly use a product not equipped conformity marking as provided for in Articles 4 and 5 or not provided with labelling in accordance with the provisions of Article 25; - Affix the conformity marking in violation of Article 22; - Present a public or use a pyrotechnic article at exhibitions, trade fairs and demonstrations for the marketing, without apparent and legible mark meeting the requirements defined by order of the Minister responsible for industrial safety; - Use a product made for research, development and testing without apparent and legible mark meeting the requirements defined by order of the Minister responsible for industrial safety; - Introduce several requests for conformity assessment with several organizations under the first paragraph of Article 15 for the same product; - Carry out handling operations, as defined in paragraph 5 of Article 28 or use products of categories 4, T2 and P2 mentioned in Article 13 without a training certificate or the authorization provided for in Article 28.
Germany	<p>Penalties and fines rules</p> <p>§ 39 Administrative offenses</p> <p>(1) An administrative offense who wilfully or negligently</p> <ol style="list-style-type: none"> 1. contrary to § 3, paragraph 3 a note, correctly, completely or not there on time, 2. contrary to § 3, paragraph 4 an instruction manual does not, not correctly, completely, not in the prescribed manner or time, 3. contrary to § 6 paragraph 1 sentence 1 number 2 a name or contact address not do so correctly, fully or not timely install, 4. contrary to § 6 paragraph 4 sentence 1 the competent market surveillance authority does not do so correctly, complete or not informed in good time, 5. contrary to § 7 paragraph 1 in conjunction with Article 30 paragraph 5

	<p>sentence 1 of the Regulation (EC) no. 765/2008 the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing</p> <p>(EEC) No. 339/93 (OJ. L 218, 13.8.2008, p 30) a marking, a Mark or inscription on a product installs,</p> <p>6. contrary to § 7 paragraph 2 makes a product available on the market,</p> <p>7. an ordinance pursuant to</p> <p>a) § 8 paragraph 1 sentence 2 No. 1 or No. 3 or § 34 paragraph 1 point 2, 4 or number 5 or</p> <p>b) § 8 paragraph 1 sentence 2 number 2 or § 34 paragraph 1 point 1 or an enforceable order based on such statutory ordinance to the extent that</p> <p>Ordinance for a specific offense to this fine provision refers,</p> <p>8. an enforceable order pursuant 1 sentence 1 or sentence 2 a) § 11 paragraph, § 26 paragraph 2 sentence 2 No. 1 or No. 3 or § 37 paragraph 7</p> <p>Sentence 2 contravenes or b) § 26 paragraph 2 sentence 2 No. 2, 4, 6 to 8 or 9 or paragraph 4 sentence 1 fails to comply,</p> <p>9. contrary to § 22 paragraph 2 sentence 2 or paragraph 4 uses a called there signs or advertise it,</p> <p>10. contrary to § 22 paragraph 3 a requirement of the plant number 1, 2, 3, 4, 7, 8, sentence 1, number 9, sentence 2 or Set 3 or number 10 is not observed,</p> <p>11. contrary to § 22 paragraph 5 sentence 2 a test is not, not correctly, completely or on time documented,</p> <p>12. contrary to § 28 paragraph 4 sentence 1 a measure does not condone or a market surveillance authority or does not support a proxy,</p> <p>13. contrary to § 28 paragraph 4 sentence 2 fails to provide information, not correctly, completely or on time granted</p> <p>14. contrary to § 36 sentence 1 makes a plant not or not timely available, a test is not allows a worker or a tool not or does not provide in time a claim does not, not correctly, completely or on time or makes a document does not or not timely submits</p> <p>15. contrary to § 38 paragraph 1 sentence 2 in connection with § 22 paragraph 2 sentence 6 of the OSH Act a Measure does not tolerate,</p>
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	<p>16. a directly applicable provision in acts of the European Community or the European Union infringes that a substance in a) point 8 letter b or b) the numbers 1 to 6, 8 letter a or the numbers 11 to 13 designated commandment or prohibition is in line, as far as an ordinance pursuant to paragraph 3 for a certain offense to this fine provision refers, or</p> <p>17. a directly applicable provision in acts of the European Community or the European Union or an enforceable order based on such provision contravenes the content corresponds to a system of which the in a) number 7 letter a or b) number 7 letter b those provisions authorize, insofar an ordinance pursuant to paragraph 3 for a given fine offense to this fine provision refers. (2) The offense may in the cases of paragraph 1, paragraph 7 letter a, number 8 letter b, Number 9, 16 point a and point 17 letter a with a fine not exceeding one hundred thousand euros, in the other cases by a fine of up to ten thousand Euro will be punished.</p> <p>(3) The Federal Government is authorized, as far as the enforcement of acts of the European Community or the European Union is required by ordinance without the consent of Federal designate the offenses as an administrative offense under paragraph 1, point 16 and 17 can be punished.</p> <p>§ 40 Penal provisions</p> <p>A prison sentence of up to one year or a fine is imposed on anyone who a in § 39 paragraph 1 point 7 Letter a, number 8 letter b, number 9, 16 letter a or number 17 letter a designated repeated intentional act persistently or life by such an intentional act or compromised health of another or foreign property of significant value.</p>
Greece	<p>1. Imposition of fines and the categorization of infringements.</p> <p>Any economic operator who in the capacity of the manufacturer, the authorized representative, the importer or distributor makes available on the Greek market of pyrotechnic articles falling within the scope of this in contravention of the provisions or impair control thereof, be punished by the competent authority market surveillance by a fine of 2,000 up to 50,000 euros, depending on the severity / gravity of the infringement and non-compliance in accordance with the categories in the following table.</p> <p>Regarding the amount of the fine takes into account the extent of non-compliance, risk and category of pyrotechnics, the status of the economic operator (manufacturer, importer, distributor) and the size of the company, the conditions under which it was committed or continues committed to the contrary, the volume of the available on the market of pyrotechnic articles, the specificities of the findings and their implications for public health and safety, any corrective actions and the subsequent compliance of the economic operator and preventing the control from the company's side and the degree of</p>

	<p>cooperation of the test with the IACs and competent service.</p> <p>These fines are per non-compliant product. If they committed simultaneously cross difference in offenses falling into the above categories A to C, the sum of duty fine cannot exceed the ceiling of 5,000 euros for all offenses falling covered only in A, 30,000 for all violations falling only in B and 50,000 for all infringements fall only in C. When committed violations that fall into more than one of the above categories A to C should only maximum level provided for the fine category. The fines imposed in category D individual for each offense separately. In any case the total fine for all breaches of the table above may not exceed EUR 50,000 per non-compliant type Pyrotechnic.</p> <p>In case of repetition offenders punished fined twice the original to a maximum of 50,000 per non-compliant pyrotechnic article.</p> <p>These fines imposed by reasoned decision of the head of the competent authority. The fine levied ensures and agree to the applicable provisions on public revenue, credited to the Special Account for Ministry of Development Agency Code: 35/110, OEM: 84 583, No. 234218/6 Bank of Greece IBAN GR 860100023000000002312186 - who established and functions for similar purposes of supervision and control of electro-technical products - cash basis lists drawn up and sent by the authority to tax office the debtor, with restore this service a copy of the summary state attestation tax filled with the relevant certification practice. Said decision allowed the exercise reasoned appeal to the General Secretary Industry-General of the Ministry of Economy, Growth Development and Tourism within thirty (30) days from the notification to the person concerned, in accordance with legislation.</p> <p><i>Table with fines (from 2.000 euros up to 50000 euros)</i></p>
Hungary	<p>Administrative service fee for the procedure (1) issuing the license rate if</p> <p>a) the application of conformity assessment certification order is directed to authorize 270 970 forint, b) the application of conformity assessment aimed at checking the order of licensing of 270 970 forint (2) entitling the conformity assessment certification and conformity assessment checks to be authorized to carry out In case the procedure for 316 700 forint administrative service fee shall be paid. (3) The administrative service fee shall be paid to the National simultaneously with the submission of the application Police Hungarian State Treasury account number 10023002-01451715-00000000. administrative service fee (4) of paragraph (1) and (2) of the National Police includes revenue. (5) The administrative service fee with respect a) 1990 XCIII to charging on fees. § 28. Law (Duties in the future.) (2) available, b) rectification in the event of non-payment of fees in respect of ITV. 73 / A. § paragraph (1) available, c) the reimbursement of fees on ITV. (1) and (2), § 79, and ITV. f) g) of § 80 paragraph (1) available should be used.</p>

