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IMPACT ASSESSMENT

Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation

Main report

Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products

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1. WHAT IS THE PROBLEM AND WHY IS IT A PROBLEM?

1.1. Introduction

In this impact assessment the potential impacts of secondary legislation *(implementing and delegated acts)*, required by Regulations (EC) No 1107/2009[1] and Regulation (EU) No 528/2012[2], are evaluated. Under these regulations, there is a legal obligation for the European Commission to set specific scientific criteria to identify substances which have endocrine disrupting properties, hereafter called "endocrine disruptors" (EDs). In particular under the Biocidal Products (BP) Regulation the Commission should adopt a delegated act as regards the criteria by December 2013. The Court judgement on the Case T-521/14 (December 2015) states that the European Commission breached EU law by failing to set criteria to identify endocrine disruptors under the BP Regulation within the legal deadline.

The impact assessment is considered important to take a sound decision based on science and evidence, in particular because the EU legislation was the first worldwide to introduce regulatory consequences on EDs and there is also no precedent of setting scientific criteria to identify EDs in a regulatory context. Recent developments have taken place outside of a regulatory context (e.g. World Health Organization[3;4;5;6] (WHO), and Organisation for Economic Co-Operation and Development[7] (OECD)), or in a context of substance prioritisation for further assessment and risk management (e.g. US EPA Endocrine Disruptor Screening Programme[8]).

The regulatory consequences for the substances identified as EDs are already defined in the regulations mentioned above with respect to plant protection or biocidal products. Active substances which are identified as ED shall not be approved (they are not allowed on the EU market) unless specific "derogations" could be applied. These derogations have a wider scope under the BP Regulation in comparison to the PPP Regulation, adding a layer of complexity to the analysis of the evidence regarding potential impacts.

Because of the regulatory consequences mentioned above (the non-approval of active substances or restricted approval if derogations apply), impacts are expected once the criteria are applied. These impacts may be on human health, environment, sectorial competiveness including agriculture, and trade. They are expected to be higher under the PPP Regulation than under the BP Regulation because of the different scope of the derogations. This was confirmed in the public consultation where respondents expressed diverging views on the expected impacts and on their different preferred options (see more details in Annex 2 and Section 5.2 of this main report).

[1] 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. OJ L 309.

[2] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. Official Journal of the European Union, L 167, 27 June 2012. doi:10.3000/19770677.L_2012.167.eng

[3] WHO/UNEP. 2012. State of the science of endocrine disrupting chemical. An assessment of the state of the science of endocrine disruptors prepared by a group of experts for the United Nations Environment Programme (UNEP).

[4] WHO 2014. Identification of risks from exposure to EDCs at the country level. Retrieved from: http://www.euro.who.int/en/publications/abstracts/identification-of-risks-from-exposure-to-endocrine-disrupting-chemicals-at-the-country-level

[5] WHO. 2015. Identification of risks of EDCs: overview of existing practices and steps ahead. Report of a meeting in Bonn, Germany 7-8 July 2014

[6] WHO/UNEP 2015 Strategic Approach to International Chemicals Management (SAICM). International Conference on Chemicals Management fourth Session. SAICM/ICCM.4/9. Emerging policy issues and other issues of concern.

[7] OECD Work Related to Endocrine Disrupters. Retrieved from: http://www.oecd.org/env/ehs/testing/oecdworkrelatedtoendocrinedisrupters.htm

[8] United States Environmental Protection Agency (EPA). Endocrine Disruptor Screening Program (EDSP) Overview. Retrieved from: http://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-edsp-overview

This impact assessment is not concluding on any preferred option for setting scientific criteria to identify endocrine disruptors, but aims at providing additional information to decision makers on the potential implications of these different options under the PPP and BP Regulations. The impact assessment is focused on PPP and BP and not directly related to other EU legislative acts, because only the PPP and BP require by law to set criteria to identify EDs. However, setting the criteria to identify EDs may have potential implications on other legislations which contain specific provisions on EDs (REACH, Cosmetics, and Water Framework Directive)[9].

1.2. Endocrine disruptors, background and general regulatory context

EDs are chemicals which can interfere with the endocrine (hormone) systems[10] in animals and humans. Both synthetic as well as naturally-occurring chemicals are known to have endocrine disrupting properties. For instance, it has been found that bisphenol F forms during mustard production from a natural ingredient of mustard grains[11,12] at high concentrations which may pose a risk to specific groups of the human population.[13] Exposure to synthetic chemicals can occur from different sources, e.g. from residues of plant protection products or biocidal products, but also from consumer products or articles used in daily life.