Ireland	<p>34. (1) A person who contravenes these Regulations (other than Part 4) commits an offence and is liable— (a) on summary conviction, to a class A fine, or (b) on conviction on indictment, to a fine not exceeding €50,000.</p> <p>(2) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of, or to be attributable to any wilful neglect on the part of, any person, being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person, as well as the body corporate, commits an offence and shall be liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.</p> <p>(3) Where the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and defaults of a member in connection with his or her functions of management as if he or she were a director or manager of the body corporate.</p> <p>(4) An offence under these Regulations may be prosecuted summarily by the market surveillance authority.</p> <p>(5) Where a person is convicted of an offence under these Regulations, the court may order the forfeiture to the market surveillance authority of any pyrotechnic article to which the offence relates.</p> <p>(6) Where an order is made under paragraph (5), the market surveillance authority may for the purpose of giving effect to it seize and detain the pyrotechnic article where it has not already been seized under this Regulation.</p> <p>(7) If a person is convicted of an offence under these Regulations the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the prosecutor the costs and expenses, measured by the court, reasonably incurred by the prosecutor in relation to the investigation, detection and prosecution of the offence, including costs incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisers.</p>
Italy	<p>Art. 33. Discipline sanctions</p> <p>1. Unless the act constitutes a more serious crime, anyone who sells fireworks or other pyrotechnic products under fourteen years shall be punished by imprisonment from three months to one year and a fine of 2,000 euro to 20,000 euro.</p> <p>2. Unless the act constitutes a more serious offense, anyone selling or delivery of fireworks and pyrotechnics F2 category of categories TI and PI under the age of eighteen or category F3 fireworks in violation of the obligations of</p>

identification and registration provided for in Article 55 of the text of public safety laws, approved by Royal decree 18 June 1931 n. 773, or in contravention of the legal authorization, it shall be punished with imprisonment from six months to two years and a fine of 20,000 euro to 200,000 euro.

3. Unless the act constitutes a more serious offense, anyone selling or delivery of fireworks of category F4 and professional pyrotechnics of T2 and P2 categories to persons and requirements referred to in 'Article 5, paragraph 2, or in violation of obligations of identification and registration provided or the requirements of the police licenses it shall be punished with imprisonment from six months to three years and a fine of 30,000 euro to 300,000 euro.

1. Unless the act constitutes a more serious offense, the violation of the prohibition laid down in 'Article 5, paragraph 8, shall be punished by imprisonment from one year to three years and a fine of 15,000 euro to 150,000 euro.

2. A police licenses for the production, trade, import and export, the products referred to in this Decree, as well as authorization to carry out the procedures for assessing the conformity of pyrotechnic articles referred to in Article 20, paragraph 1, they cannot be con-ceded, or if granted, may not be renewed, the organization lacking the requirements of Article 43 of the consolidated public safety laws, approved by Royal decree 18 June 1931 n. 773.

3. For violations referred to in this Article, with regard to police license holders referred to in paragraph 5, as well as the police license holders for the transport, storage, possession, and disposal of the products referred to in this decree, may be ordered police authorization suspended in accordance with Article 10 of the consolidated version of the laws on public order. In the most serious cases, or in case of relapse, it may be, also, ordered the revocation.

4. Unless the act constitutes a crime, failure to notify the prefect of Article 14 involves the application of administrative fine of 500 euro to 3,000 euro.

5. Unless the act constitutes a crime, the total omission regulations for affixing the labels on fireworks, still held, under this decree, involves the application of administrative fine of 200 euro to 700 euro for each piece labelled or not for each package is still intact, if the individual parts are not labelled in the same content.

6. Unless the act constitutes a crime, the penalty referred to in paragraph 6 applies also against anyone who holds, for its placing on the market, a product, or, if applicable, its smallest piece of packaging, which does not bear anyway:

a) the 'CE-type' or a reference to the recognition under Article 53 of the consolidated text of public safety laws, approved by Royal Decree 18 June

	<p>1931 n. 773;</p> <p>b) a reference to the award decision and the classification of the Ministry internal, if any;</p> <p>c) complete instructions for use, warnings and instructions for safe transport, as well as the expiration date, if any, and the year of production, written in Italian, in clear, easily readable;</p> <p>d) precise and unambiguous guidance on the essential elements for the identification of the manufacturer, importer, distributor and to trace the product, including the indication in grams of the NEC (net explosive content).</p> <p>7. Against the entity that holds, for the placing on the market, a product on which were omitted, even partially, indications provided by law, other than those referred to in paragraph 8, applies an administrative sanction from 20 euro to 60 euro for each piece partially labelled.</p> <p>8. Unless the act constitutes a crime, a violation of the prohibition of Article 19, paragraph 6, involves the application of administrative fine of 200 euro to 700 euro for each piece.</p>
Latvia	<p>Article 23. Responsibility for the pyrotechnic movement rules violation: For this Law and other statutory pyrotechnic movement rules of persons prosecuted in accordance with the law. Supplying an unsafe product can result in a fine of up to LVL 5,000 for each offence, and/or a term of imprisonment of up to three months. (http://www.ptac.gov.lv/en/content/product-safety-0)</p>
Lithuania	<p>Amendment of the Administrative Code (2014. 16 October. No. XII-1236)</p> <p>Non-admission or otherwise or the Weaponry Fund of the Republic of Lithuania under the Lithuanian Ministry of Internal Affairs officials to companies active in the manufacturing of weapons, their parts, ammunition, explosives, pyrotechnic products, businesses in the sex trade in explosives, weapons, explosives, weapons and ammunition for the repair of the processing of their documents, false information or concealment of documents, these officials also constitutes a legitimate requirements shall entail a fine on the managers of undertakings from seventy two and one hundred and forty four euros.</p> <p>The same acts committed by a person who has already received an administrative penalty for the infringements referred to in the first paragraph of this Article — shall attract a fine of between one hundred and forty four up to two hundred eighty nine euro.”</p> <p>Civil pyrotechnic means the production, import, export, transit, import, export, storage, trade, destruction, accounting of irregularity shall attract a fine of between fifty seven and one hundred and fifteen euros. The same acts</p>