Knowledge about the potential toxicity of chemicals, including which chemicals may induce certain adverse effects, is available since long time and is already reflected in the EU legislation on chemicals (since the 90'ies for PPP and BP). Compared to this, endocrine disruption is a relatively recent way of looking at the toxicity of chemicals, where first scientific discussions started in the 1990s.[14] Endocrine disruption aims to understand the mode of action, i.e. *how* exposure to chemicals leads to the adverse effects observed.

Although the focus on EDs is recent in a regulatory context, many of the adverse effects which may be caused by EDs (e.g. carcinogenicity or reproductive effects) have already been studied and regulated for many years in the EU chemical's legislation, without detailed knowledge of the potential endocrine mode of action. This resulted in a reduction in general terms of the exposure of humans and the environment to the number of chemicals and to an increase of protection of humans and the environment. In Section 1.3 more details on the regulatory context are given.

Focusing on the EU, in 1999 the European Commission's Scientific Committee for Toxicity, Ecotoxicity and the Environment (CSTEE) stated that EDs posed a 'potential global problem

[9] REACH (Regulation (EC) 1907/2006), Cosmetics (Regulation (EC) 1223/2009), Water Framework Directive (Directive 2000/60/EC),

[10] The endocrine system is the system in the body which produces hormones to provide an internal communication system between cells located in distant parts of the body. Retrieved from: http://www.yourhormones.info/, Society of Endocrinology, UK

[11] Swiss Federal Department of Home Affairs FDHA. Federal Food Safety and Veterinary Office FSVO. Risk Assessment. Bisphenol F in mustard. Retrieved from: http://www.efsa.europa.eu/sites/default/files/assets/af150611a-ax11.6.pdf

[12] Zoller, O. et al. 2016. Natural occurrence of bisphenol F in mustard, Food Additives & Contaminants: Part A, 33:1, 137-146, DOI: 10.1080/19440049.2015.1110623

[13] Higashihara N, et al. 2007. Subacute oral toxicity study of bisphenol F based on the draft protocol for the "Enhanced OECD Test Guideline no. 407". Arch Toxicol. Dec;81(12):825-32. Epub 2007 Jul 13. Retrieved from: http://www.ncbi.nlm.nih.gov/pubmed/17628788

[14] "The Impact of Endocrine Disruptors on Human Health and Wildlife" workshop, Weybridge (UK), 2 to 4 December 1996. The workshop was supported by European Commission, European Environment Agency, WHO European Centre for Environment and Health, OECD, national authorities and agencies of the UK, Germany, Sweden and The Netherlands, CEFIC and ECETOC.

for wildlife'[15] and subsequently the Community Strategy for EDs[16] was adopted. Since then, different *specific* provisions on EDs have been included in various pieces of EU legislation[17] with the aim of being able to take regulatory decisions based on more detailed knowledge.

Although these provisions on EDs are in force, agreed scientific criteria for identifying EDs *in a regulatory context* are so far lacking, internationally or at EU level. In the context of the PPP and BP Regulations the European Commission has the legal obligation to establish scientific criteria to identify substances with endocrine disrupting properties by December 2013. Further, both the Council of the European Union and the European Parliament have addressed EDs at several occasions during the last years. In particular, in 2000[18] and 2013[19] the European Parliament adopted Resolutions on EDs. In 2000, the Environment Council adopted Conclusions[20] on EDs.

1.2.1. Scientific developments which are relevant in the EU regulatory context

In 2002 the WHO/International Programme for Chemical Safety (WHO/IPCS) defined an ED as: "*an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations"*. This definition serves as a basis for the options developed for this impact assessment because it reached wide consensus among scientists.

Several relevant scientific reports relevant in the EU regulatory context have been published during the last years by EU agencies, EU Scientific Committees, or in the context of activities co-ordinated or commissioned by the European Commission, indicating the advancement of the scientific discussion on some concepts. In particular:

- In 2010 the European Food Safety Authority (EFSA) published a scientific report[21] which provides an overview of existing knowledge on endocrine active substances and of the challenges for risk assessment in relation to food and feed, as well as a summary of current initiatives at national, EU and international levels.[5]
- The report "State of the Art Assessment of Endocrine Disruptors"[22] commissioned by the European Commission summarises advances in the state of the science from 2002 to 2011

[15] European Commission's Scientific Committee for Toxicity, Ecotoxicity and the Environment (CSTEE) Opinion on Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with Emphasis on Wildlife and on Ecotoxicology Test Methods: March 1999. Available at: http://ec.europa.eu/health/ph_risk/committees/sct/documents/out37_en.pdf

[16] Communication from the Commission to the Council and the European Parliament - Community strategy for endocrine disruptors - A range of substances suspected of interfering with the hormone systems of humans and wildlife /* COM/99/0706 final */

[17] Provisions were added into the Water Framework Directive (Directive 2000/60/EC), the chemicals regulation REACH (Regulation (EC) 1907/2006), the Plant Protection Products Regulation (EC) 1107/2009, the Biocidal Products Regulation (EU) 528/2012, and the Regulations on Cosmetics (Regulation (EC) 1223/2009). Provisions were also included in the Proposal for a regulation on medical devices (amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009).