	<p>committed by a person on whom an administrative penalty has already been imposed in respect of the infringement referred to in the first paragraph of this Article shall be subject to a fine from one hundred to two hundred forty four Euro and eighty nine civilian pyrotechnic devices, with or without confiscation.</p> <p>Civilian pyrotechnic devices whose placing on the market, storage, sale or use of which is restricted, making available on the market, possession, sale or use of non-respect of the restrictions shall attract a fine of eighty six and two hundred thirty one euro with the measures in question.</p> <p>Civilian pyrotechnic devices whose placing on the market, storage, sale or use is prohibited, the making available on the market, possession, sale or use of shall be subject to a fine from one hundred to two hundred forty four Euro and eighty nine of the confiscation.</p> <p>The same acts committed by a person who has already received an administrative penalty for the infringements referred to in the first and the second paragraph shall attract a fine of two hundred and eighty nine to five hundred seventy nine euros to the measures in question.</p> <p>The use of civil pyrotechnic means, in violation of the established procedure for the acquisition of shall attract a warning or a fine of between fourteen to twenty eight euro with or without confiscation of pyrotechnic devices.</p> <p>The same acts committed by a person on whom an administrative penalty has already been imposed in respect of the infringement referred to in the first paragraph of this Article shall attract a fine of between fifty seven euros and twenty eight civilian pyrotechnic devices, with or without confiscation.</p> <p>The first paragraph of this Article for an infringement committed from fourteen to sixteen years — shall attract a warning or a fine of parents or guardians (rūpintojams) from fourteen to twenty eight euro civilian pyrotechnic devices, with or without confiscation</p>
Luxembourg	<p>Art. 37. Sanctions: (1) shall apply administrative measures in the context of market surveillance referred to in Article 13 of the Law of 4 July 2014 reorganizing ILNAS. (2) The application of the administrative fines provided for in Article 17 of the Act of July 4, 2014 reorganizing ILNAS. (3) Criminal penalties are those laid down in Articles 18 and 19 of the Act of July 4, 2014 reorganizing ILNAS.</p>
Malta	<p>(1) The penalties applicable for the infringement of any of the provisions of these regulations shall be those provided for in Part IV of the Product Safety Act. Provided that, where it constitutes an offence punishable with a higher punishment under any other law, the higher punishment laid down in that law shall apply.</p>

	<p>(2) The necessary measures allowing the detainment of consignments of pyrotechnic articles that fail to comply with the provisions of these regulations shall be those under the Product Safety Act and the Ordinance.</p> <p>Product Safety Act – Part IV Fines. Amended by: L.N. 426 of 2007.</p> <p>32. (1) A person found guilty of an offence under article 23 shall, on conviction, be liable to a fine (multa) of not less than four hundred and sixty-five euro and eighty-seven cents (465.87) and not exceeding two thousand and three hundred and twenty-nine euro and thirty-seven cents (2,329.37), or to imprisonment for a term not exceeding six months or to both such fine and imprisonment.</p> <p>(2) A person found guilty of any other offence under this Act shall be liable, on conviction, to a fine (multa) of not less than one thousand and one hundred and sixty-four euro and sixty-nine cents (1,164.69) but not exceeding eleven thousand and six hundred and f o r t y - six euro and eighty-seven cents (11,646.87) or to imprisonment for a term not exceeding three years or to both such fine and imprisonment.</p> <p>(3) A person found guilty of a second or subsequent offence shall, on conviction, be liable to a fine (multa) of not less than one thousand and seven hundred and forty-seven euro and three cents (1,747.03) but not exceeding twenty-three thousand and two hundred and ninety-three euro and seventy-three cents (23,293.73) or to imprisonment not exceeding four years or to both such fine and imprisonment.</p> <p>(4) The Court may, upon conviction for any offence committed under this Act, with the exception of offences committed under article 23, if it feels that circumstances so warrant, additionally order the suspension or cancellation of any licence or licences issued in favour of the person charged or in respect of the premises involved in the proceedings.</p> <p>(5) Without prejudice to the generality of the foregoing, any person convicted in relation to an offence under articles 26 or 29 shall additionally be liable to the additional fine (multa) of not more than four hundred and sixty-five euro and eighty-seven cents (465.87) for each day that a notice or undertaking has not been complied with.</p>
Netherlands	<p>Economic Offences Act</p> <p>Title II. Of penalties and measures</p> <p>Article 5</p> <p>Unless otherwise provided by law, may in respect of economic offenses to impose no other arrangements are made with the purpose of punishment or disciplinary measure than the penalties and measures in accordance with this</p>

law.

Article 6

1 He who commits an economic offense, shall be punished:

1 °. in the case of crime, as far as an economic offense referred to in Article 1, under 1 or in Article 1a, under 1, with imprisonment not exceeding six years, community service or a fine of the fifth category;

2 °. in case of another crime with imprisonment not exceeding two years, community service or a fine of the fourth category;

3 °. if he commit the offense referred to under 2 ° has made a habit of imprisonment not exceeding four years, community service or a fine of the fifth category;

4 °. in case of violation, as far as an economic offense referred to in Article 1, under 1 or in Article 1a, under 1, with imprisonment not exceeding one year, community service or a fine of the fourth category;

5 °. in the case of any other offense, with imprisonment not exceeding six months, community service or a fine of the fourth category.

If the value of the goods with which or with respect to which the economic offense was committed, or wholly or partly obtained by means of the economic offense, exceeds the fourth of the maximum of the fine that in the cases under 1 to 5 ° may be imposed, may, without prejudice to Article 23, paragraph, of the Criminal Code, be fined in the next higher category.

2 Moreover, the additional penalties may, under Article 7, and the measures mentioned in Article 8 imposed, without prejudice to the imposition, in the next cases previously considered, the measures provided elsewhere in law.

3 Notwithstanding the provisions in the first and second paragraph it is that a provision laid down in Article 15, second paragraph, of the Distribution Act, violates punished with imprisonment not exceeding two months or a fine of the first category.

4 Notwithstanding the provisions of paragraph he who violates a regulation laid down by or under Articles 2 and 3, first paragraph, of the Chemical Weapons Convention, Article 3, first and second paragraph of the Law precursors explosives, or articles 2, first and third paragraphs 3 and 4 of the biological weapons Convention, shall be punished with imprisonment not exceeding eight years or a fine of the fifth category, if the offense was intentionally committed with a terrorist intent as provided Article 83a of the Penal Code, or with the objective of preparing or facilitating a terrorist crime under Article 83 of the Code.

Article 7

The additional penalties are:

- a. deprivation of the rights mentioned in Article 28, first paragraph, under 1 °, 2 °, 4 ° and 5 ° of the Criminal Code, for a time, the term of imprisonment of at least six months and at most six years exceeding, or in the case of conviction to fines as the sole principal punishment for a period of at least six months and a maximum of six years;
- b. [Red: expired;]
- c. total or partial closure of the undertaking of the offender, which the economic offense was committed, for a period not exceeding one year;
- d. forfeiture of the objects referred to in Article 33a of the Penal Code;
- e. confiscation of property belonging to the company of the convicted person, in which the economic offense was committed, to the extent that they are similar to and related to keeping the offense related to those mentioned in Article 33a of the Penal Code;
- f. total or partial withdrawal of certain rights or full or partial denial of certain benefits, the rights or benefits the offender or may be granted in connection with his undertaking by the government, for a period not exceeding two years;
- g. publication of the court decision.

Article 8

Measures include:

- A. The measures provided for in Title IIA of the First Book of the Penal Code;
- b. receivership of the company of the offender, which the economic offense was committed, in the case of crime for a period not exceeding three years and in case of violation for a period not exceeding two years;
- c. imposing the obligation to provision of what is left illegally, negation of what has been done illegally and provision of services to the make up of the foregoing, all at the expense of the convicted person, as far as the court decides otherwise.

Article 9

The measures set out in Article 8, b and c, can together with penalties to be imposed by other measures.

Article 10

1 The ruling, in which an additional penalty or a measure, as stated in Article 8, is imposed shall, so far as necessary, all the details and consequences arranged as needed, including in receivership appointing one or more administrators. By imposing an additional penalty as stated in Article 7, c, can also be ordered that the convicted him by the government on behalf of his company provided modest surrenders; sells his company stocks under supervision; and cooperates in identifying those stocks.

2 Subject to the provisions of Article 577b of the Code of Criminal Procedure, the court which imposed the additional sentence or order, after receipt of an application by the public prosecutor or at the request of the offender in subsequent decision still lay down rules as referred to above, then or in the lead already given regime change or add any relevant supplementary scheme. The proceedings take place in camera; the ruling is made in public. The decision is supported by reasons; it is not subject to any appeal.