[18] European Parliament resolution on the Commission communication to the Council and the European Parliament on a Community strategy for endocrine disruptors - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM(1999) 706 - C5-0107/2000 - 2000/2071(COS))

[19] European Parliament resolution of 14 March 2013 on the protection of public health from endocrine disrupters (2012/2066(INI))

[20] Council conclusions (Environment) on endocrine disrupters. Brussels, 30 March 2000. Retrieved from: http://www.consilium.europa.eu/en/uedocs/cms_data/docs/pressdata/en/envir/07352.en0.html#_Toc480100459

[21] European Food Safety Authority; EFSA scientific report of the Endocrine Active Substances Task Force. EFSA Journal 2010; 8(11):1932. [59 pp.] doi:10.2903/j.efsa.2010.1932.

[22] Kortenkamp, Martin, Faust, Evans, McKinlay, Orton, Rosivatz. 2011. State of the art assessment of endocrine disruptors. Final Report, Project Contract Number 070307/2009/550687/SER/D3. Retrieved from: http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf

and maps ways of addressing EDs in important pieces of EU chemicals legislation (e.g. PPP Regulation, BP Regulation, REACH).

- In 2013, two reports published by the Joint Research Centre (JRC) summarise the work of the "Endocrine Disruptors Expert Advisory Group".[23,24] The reports indicate that the experts agreed that existing standardised assays are mainly available only for the estrogenic, androgenic, thyroid and steroidogenic modalities (EATS), and that test guidelines are lacking for birds and invertebrates. Agreement was not reached on some elements, e.g. the role of hazard characterisation (potency, severity, lead toxicity, irreversibility) when identifying EDs, whether a threshold approach should be followed in the evaluation of EDs, regarding the evidence for low-dose effects and the relevance of non-monotonic dose-response curves.
- Also in 2013, EFSA published a "Scientific Opinion on the Hazard Assessment of Endocrine Disruptors".[25] The EFSA opinion supports the WHO/IPCS definition for EDs and a case-by-case risk assessment approach to assess EDs for regulatory decision making. Further, EFSA clarifies that issues regarding mixtures, critical windows of susceptibility and non-monotonic dose-response curves were general issues applicable to all chemicals (and not specific to EDs).
- Further, the Scientific Committee on Consumer Safety (SCCS) issued a "Memorandum on EDs",[26] in 2014, in which it supports the EFSA Opinion with respect of the use of risk assessment to assess EDs for decision making.
- A recent external scientific report of EFSA [27] (2016) evaluated the evidence for the non-monotonic dose-response (NMDR) hypothesis for substances in the area of food safety. The plausibility of NMDRs was assessed based on a systematic review methodology, which identified over 10'000 potentially relevant scientific studies. From these studies, 142 studies could be selected for the evaluation (49 in-vivo, 91 in-vitro, and 2 epidemiological studies). The report indicates that the empirical evidence for NMDR was limited or weak for most in vivo datasets that were selected for substances in the area of food safety. The report also indicates that *evaluation regarding the biological meaning (e.g. dose range studies, adversity of the effects, and toxicity at high doses leading to NMDR) and relevance for risk assessment were not part of this data analysis*, thus questioning the relevance of the evidence for the adverse effects.

Further, at the occasion of an expert conference organised by the German Federal Institute for Risk Assessment (BfR), held in Berlin in April 2016, a consensus statement on "Scientific principles for the identification of endocrine disrupting chemicals"[28] was signed by 20 internationally renowned scientists present at the conference. This document has been made available via the website of BfR recently, however it has not yet been published in a scientific

[23] Munn S., Goumenou M-P., Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances - Report of the Endocrine Disrupters Expert Advisory Group (ED EAG). JRC-IHCP 2013. [29 pp.]DOI: 10.2788/8659 (online). Retrieved from: http://publications.jrc.ec.europa.eu/repository/bitstream/JRC79981/lbna25919enn.pdf

[24] Munn S., Goumenou M-P., Thresholds for Endocrine Disrupters and Related Uncertainties Report of the Endocrine Disrupters Expert Advisory Group (ED EAG). JRC-IHCP 2013. [19 pp.]DOI: 10.2788/8659 (online). Retrieved from: http://publications.jrc.ec.europa.eu/repository/bitstream/JRC83204/lb-na-26-068-en-n.pdf

[25] EFSA Scientific Committee; Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132. [84 pp.] doi: 10.2903/j.efsa.2013.3132.