3 We reserve before, giving detailed rules for implementing this article.

Article 11

If the court does not decide otherwise, a receiver appointed under the preceding Article or Article 29, the same rights and obligations as the administrator referred to in section 409 of Book 1 of the Civil Code, and to any other person without his authorization perform any act of management in the company.

2 The decision under administration by the clerk of the court at first instance that the given decision, published in the Dutch Government Gazette and in one or more by the court to appoint newspapers. The decision receivership is registered in the commercial register pursuant to the provisions under the Trade Register Act 2007.

Article 12 [repealed on 01-05-1983]

Article 13

1 The right to carry out confiscation does not expire by the death of the condemned.

2 The measure referred to in Article 8 b lapses by the death of the condemned.

Article 14

The implementation of an order for the payment of costs, other than that of publication of the judgment made on the manner of implementation exhilarating conviction to a fine, provided that is applied no substitute

	<p>imprisonment.</p> <p>Article 15 [repealed on 01-09-1976]</p>
Poland	<p>Art. 88. The manufacturer or importer or installer that the market or puts into service nonconforming product requirements, is subject to a fine of up to 100 000 zł.</p> <p>Art. 89. The manufacturer or importer or installer that the market or puts into service the product under CE marking, and in the case of measuring instruments also additional labelling or distributor who provides the market a product without this marking is subject to a fine of up to 20 000 zł.</p> <p>Art. 90. 1. The manufacturer or the installer of the product on the market or put into use, which does not comply obligations attaching to the product prepared in a clear, understandable and comprehensible form, in Polish:</p> <ol style="list-style-type: none"> 1) instruction or 2) information regarding the safety or 3) a copy of the declaration of conformity or label <p>- Subject to a fine of up to 10 000 zł.</p> <p>2. The manufacturer or installer of the product on the market or put into use, which does not fulfil the obligations in relation to the attachment to the product:</p> <ol style="list-style-type: none"> 1) information enabling their identification, made in Polish or 2) information allowing identification of the product <p>- Subject to a fine of up to 10 000 zł.</p> <p>Art. 91. The importer of the product on the market or put into use, which does not fulfil the obligations in terms of:</p> <ol style="list-style-type: none"> 1) ensure that attach to a product made in a clear, understandable and comprehensible form, in Polish: <ol style="list-style-type: none"> a) instructions or b) information regarding the safety or c) the label, or 2) ensure that attach to the product information to enable identification of the

	<p>product or</p> <p>3) placed on the product information that will enable him to be identified, prepared in Polish or</p> <p>4) ensure connection to the product, if applicable, a copy of the declaration of conformity and other documents</p> <p>- Subject to a fine of up to 10 000 zł.</p> <p>Art. 92. The manufacturer or installer that fails to prepare and keep the technical documentation product, the declaration of compliance and documentation necessary to demonstrate the conformity of the product, be fined up to 10 000 zł.</p> <p>Art. 93. The importer who fails to store a copy of the declaration of conformity or the obligation to ensure share market supervisory authority of the technical documentation shall be subject to a fine of up to 10 000 zł.</p> <p>Art. 94. An authorized representative who does not fulfil the obligations in respect of:</p> <p>1) keep the technical documentation, declaration of conformity and documentation necessary to demonstrate compliance or</p> <p>2) granting authority to the market surveillance information and documentation in Polish to show product compliance with the requirements of</p> <p>- Subject to a fine of up to 10 000 zł.</p> <p>Art. 95. The operator and entrepreneur who is a user of the product, which prevents or hinders authority to carry out market surveillance checks referred to in Article. 64 paragraph. 1, Art. 82 paragraph. 4 or art. 84 para. 8, subject to a fine of up to 30 000 zł.</p> <p>Art. 96. Controlled who:</p> <p>1) destroy the control sample, or</p> <p>2) remove it from the security, or</p> <p>3) prevents the examination of this sample, or</p> <p>4) keep it in breach of the conditions laid down in Article. 72 paragraph. 4</p> <p>- Subject to a fine of up to 30 000 zł.</p> <p>Art. 97. 1. Fines referred to in Article. 88-94, impose, by decision, the market</p>
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	<p>surveillance authority lead the procedure referred to in Article. 76 paragraph. 1 or art. 85 paragraph. 1.</p> <p>2. The fines referred to in Article. 95 and Art. 96, impose, by decision, the market surveillance authority lead control and, in the case of checks by market surveillance authority referred to in Article. 58 paragraph. 2, point 2, district labour inspector.</p> <p>3. When determining the amount of fines, the market surveillance authority shall take into account in particular:</p> <ol style="list-style-type: none"> 1) the degree and circumstances of the breach of the Act; 2) the number of non-conforming with the requirements placed on the market, put into use or made available on the market; 3) prior violation of the law; 4) cooperation with the regulatory authority conducting an investigation, referred to in art. 76 paragraph. 1 or art. 85 paragraph. 1 in particular to contribute to the rapid and efficient conduct of the proceedings. <p>4. The market surveillance authority withdraws from imposing a financial penalty if the trader, punishable,</p> <p>He presented evidence of the execution of the provisions referred to in Article. 82 paragraph. 1.</p> <p>Art. 98. 1. The deadline for payment of the penalty payment is 30 days from the day when the decision becomes final.</p> <p>2. The fine shall be paid into the bank account market surveillance authority, which it imposed.</p> <p>3. Do not initiated proceedings on the imposition of a fine, if the date of the offense, which referred to in Article. 88-96, 3 years have elapsed from the end of the year in which the act was committed.</p> <p>4. Financial penalties shall not be collected after 3 years from the date of the final decision to impose a penalty.</p> <p>5. Funds from fines shall constitute the revenue of the state budget.</p> <p>6. fines, not covered in the law, the provisions of Section III of the Act of 29 August 1997. - Tax Ordinance.</p> <p>7. Fines are subject to execution under the provisions on administrative enforcement proceedings in the field execution of financial obligations</p>
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Portugal	<p>1 - It is punishable administrative offense, to a fine from € 1,850 to € 3,740 if the offender is a natural person and € 5,550 to € 44,890 if the offender is legal person:</p> <ul style="list-style-type: none"> a) Violation of the age limit for availability, provided for in paragraphs 1 to 3 of Article 7; b) Breach of the obligations of economic operators provided for in Articles 8, 9, 10, 11, 12, 13, 14 and 15; c) Violation of the requirements for the EU statement compliance provided for in Article 18; d) Violation of the rules and conditions for affixing CE marking and other markings provided for in Article 20; e) Violation of the rules pertaining to subsidiaries and subcontractors of notified bodies, provided in Article 26; f) Breach of the proper discharge of official duties of the notified bodies referred to in Article 27; g) Violation of the obligation of bodies notified under paragraph 1 of Article 28; h) Violation of rules for the accreditation of people with expertise and available beyond established limits, provided for in specific regulations. <p>2 - The use of pyrotechnic articles violation the provisions contained in the respective labels or technical standard governing such use, particularly on the location, use or failure the minimum distances required security, is administrative offense punishable with a fine of:</p> <ul style="list-style-type: none"> a) From € 125 to € 875, in the case of fireworks F1 category; b) € 250 to € 1,750, in the case of category F2; c) € 500 to € 3,500, in the case of category F3; d) From € 1,500 to € 3,740, in the case of F4 category; e) € 250 to € 1,750, in the case of articles Pyrotechnics T1 category; f) € 1500-3740, in the case of articles Pyrotechnics T2 category; category P1; h) From € 1,500 to € 3,740, in the case of articles Pyrotechnics category P2. <p>3 - If a more severe penalty does not punish such violations, possession,</p>
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	<p>transport and storage of pyrotechnic articles in breach of the provisions contained in regulations to this ordinance, it is administrative offense punishable by a fine of:</p> <ul style="list-style-type: none"> a) From € 125 to € 875, in the case of fireworks F1 category; b) € 250 to € 1,750, in the case of category F2; c) € 500 to € 3,500, in the case of category F3; d) From € 1,500 to € 3,740, in the case of the F4 category; e) € 250 to € 1,750, in the case of articles Pyrotechnics T1 category; f) From € 250 to € 1,750, in the case of articles Pyrotechnics category P1. <p>4 - At offenses provided for in Article 19 apply –If provisions of Article 6 of the Decree-Law No. 23/2011, February 11, implementing the national legal system</p> <p>Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008.</p> <p>5 - Negligence is punishable, and the minimum limits and maximum fines halved.</p> <p>6 - The attempt is punishable by the fine for administrative offense consummated, mitigated.</p>
Romania	<p>(1) In as follows:</p> <ul style="list-style-type: none"> a) non-compliance with art. 10 para. (1), Art. 20, art. 22 and art. 57; b) Violation of art. 16; c) Violation of art. 24, art. 25, art. 26, art. 27 para. (1), Art. 28; d) Violation of art. 39-47; e) Violation of art. 49-52; f) Violation of art. 59; g) Violation of art. 62-65; h) Violation of art. 29 para. (1), Art. 30; i) non-compliance with art. 54-55.