[26] Scientific Committee on Consumer Safety (SCCS) Memorandum on Endocrine Disruptors. 2014. SCCS/1544/14. Retrieved from: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_009.pdf

[27] Beausoleil et al, 2016. Review of non-monotonic dose-responses of substances for human risk assessment. EFSA supporting publication 2016:EN-1027. 290pp.

[28] International Expert Meeting on Endocrine Disruptors (Berlin, April 2016). Available at: http://www.bfr.bund.de/en/international_expert_meeting_on_endocrine_disruptors-197246.html

peer reviewed journal. Among others, the document lists the criteria for identifying the hazard potential of harmful endocrine substances. It also indicates that the assessment of the corresponding risks from EDs on human health and wildlife would require consideration of dose-response relationships, including potency, exposure assessment, and risk characterization, including susceptible sub-populations, severity and reversibility of effects. See for more details Box 1, which quotes from the consensus paper.

Box 1. Scientific principles for the identification of endocrine disrupting chemicals – a consensus statement - Outcome of an international expert meeting organized by the German Federal Institute for Risk Assessment (BfR). (Solecki, R.; Kortenkamp, A.; Bergman, Å.; et al. 2016.; in press)

"…

Scientific foundations of regulatory decision-making

19. The various relevant pieces of EU chemicals regulation require both hazard and risk assessment approaches to enable decision making to be applied in different ways.*

20. The identification of a compound as an endocrine disruptor is a hazard identification procedure. Established principles governing disruption of the programming function of hormones mean that hazard identification for endocrine disruption has to take account of the timing of exposure relative to life stage and that transient indices or effects should not necessarily be considered adverse.

21. We recognize that certain adverse outcomes appearing to arise from endocrine disruption can also occur through non-endocrine modes of action. Moreover, adverse effects or modes of action consistent with endocrine disrupting characteristics but demonstrated to be non-specific effects secondary to another toxic effect are not considered appropriate for identification of endocrine disruption. The identification of a chemical as an endocrine disruptor therefore has to rely on weight-of-evidence evaluations of both adversity and mode of action together. We agree that endocrine activity on its own should not trigger a chemical's identification as an endocrine disruptor.

22. We agree that a chemical's potency to induce an adverse effect is an important factor for consideration during the characterization of the hazards of endocrine disruptors. However, potency is not relevant for identification of a compound as an endocrine disruptor. However, there may be high doses (e.g. the oral toxicity limit of 1000 mg/kg body weight/day) above which identification as an ED would not be warranted.

23. Criteria for identifying chemicals as endocrine disruptors would need be accompanied by the implementation of relevant test systems in EU regulations. We note that many relevant OECD guidelines exist which have not yet been consistently integrated into the regulatory frameworks. There is lack of validated tests for a number of modes of actions. We recommend that respective EU directives, regulations and other relevant guidance are updated to incorporate validated and internationally agreed test systems for endocrine disruptors. In this context, guidance and scientific advice need to be up-dated to indicate how the outcome of those tests should be evaluated in the regulatory context, and to include endocrine pathways and adverse health effects that are insufficiently explored by current toxicological testing.

24. This document has focused on the identification of endocrine disruptors. However, the assessment of the corresponding risks on human health and wildlife would further require consideration of dose-response relationships, including potency, exposure assessment, and risk characterization, including susceptible sub-populations, severity and reversibility of effects. This emphasizes the importance of the "One Substance – One Toxicological Assessment" philosophy, and has implications for data generation of both regulated and unregulated chemicals.

** The WHO IPCS definitions for the four steps in risk assessment: hazard identification, hazard characterization, exposure assessment and risk characterization, have been used throughout this document.*

…"

In summary, the available relevant reports indicate that:

- There is consensus on the WHO/IPCS definition (2002) for identifying ED
- There are different endocrine modes of actions. Four modalities (pathways) are relatively well known and internationally agreed tests exist (the estrogen, androgen, thyroid and steroidogen modalities). There are other modalities which are not yet well known and for which no internationally agreed tests exist. For these modalities, still under discussion, science is under development and there is no consensus on the extent of evidence (e.g. diabetes) available.
- There is no consensus on the relevance of some scientific aspects for regulatory decision making (e.g. non-monotonic dose response curve, low dose effects and existence of safety thresholds for EDs), but a recent EU review on the empirical evidence and the BfR consensus statement mentioned above indicate that the evidence for this kind of curves is weak for most in vivo data.
- There is consensus that the assessment of potential risks from ED on human health and the environment would require consideration of dose-response relationships, exposure assessment, and risk characterisation (risk assessment).