	<p>(2) The provisions of par. (1) shall be sanctioned as follows:</p> <p>a) those referred to a) with a fine of 8.000 to 10.000 lei, withdrawal from the market and prohibit the making available on the market;</p> <p>b) those in point b) a fine from 2,000 lei to 3,000 lei and confiscation of pyrotechnic articles;</p> <p>c) those in point c), f) and g), a fine of 4,000 lei 8,000 lei and prohibition to provide marketing or marketing;</p> <p>d) those referred to d), h), i), with a fine of 2,000 lei 4,000 lei and prohibition to provide marketing or marketing;</p> <p>e) those in point e) with a fine from 500 lei to 1,000 lei and prohibition to make available on the market of pyrotechnic articles without marking of conformity or incorrect marking.</p> <p>(3) The contraventions and penalties are as follows:</p> <p>a) by the authorized staff of the Labour Inspection, for the offenses referred to in para. (1) a) and c) -i);</p> <p>b) the officers and agents of the Romanian Police, for offenses in para. (1) b).</p>
Slovakia	<p>The supervisory authority, the manufacturer, importer or distributor fine for breach of the obligations set in this Government Regulation under special regulations. (§ 32 of Act no. 264/1999 Coll. § 24 Act no. 250/2007 Coll. consumer protection and the amendment of the Slovak National Council. 372/1990 Coll. on offenses as amended, as amended.)</p> <p>§ 32 of Act no. 264/1999 - Fines</p> <p>(1) The surveillance body shall inflict a fine of up to a 5 000 000. - Slovak Crowns (SKK) on anyone who:</p> <p>a) has used the conformity mark or certificate or declaration of conformity illegally or deceptively,</p> <p>b) has placed on the market or distributed determined product without declaration of conformity under § 10 sub-paragraph 4, without certificate of conformity or without the prescribed marking of products with the Slovak conformity mark under § 17 sub-paragraph 3, or has placed the product on the market without authority.</p> <p>c) has failed to comply with the decision on protective measure.</p>

(2) The Office shall, based on an initiative from outside or on its own findings, inflict a fine of up to 1 000 000. - Slovak Crowns on anyone who without authority:

- a) has used on the document the denomination "STN",
- b) has duplicated or distributed a Slovak technical standard,
- c) has declared himself as an authorised body,
- d) has issued a certificate.

(3) The Ministry of Economy shall, based on an initiative or on its own findings, inflict a fine of up to 1 000. - Slovak Crowns on anyone who has declared himself without authority as an accreditation body or an body for which accreditation certificate has been issued, or failed to return the accreditation certificate (§ 27 sub-paragraph 5).

(4) In case of repeated unlawful action there can be inflicted a fine under sub-paragraphs 1 -3 up to the double of inflicted fine.

(5) In the process of the infliction of fines there shall be taken into account the price of the product, seriousness, way, duration and consequences of the unlawful action.

(6) The fine may be inflicted within one year from the date the body authorised for infliction of fines has learned about the breach of duty, but not later than three years from the date on which such breach of duty has occurred.

(7) The fine shall be payable within 30 days from the date of maturity of the decision on the infliction of the fine.

(8) The money received from fines is the income of the state budget.

§23 act no. 250/2007

Offences

(1) Anyone who harms consumer rights by having acted in breach of this Act or separate consumer protection regulations²⁶⁾ is deemed to have committed an offence.

(2) A fine up to the amount of SKK 10,000 may be imposed for the offence referred to in paragraph 1.

(3) A general regulation on offences shall apply to offences under this Act and related proceedings.²⁷⁾

(4) Revenues from the fines imposed by a municipal authority for committed

	<p>offences constitute revenues of the municipal budget.</p> <p>§24 act no. 250/2007</p> <p>Sanctions</p> <p>(1) Where the obligations laid down in this Act or in European Community consumer protection laws²⁸) are breached, the supervisory authority shall fine the producer, trader, importer or supplier or the person referred to in §26 up to SKK2,000,000; where the breach recurs within 12 months the authority shall impose a fine up to SKK5,000,000.</p> <p>(2) The supervisory authority shall impose a fine up to SKK10,000,000 upon the producer, trader, importer, supplier or the person referred to in §26 who had produced, sold, imported or supplied a product whose defect caused damage to life or health. The identical fine shall be imposed upon anyone who caused such damage by defective delivery of a service. The fine may not be imposed upon persons who demonstrate that they could not have avoided such damage despite having exerted all effort which could reasonably be expected.</p> <p>(3) A disciplinary fine up to SKK50,000 shall be imposed by the supervisory authority upon the producer, trader, importer and supplier or the person referred to in §26 who mars, thwarts or otherwise hinders the performance of supervisory activities or who, as the case might be, fails to meet the binding instruction referred to in §20(3)(h); the fine may be imposed repeatedly.</p> <p>(4) The fine referred to in paragraph 1 shall not be imposed where a fine under a separate regulation was imposed, or if the fine referred to in paragraph 2 may be imposed.</p> <p>(5) When determining the amount of the fine, an account shall be taken of the nature of the unlawful conduct, gravity of the breach of an obligation and the method and consequences of the breach.</p> <p>(6) Revenues from the fines imposed pursuant to paragraph 1 through 3 constitute revenues of the state budget.</p> <p>(7) The fine may be imposed within one year from the day when the supervisory authority ascertained the breach of an obligation under this Act, however no later than within three years for fines set out in paragraphs 1 and 3 and, for fines set out in paragraph 3, no later than within ten years from the day on which such breach occurred.</p>
Slovenia	<p>8. PENALTY PROVISIONS</p> <p>Article 46</p> <p>(1) A fine of 5,000 to 50,000 euros shall be imposed on a legal person:</p>

	<ol style="list-style-type: none"> 1. In performing transport explosives or pyrotechnic articles as well as the implementation of fireworks does not ensure the security of persons and property, fire protection, and does not carry out any other measures specified in the regulations issued under this Act (first paragraph of Article 6); 2. carry out the production or transport explosives or pyrotechnic articles without the permission of the Ministry or the competent authority (the first paragraph of Article 9); 3. to change the activity does not obtain a new license (fourth paragraph of Article 9); 4. manufactured, sold or stored explosives or pyrotechnic articles in premises which are not properly constructed or equipped or not secured against access by unauthorized persons (first and third paragraphs of Article 14); 5. preparing explosives on site without specialized equipment or permission of the Ministry (Article 16); 6. allow the explosives destroys a person who is not qualified (first paragraph of Article 19); 7. In case of destruction of explosives, acts contrary to the manufacturer's instructions or destroys explosives in places where this is not allowed in the destruction of not ensuring the safety not destroys or unstable explosive individually (Article 19); 8. research for the development of new types of explosives does not provide the technical and safety measures (first paragraph of Article 20); 9. act contrary to the obligations of the manufacturer, importer or distributor (20a, Article 20.b and 20.c); 10 placed explosives or pyrotechnic articles which do not have the CE marking or has incorrectly CE-marked or do not meet safety requirements (first paragraph of Article 21); 11 placed explosives or pyrotechnic pre-notification ministry or the ministry before it issues a certificate of notification (second paragraph of Article 21); 12 on the market, download or use of explosives that are not in original packaging or it does not contain all the prescribed data (Article 23); 13 in the market of pyrotechnic articles that are not properly labelled or label does not contain all the prescribed data (Article 24); 14. purchases or transfers of explosives or pyrotechnic articles without the appropriate permit (first paragraph of Article 26);
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	<p>15. The use of explosives in contradiction with the purposes or in other places, as set out in the authorization for the purchase and transfer (first paragraph of Article 28);</p> <p>16 in the implementation of fireworks is not implemented security measures listed in the study or carry fireworks without a study (second paragraph of Article 28);</p> <p>17 performs transmission to the European Union, import, export or transit of explosives or pyrotechnic articles or ammunition without the permission of the ministry or does not comply with specific safety measures specified in the license (first and third paragraphs of Article 31);</p> <p>18 types of pyrotechnic articles not in the appropriate category depending on the purpose level of hazard and the level of noise (Article 33);</p> <p>19. enable the purchase of pyrotechnic articles in categories F3, F4, P2 and T2 to a person who does not have the appropriate license or purchase batteries from category F3 to 1000 g net weight of explosive substances and fountains from category F3 to 750 g net weight of explosives in a single physical product a person who is not yet 18 years old or selling fireworks of category F2 and F3, where an explosion (third and fifth paragraphs of Article 35);</p> <p>20 individuals selling other pyrotechnic articles of category P1 for vehicles, including airbags and belt tensioners, unless they are mounted on the vehicle or detachable part of the vehicle (eighth paragraph of Article 35);</p> <p>21. Despite the order of the inspector of the withdrawal or recall of an explosive or pyrotechnic product continues to allow its availability on the market (Article 37.a and 37.b);</p> <p>22. Despite the order of the inspector makes an explosive or pyrotechnic product on the market, which represents a risk to the health or safety of persons or property or the environment (Article 37.c).</p> <p>(2) A fine of EUR 2,000 to EUR 20,000 shall be imposed on an entrepreneur who commits an offense referred to in the preceding paragraph.</p> <p>(3) A fine of 400 to 4,000 euros for an offense from the first paragraph of this Article shall be imposed on the responsible person of the legal entity or entrepreneur.</p> <p>(4) For the offenses referred to in Articles 1, 2, 4, 5, 7, 8, 9, 10, 11, 13, 14, 15 and 16 of the first paragraph of this Article imposed a side sanction the withdrawal of explosives or fireworks. Side sanction shall be imposed even if the products are not owned by the perpetrator.</p> <p>Article 47</p>
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	<p>(1) A fine of 3,000 to 15,000 euros shall be imposed on a legal person:</p> <ol style="list-style-type: none"> 1. does not prepare a management plan in case of accident or other incident (the second paragraph of Article 6); 2. fails to inform people that it engaged in individual work with explosives or pyrotechnic articles with the measures laid down in the general rules and specific plan (third paragraph of Article 6); 3. the loss or theft of explosives or pyrotechnic not informed immediately or within 12 hours of the nearest police station (sixth paragraph of Article 6); 4. do not take into account the additional permit conditions (second paragraph of Article 9); 5. Within eight days does not inform the competent authority or the ministry of the status change, the change in the responsible person or the cessation of activities (third paragraph of Article 9); 6. authorized to carry out the production or transport explosives or pyrotechnic articles a person who does not satisfy the personal conditions (Article 10); 7. not immediately return unused explosives or returned to the seller refuses to accept explosives (fourth paragraph of Article 19); 8. exhibits at fairs or exhibitions or presentations perform for the marketing of pyrotechnic products, which are not adequately labelled or carry out a presentation for marketing without the permission of the competent authority (third and fourth paragraphs of Article 24); 9. Within eight days after the expiration does not return the permission to purchase and transfer of explosives or pyrotechnic products in the Republic of Slovenia (second paragraph of Article 26); 10 not ensure that the authorization for the purchase and transfer of explosives or pyrotechnic products in the Republic of Slovenia during the transport in addition to explosives or pyrotechnic articles (third paragraph of Article 26); 11 sold gunpowder, primers or tubes with primers person who has a valid arms license and a certificate for charging ammunition for its own purposes or sell the black powder to a person who is not authorized by the competent authority (Article 30); 12 not ensure that the authorization for the transfer, import, export or transit throughout transport in addition to explosives, pyrotechnic articles or ammunition (fourth paragraph of Article 31); 13. does not consider age limits for selling pyrotechnic articles (first paragraph
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	<p>of Article 35);</p> <p>14 sell fireworks F1 category, where an explosion outside the allowable time (sixth paragraph of Article 35);</p> <p>15. does not keep prescribed records are not kept in the prescribed manner, information is not held by the prescribed time does not allow access, inspect and search the data or not allow access to the records outside normal working hours (Article 45);</p> <p>16. The placing on the market of pyrotechnic articles which have been withdrawn consent to the instructions for the safe use or pyrotechnic articles, which have a temporary certificate of notification or within the prescribed period is not harmonized indications of pyrotechnic articles which are intended for sale or sold within this period contrary to Article 35 (Article 51).</p> <p>(2) A fine of 1,000 to 3,000 euros shall be imposed on an entrepreneur who commits an offense referred to in the preceding paragraph.</p> <p>(3) A fine of 400 to 1,500 euros for an offense from the first paragraph of this Article shall be imposed on the responsible person of the legal entity or entrepreneur.</p> <p>Article 48</p> <p>(1) A fine of 400 to 1,200 shall be imposed on an individual or natural person who:</p> <ol style="list-style-type: none"> 1. carry out individual work with explosives or pyrotechnic articles or carry fireworks and the work is not carried out measures for each type of work set out in this Act and regulations issued pursuant to this Law (paragraph 4 of Article 6); 2. is engaged in research for the development of new types of explosives or experimenting with making the already known types of explosives (second paragraph of Article 20); 3. The driver on the officer's request does not indicate authorization for the purchase and transfer of explosives or pyrotechnic articles (third paragraph of Article 26); 4. possession of gunpowder, primers or tubes with primers without a valid arms license and a certificate for charging ammunition for their own use or possession of black powder without the permission of the competent authority (Article 30); 5. driver to a police officer or request does not indicate transfer license in the European Union, import, export or transit (fourth paragraph of Article 31);
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	<p>6. sale, purchase, possession or use of fireworks which are intended only for legal persons or entrepreneurs who have the appropriate license or fireworks of category F2 and F3, where an explosion, or be permitted to use the battery from category F3 to 1000 g net mass of explosive substances and fountains from category F3 to 750 g net weight of explosives in a single product a natural person who is not yet 18 years old (third and fifth paragraphs of Article 35);</p> <p>7. uses fireworks F1 category, where an explosion in places where their use is prohibited or used outside of the allowed time (seventh paragraph of Article 35);</p> <p>8. The sale, possession or use other pyrotechnic articles of category P1 for vehicles, including airbags and belt tensioners, unless they are mounted on the vehicle or detachable part of the vehicle (eighth paragraph of Article 35);</p> <p>9. uses fireworks as opposed to the manufacturer's instructions and do not take into account the general prohibition (ninth and tenth paragraphs of Article 35).</p> <p>(2) For the offenses referred to in Articles 2, 4, 6, 7, 8 and 9 of the preceding paragraph shall be taken as secondary sanction of deprivation of explosives, pyrotechnic articles and parts of ammunition. Side sanction shall be imposed even if the products are not owned by the perpetrator.</p> <p>Article 49</p> <p>(Responsibility for deciding on minor offenses)</p> <p>(1) In deciding on minor offenses from 46, 47 and 48 of this Act is responsible inspectorate. To decide on the offenses referred to in Articles 13, 14 and 16 of the first paragraph of Article 46, 3, 8, 10 and 11 of the first paragraph of Article 47 and the offenses referred to in Article 48 of this Law is also in charge of the police. To decide on the offenses referred to in point 16 of Article 46 and 11 of Article 47 of this Law is also in charge of the customs service. To decide on the offenses referred to in Articles 1, 2, 3 and 4 of Article 46 and 1, 2, 3, 4 and 5 of Article 47 of this Law is also responsible trade inspectorate.</p> <p>(2) The authorities referred to in the preceding paragraph may impose fines for offenses under criminal provisions within the range prescribed by this Act.</p>
Spain	<p>Article 195. Minor offenses.</p> <p>The following behaviours are considered minor offenses:</p> <ol style="list-style-type: none"> 1. The omission or failure in security measures for the custody of the documents relating to regulated materials, when leading to their loss or theft. 2. The omission of the duty to report to the Weapons and Explosives loss or