1.3. Regulatory context of Plant Protection Products (PPP) and Biocidal Products (BP)

A 'pesticide' prevents, destroys, or controls a harmful organism ('pest') or disease. This expression covers plant protection products and biocidal products.

Plant protection products (PPP) protect crops as well as desirable or useful plants. They are used in agriculture, forestry, horticulture, industrial areas (e.g. railways), amenity areas and in gardens.

Biocidal products (BP) control unwanted organisms that are harmful to human or animal health, or that cause damage to human activities. BP include products such as insecticides, insect repellents, disinfectants, preservatives for materials and anti-fouling paints for the protection of ship hulls.

Both PPP and BP are formulated products (e.g. liquid concentrates, wettable powder, granules) that contain at least one active substance that is responsible for the effect of the PPP or BP, which could be a chemical, a plant extract, a pheromone or a micro-organism (including viruses).

In the EU, both PPP and BP have been regulated since the 1990s via Regulation (EC) No 1107/2009 (replacing Directive 91/414/EC) and Regulation (EU) No 528/2012 (replacing Directive 98/8/EC) with the objective of ensuring a high level of protection of human health and the environment, strengthening the functioning of the internal market, and for the PPP Regulation improving agricultural production.

As a consequence of the strict legislation in place since the 1990s, a significant number (about 60%) of active substances used in PPP have been taken off the market or have had their use restricted. This resulted in a reduction in general terms of the exposure of humans and the environment to the number of chemicals used in PPP . A recent study on the "Calculation of the Benefits of Chemical Legislation on Human Health and the Environment", commissioned by the European Commission[29], concluded that, as a consequence of the EU legislative

[29] RPA et al (2015): Study on the Calculation of the Benefits of Chemical Legislation on Human Health and the Environment, Final report for DG Environment, March 2016, London, Norfolk, UK.

measures taken over the last years, the exposure to certain substances known to have adverse effects on human health and the environment was reduced.

Both the PPP and BP regulations are based on pre-market approval ("positive list") and shift the responsibility for producing scientific evidence (burden of proof) to the industry[30]. Only PPP and BP which contain active substances placed on a "positive list" (via an EU approval process) can be used in PPP or BP in the EU (via authorisation processes at national level), provided the respective uses have been considered not to cause adverse effects on human or animal health or unacceptable effects to the environment. In other words, under the PPP and BP Regulations, no use of a substance – whether the mode of action of the substance is known or not – is authorised in the EU if an unacceptable risk of causing adverse effects to human health or the environment is identified. Further, approvals of active substances and authorisations of PPP or BP are granted only for a limited number of years, after which the approvals need to be renewed following similar processes as for the 1st approvals.

The two-step pre-market approval system described above (active substances approval at EU level, product authorisation at national level) is considered as one of the strictest worldwide. The Regulations (and their preceding Directives) also specify comprehensive data requirements[31;32] which have to be addressed and fulfilled before any approval of active substance or authorisation of a product can be considered. The data requirements list the experimental studies according to international agreed guidelines which need to be performed, and which results need to be submitted as part of the application dossiers, and already cover studies relevant for EDs. This implies that both PPP and BP are among the most "data rich" regulated product groups in the EU.

Besides assessment of toxicological properties of the substance with respect to human health and environment, traces of residues of PPP which may be found on the crop are also considered in the assessment done before any approval or authorisation can be granted. The levels of residues are assessed and maximum residue levels[33] (MRL) are established under Regulation (EC) No 396/2005.[34] MRLs must be respected in commodities produced in the EU or imported into the EU, in order to ensure consumers' safety. In addition, Regulation (EC) No 396/2005 provides that the Community's trading partners should be consulted via the WTO about the MRLs proposed. MRLs set at the international level by the Codex Alimentarius Commission should also be considered when Community MRLs are being set, taking into account the corresponding good agricultural practices.

1.3.1. Provisions on endocrine active substances under the PPP and BP Regulation

Both Regulation (EC) No 1107/2009 and Regulation (EU) No 528/2012 have introduced, compared to the previous legislation, specific hazard-based provisions (often referred to as

[30] These are elements of the precautionary principle, see Communication from the Commission on the precautionary principle, COM(2000) 1 final. Retrieved from: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52000DC0001

[31] Regulations EU 283/2013 and EU 284/2013, setting data requirements for active substances and for PPP, respectively; Communications 2013/C 95/01 and 2013/C 95/02, detailing the list of test methods and guidance documents for active substances and for PPP, respectively.

[32] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. Official Journal of the European Union, L 167, 27 June 2012. doi:10.3000/19770677.L_2012.167.eng

[33] An MRL is the upper legally allowed concentration for a residue in food or feed, based on good agricultural practice and protection of vulnerable consumers.

[34] Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC OJ L 70, 16.3.2005, p. 1

“cut-off criteria") for certain hazardous classes of substances (e.g. mutagens, carcinogens). These provisions include substances identified as EDs, under both pieces of legislation, EDs are not approved unless certain derogations apply. These derogations have a wider scope under the BP Regulation in comparison with the PPP Regulation: while under the PPP Regulation the derogations are mainly hazard based, under the BP Regulation the derogations have a stronger risk component and include also socio-economic provisions (see Figure 1 and a more detailed description under Section 1.5).

In cases of approval of active substances under application of these derogations, special conditions apply: the substances are approved as "candidates for substitution". This implies shorter approval periods and the obligation for Member States (MS) to consider safer alternatives when authorising PPP or BP (comparative assessment). In addition, under both Regulations, if a substance is not identified as ED, it will still undergo a full risk assessment. This risk assessment is similar to the one in place in the previous legislations which focused on potential adverse effects irrespectively of the mode of action which causes this adverse effect. In other words, the ED provisions in the PPP and BP Regulations currently act as a "switch (with respect to adverse effects potentially linked to EDs)" which either leads to a non-approval of the active substances identified as ED (subject to derogations), or to a "standard" risk assessment which would cover any potential adverse effect and if appropriate lead to non-approval or restrictions of use of the active substance (this "standard" risk assessment is carried out in any case as all potential adverse effects are assessed). Most of the adverse effects which may be caused by EDs (e.g. carcinogenicity or reproductive effects) are already regulated since many years, without detailed knowledge of their mode of action. For instance, many of the PPP and BP often cited as EDs (atrazine, DDT, lindane, dieldrin, triphenyltin, tributyltin, etc.) have already been banned since years in the EU, as a consequence of the EU regulatory system (see more details in Annex 9 on human health – hormone related diseases).

As the difference between hazard and risk plays an important role in this impact assessment, it needs to be briefly explained: hazard is anything that can cause harm, whereas risk is the potential that a hazard will cause harm. In other words a hazard will not pose any risk unless exposure to that hazard is high enough so that it may cause harm. Risks associated with hazards can be zero, or at least greatly reduced, by reducing exposure. For instance, a knife – a hazardous object per se - would be banned completely if the decision is taken based on hazard, while it would be allowed for certain uses or restricted (e.g. not allowed for small children) if the decision is taken based on risk. Similarly, a substance (e.g. a drug or a pesticide active substance) is banned if the regulatory decision is based on its hazard, while it is allowed for certain uses, under certain (restricted) conditions and doses, if the decision is taken based on risk.