	<p>theft of documents relating to controlled substances.</p> <p>3. The omission of the obligation to submit to the Administration the parties and other documents relating to the matters covered in the fields of industrial or public safety.</p> <p>4. The omission of data communications is required to refer to the Administration, relating to the matters covered in the fields of industrial or public safety.</p> <p>5. Irregularities in completing the required books and records relating to controlled substances.</p> <p>6. Disobedience and / or lack of consideration of the mandates of the competent authority or its agents provided they comply with current regulations in the course of the mission legally entrusted with respect to the regulated materials.</p> <p>7. All those behaviours which, although not qualified as very serious or serious violations constitute breaches of obligations or requirements or violation of the prohibitions contained in this regulation and its complementary technical instructions, the Organic Law 4/2015, of 30 March protection of public safety, the Law 21/1992 of 16 July, of Industry, or other special laws.</p> <p>8. Failure to comply with the requirements for associates Administration and notified in the field of industrial safety agencies</p> <p>Article 196. Grave breaches.</p> <p>The following behaviours are considered serious offenses:</p> <p>1. The manufacture, storage, sale, distribution, purchase or sale, possession or use of controlled substances, in violation of applicable regulations, lacking the documentation and the necessary authorizations or who exceeds the authorized limits.</p> <p>2. The manufacture, storage, sale, distribution and use of controlled substances, in greater quantity than authorized.</p> <p>3. The omission or failure in the adoption or effectiveness of the measures or mandatory public safety precautions in the manufacture, storage, distribution, circulation, trade, possession or use of regulated materials.</p> <p>4. The omission or failure in the adoption or effectiveness of industrial safety measures in the manufacture, storage, possession or use of controlled substances, when involving danger or serious damage to people, flora, fauna, property or the environment.</p>
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	<p>5. The movement or transport of controlled materials, without meeting the requirements for documentation, or public safety measures regarding industrial safety measures when, in the latter case, such failure behave danger or harm to persons , flora, fauna, property or the environment.</p> <p>6. The claim or provision of false information or circumstances to justify unauthorized commercial transactions or obtain authorizations or documentation relating to controlled substances.</p> <p>7. The refusal of access to the competent authorities or their agents or hindering the exercise of inspections or regulatory controls in workshops, transportation, warehouses and other facilities relating to regulated materials.</p> <p>8. The resistance or impedance to provide the information required by the government, when there were legal or regulatory obligation to respond to such a request for information.</p> <p>9. The start or performance of any activity relating to matters governed without proper authorization.</p> <p>10. The opening or operation of any establishment, or the start or performance of any activity relating to matters regulated without adopting mandatory security measures, or when they are insufficient.</p> <p>11. The lack of books or records that are required with respect to regulated materials.</p> <p>12. The use of any other marking that may lead to confusion with the CE marking to pyrotechnic articles.</p> <p>13. Repeated failure to comply with the requirements set for associates Administration and notified in the field of industrial safety agencies.</p> <p>Article 197. Very serious offenses.</p> <p>The following behaviours are considered very serious infringements:</p> <p>1. The acts described in paragraphs 1 and 4 of the previous article, if, as a result of them very serious damage is caused.</p> <p>2. The acts described in paragraphs 3 and 5 of the previous article, if, as a result of which the loss or theft of controlled substances occurs.</p> <p>3. The illicit use of CE marking, when the same result a serious injury or a serious and imminent danger to people, flora, fauna, property or the environment arises.</p> <p>4. The improper execution by the notified of the actions entrusted body and continue to certify once the withdrawal notification when such conduct is a</p>
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serious injury or a serious and imminent danger to persons arising, flora, fauna, property or the environment.

5. Failure to comply with the requirements for notified bodies, when the same result a serious injury or a serious and imminent danger for people, flora, fauna, property or the environment arises.

Article 198. Inspection and sanctions.

1. Inspection.

a) For the development of the inspection function, Functional Areas of Industry and Energy of delegations or sub-delegations of Government, may establish mechanisms for collaboration with bodies or authorities with competence and responsibilities in the workplace as well as in the fields public security and safety.

b) Staff Functional Area Industry and Energy to perform the inspection task has in the exercise of their functions the character of public authority.

c) The inspection activity was documented by minutes that will be equipped with presumption of certainty regarding the facts reflected in them that have been found by the inspector, notwithstanding evidence to the contrary. In the case of inspections workshops and warehouses of finished products ready content model will be adjusted in the ITC number 24.

2. Penalties.

a) The conduct classified as minor breaches in paragraphs 1, 2, 5, and 6 of Article 195 shall be punished with fine from 100 euros to 600 euros. The conduct described as a minor offense in paragraph 8 of Article 195 shall be punished by a fine of up to 3,005.06 euros. The acts described as minor offenses in paragraphs 3, 4, and 7 of Article 195 shall be punished with fine from 100 euros to 600 euros or up to 3,005.06 euros as they relate to issues of public safety or industrial safety respectively.

b) The acts described as grave breaches in paragraphs 1, 2, 3, 6, 11 and 12 of Article 196 shall be punished with fine from 601 euros to 30,000 euros. The acts described as grave breaches in paragraphs 4 and 13 of Article 196 shall be punished with fine from EUR 3,005.07 to 90,151.81 euros. The acts described as grave breaches in paragraphs 5, 7, 8, 9 and 10 of Article 196 shall be punished with fine from 601 euros to 30,000 euros or a fine from EUR 3,005.07 to 90,151.81 euros as they relate to aspects of citizen or industrial, security respectively.