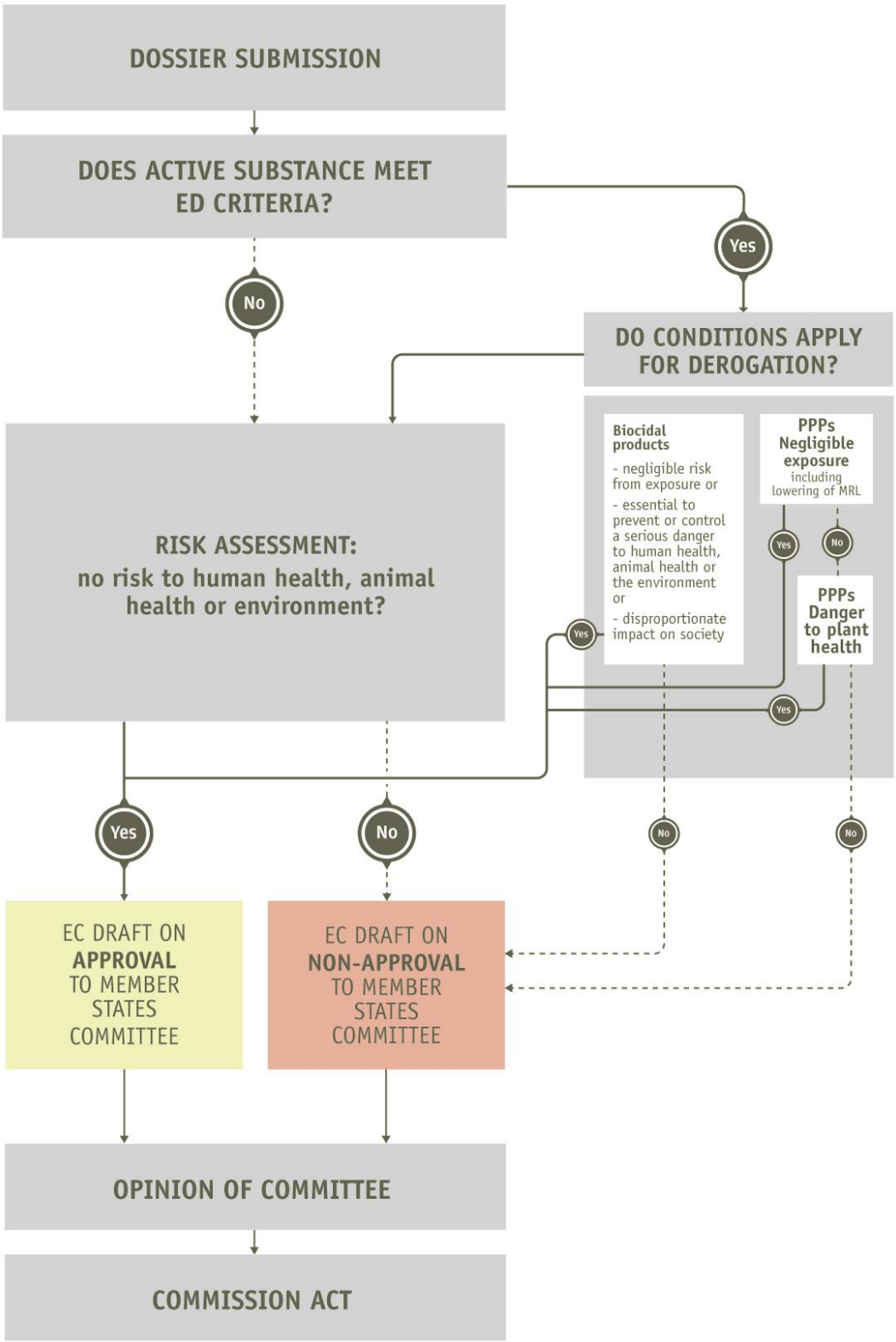


Figure 1: Regulatory decision making in the PPP and BP Regulations, under consideration of derogations for active substances identified as EDs

1.4. Problem identification

1.4.1. Problem definition: Absence of scientific criteria to identify EDs under the PPP and BP legislation – the interim criteria in place are not able to correctly identify EDs according to the latest scientific developments.

Regulation (EC) No 1107/2009 and Regulation (EU) No 528/2012 both lack scientific criteria to identify EDs, which are needed in order to be able to correctly implement the provisions set in the Regulations concerning these kind of substances (Annex II, Section 3.6.5 of the PPP Regulation and Article 5.2 of the BP Regulation).

Both legislations set a legal obligation for the European Commission to establish scientific criteria by December 2013. Until these legal obligations are fulfilled, both Regulations have set the *same* interim criteria to identify EDs.

These interim criteria are not based on the latest scientific developments on endocrine disruption, but they are based on classification of substances that are suspected of being carcinogenic and/or suspected of being toxic to reproduction (C2 and/or R2 according to Regulation (EC) No 1272/2008[35]). They are able to identify some substances with ED properties but may miss some other ED substances ("false negatives"[36]) or identify some substances as having endocrine disrupting properties which are not EDs ("false positives"[37]).

In order to protect human health and the environment, it is important to set scientific criteria which are able to identify EDs correctly. For the same reasons, the criteria should be the same for both Regulations. A harmonised definition is also important because it would enhance greater coherence between the regulatory frameworks as some chemical substances are regulated under both Regulations, since they can be used either in PPP or BP. Further, any potential endocrine disrupting property of a chemical substance does not depend on its use, but is an inherent characteristic of the substance.

The legal obligation to define criteria is only set under the PPP and BP Regulations. However, it is expected that the new criteria may also influence other EU regulatory areas, where so far no criteria for EDs have been set or requested. In light of the legal obligations, this impact assessment focusses on the PPP and BP Regulations only.

1.4.2. Affected parties

Once the criteria to identify EDs are set, they will be applied subsequently to the approvals (or the renewals of approvals) of active substances falling under the PPP and BP Regulations. This is expected to affect – directly and indirectly - society because PPP and BP are used in many ways and play an important role in some economic sectors.