Moreover, the acts described in paragraphs 1, 2 and 12 of Article 196 shall be punished with the seizure of all the seized material or any material that excess

<p>amount, if any, of the authorized amount.</p> <p>In turn, the conduct described in paragraph 13 of Article 196 shall also be punished with the temporary withdrawal of the authorization of up to one year.</p> <p>The conduct described in paragraph 1 of Article 196 shall entail, where appropriate, closure of the establishment where the offense occurs for a period not exceeding six months.</p> <p>The acts described in paragraphs 3 and 10 of Article 196 entail the closure of the establishment where the infringement occurred until such security measures are established or existing anomalies are corrected.</p> <p>c) The conduct classified as very serious infringements in paragraph 3 of Article 197 shall be punished with fine from 30,001 euros to 600,000 euros. Behaviours classified as very serious infringements in paragraphs 4 and 5 of Article 197 shall be punished with fine from 90,151.82 to 601,012.10 euros. Behaviours classified as very serious infringements in paragraphs 1 and 2 of Article 197 shall be punished with fine from 30,001 euros to 600,000 euros or a fine from 90,151.82 to 601,012.10 euros as they relate to issues of public safety or security Industrial respectively.</p> <p>On the other hand, the conduct described in paragraph 1 of Article 197 shall be punished, where appropriate, with the closure of the establishment where the infringement for a period of six months and one day to two years to occur.</p> <p>Similarly, the conduct described in paragraph 2 of Article 197 shall be punished, where appropriate, with the closure of the establishment where the offense or carrier occurs for a period of six months and one day to two years, provided that the amount stolen or lost, the mode or subtraction authors cause alarm.</p> <p>In turn, the conduct described in paragraph 3 of Article 197 shall be punished, where appropriate, with the seizure of equipment.</p> <p>The conduct described in paragraph 5 of Article 197 shall also be punished, where appropriate, with the suspension of activity or closure of the establishment for a maximum period of five years.</p> <p>d) To determine the amount and graduation of sanctions and basis of the principle of proportionality, the following circumstances are taken into account:</p> <ul style="list-style-type: none">i. The importance of damage or deterioration caused.ii. The degree of participation and benefit gained.iii. The economic capacity of the offender.
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	<p>iv. The intent in the commission of the offense.</p> <p>v. The intent, guilt and recidivism.</p> <p>e) The material seized will be destroyed if its use constituted a safety hazard. The sanctioning body shall, in any event, determine the final destination to be given to the seized material.</p> <p>The expenses resulting from intervention operations, storage, transportation and destruction shall be to the infringer.</p> <p>Article 199. Prescription of offenses.</p> <p>1. The administrative offenses referred to in the preceding articles relating to public safety aspects expire after six months, a year or two years if committed, as are mild, serious or very serious, respectively.</p> <p>2. The administrative offenses referred to in the preceding articles relating to industrial safety aspects prescribed a year, three years or five years if committed, as are mild, serious or very serious, respectively.</p> <p>Article 200. Prescription of sanctions.</p> <p>1. Penalties imposed for offenses relating to public safety issues classified as very serious lapse after three years, those imposed for serious violations after two years, and those imposed for minor infractions per year, calculated from the day following one in which becomes final in administrative resolution for which the penalty is imposed.</p> <p>Interrupt prescription initiation, with knowledge of the subject, the execution procedure, returning to the period of time if it is paralyzed for more than a month for reasons not attributable to the offender cause.</p> <p>2. The penalties prescribed a year, three years or five years, depending on the respective infringements relating to industrial safety aspects have been classified as minor, serious or very serious, respectively, calculated from the day following that that becomes final in administrative resolution for which the penalty is imposed.</p>
Sweden	<p>Liquidated damages and the threat of performance: The supervisory authority may attach to a prohibition or injunction as issued under this law with a fine or with the threat that the neglected measure is carried out at the defaulter's expense.</p> <p>Penalty provisions: Provisions on penalties for breaches of explosives found in Chapter 44. § 11 of the Criminal Code. Anyone who wilfully or negligently violates the obligation under § 5 of this Act, the manufacturer's obligation under § 7-12, the importer's obligations under § 13, the distributor's obligations under § 14 or a prohibition or injunction issued pursuant to § 42-44</p>

	shall, unless more severe penalty is provided elsewhere in the law, for violation of the provisions of pyrotechnics sentenced to a fine.
United Kingdom	<p>1) A person guilty of an offence under regulation 62 in respect of a category F1 firework, a category F2 firework, or a category F3 firework is liable on summary conviction—</p> <p>(a) in England and Wales, to a fine or imprisonment for a term not exceeding 3 months or to both;</p> <p>(b) in Scotland or Northern Ireland, to a fine not exceeding level 5 on the standard scale or imprisonment for a term not exceeding 3 months or to both.</p> <p>(2) A person guilty of an offence under regulation 62 in respect of a pyrotechnic article to which paragraph (1) does not apply is liable—</p> <p>(a) on summary conviction—</p> <p>(i) in England and Wales, to a fine or imprisonment for a term not exceeding 3 months or to both;</p> <p>(ii) in Scotland or Northern Ireland, to a fine not exceeding the statutory maximum or imprisonment for a term not exceeding 3 months or to both;</p> <p>(b) on conviction on indictment, to a fine or imprisonment for a term not exceeding 2 years or to both.</p>

3.17. Case study on application of sanctions in the toys sector

Case Study: *An informal inquiry in the field of toys safety showed that 26 Member States as well as Iceland and Norway reported to have the possibility of imposing economic sanctions. 24 Member States, Iceland and Norway reported to also have the possibility of imposing other than economic sanctions. In particular:*

1. *Economic sanctions – BG, BE, CZ, DK, EE, IE, EL, ES, FR, HR, IT, CY, LV, LT, LU, MT, NL, AT, PL, PT, RO, SI, SK, FI, SE, UK, IS, NO*
2. *Imprisonment – EE, IE, EL, IT, CY, LV, LU, MT, NL, SI, UK, IS, NO*
3. *Seizure or destruction of the product – BG, CZ, DK, EE, IE, EL, ES, FR, HR, IT, CY, LV, LU, NL, AT, PT, RO, FI, SE, UK, IS, NO*
4. *Publication of the fines imposed or of the judgment – BE, IE, EL, ES, CY, NL, AT, SK, UK, IS*
5. *Temporary or permanent disqualification from the practice of industrial or commercial activities, including stopping production – BE, ES, FR, HR, LV, LU, MT, NL, AT, RO, SE, IS*

6. *Others: Measures on the product (withdrawal) BE, BG, EL, FR, FI + Community service: LV*

However despite this apparently broad range of available tools an analysis of overall sanctions (voluntary corrective action, compulsory restrictive measures, penalties) actually imposed in the toys sector between 2010 and 2013 shows that following inspections with finding of non-compliance on average the EU authorities were able to impose some sanction in two-thirds of cases at most, as illustrated by the following table.²⁴⁰

Table 13-3: Follow up to inspections in the toys sector: percentage of cases of non-compliance where measures and/or penalties were applied in the 2010-2013 period

BE	n.a.
BG	37
CZ	37
DK	68
DE	n.a.
EE	100
IE	100
EL	52
ES	n.a.
FR	29
HR	n.a.
IT	n.a.
CY	46
LV	86
LT	n.a.
LU	71
HU	98

²⁴⁰ This average is based on data provided by 17 Member States. Notably, it excludes Germany, Spain, Lithuania and the Netherlands for which no information on investigations in the toys sectors is provided. It also excludes the UK, Belgium, Poland, Slovenia, Croatia, Italy and Austria whose data are incomplete or contained inconsistencies so that the share of self-initiated investigations could not be calculated. The average probably overestimates the number of inspections with a follow-up, as in some case both corrective action and sanctions were imposed in a given inspection, so the figures worked out by the Commission involve some double counting.

MT	52
NL	n.a.
AT	n.a.
PL	n.a.
PT	75
RO	100
SI	n.a.
SK	14
FI	69
SE	36
UK	n.a.