The impacts on society are thus driven by the regulatory consequences for the substances which are identified as EDs which are already set under the PPP and BP Regulations. In both cases, these substances shall not be approved unless some specific conditions ("derogations") apply. The derogations and how they are implemented differ between the PPP and BP Regulations (see Figure 1 and Section 1.5 for more details). While the derogations under the BP Regulation consider negligible risk and a wider scope of socio/economic considerations,

[35] 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

[36] False negative: test result that is incorrect because the test failed to recognise an existing condition or finding. Retrieved from http://www.dictionary.com/browse/false--negative?s=t

[37] False positive: a test result that is incorrect because the test indicated a condition or finding that does not exist. Retrieved from http://www.dictionary.com/browse/false--positive?s=t

under the PPP Regulation the derogations are mainly based on hazard (negligible exposure and almost zero exposure via food by lowering the MRLs[38] to the limit of determination) and limited socio-economic considerations (serious danger to plant health). Consequently the impacts under the PPP Regulation are expected to be higher compared to the BP Regulation.

In addition, the regulatory consequences set in both the PPP and BP Regulations must be consistent with provisions of international law, such as customary international law and treaties ratified by the EU.

The establishment of criteria under the PPP and BP Regulations, following this impact assessment, may have repercussions on other EU-chemical legislation. The BP Regulation can be taken as an illustration of what would happen for sectors where derogations taking into account risk and/or socio economic considerations apply, whereas the PPP Regulation can be taken as an illustration of what would happen for sectors where the decision making is mainly based on hazard.

As a consequence of the regulatory context described above, the health of the general population, consumers, and workers exposed to EDs (e.g. professional users) may be affected directly or via the quality of the environment or the safety of the food. However, there may also be indirect impacts for consumers in terms of variation in availability or costs for certain products including agricultural commodities.

Economic operators affected may be manufacturers, importers, exporters, traders, industries marketing chemical substances and downstream industries. In particular food chain operators (for instance those using disinfectants), health care facilities, small and medium sized enterprises and professional users like farmers producing plant or animal products are all expected to be affected. Parties may be affected to different extents depending on the type of products they produce and use and the geographical location of their activity.

MS and third countries may be affected via international trade through the lowering of the MRLs for food and feed to the default value (limit of determination, i.e. analytical zero) for substances identified as EDs, which have to be applied for EU production but also for imports. International trade is also expected to be impacted via imports of articles, because articles treated with active substances not approved in the EU for BP cannot be imported into the EU. The operability for implementing the criteria may also have an impact on national administrations because of inter alia, shorter approval periods and more complex assessments when applying the derogations.

Since the criteria that the European Commission will present under the PPP and BP Regulations may have repercussions on other EU legislation containing specific provisions governing EDs (e.g. REACH, the Water Framework Directive, the Cosmetics products legislation), parties may also be affected indirectly via these pieces of legislation.

1.5. Underlying drivers

The ***absence of scientific criteria to identify EDs*** in Regulations (EC) No 1107/2009 and (EU) No 528/2012 is a consequence of the fact that when these Regulations were drafted, the co-legislators felt that it was too early to set scientific criteria in a regulatory context and instead requested the European Commission to set them by December 2013.

[38] The levels of residues are assessed and maximum residue levels (MRL) are established under Regulation (EC) No 396/2005[38]. An MRL is the upper legally allowed concentration for a residue in food or feed, based on good agricultural practice and protection of vulnerable consumers. MRLs must be respected in commodities produced in the EU or imported into the EU, in order to ensure consumers' safety.

The interim criteria currently applicable under these Regulations may fail to identify some EDs because: 1) they only refer to certain adverse effects for human health (carcinogenicity and toxicity for reproduction) and do not consider wildlife species and 2) they do not consider the endocrine mode of action of substances. For these reasons, they may identify "false negatives" and "false positives".

The scientific criteria to identify EDs are set in a regulatory context (PPP and BP Regulations), which plays a significant role in determining the impacts of the criteria on the approval of active substances and on society in general. Thus, the ***regulatory consequences for substances identified as EDs*** are identified as an additional driver which adds complexity to the analysis of the impacts.

The regulatory consequences for substances identified as EDs are different between the PPP and BP Regulations. In both cases, substances identified as EDs shall not be approved unless some specific conditions ("derogations") apply. However, these derogations differ in their scope and possibilities of implementation (see Annex II, Section 3.6.5 and Article 4.7 of the PPP Regulation and Article 5 of the BP Regulation for details). This implies that substances identified as EDs will be subject to one of the following regulatory consequences:

- a non-approval of the active substance (BP for general public, most cases for PPP)
- approvals limited to situations where negligible exposure is assessed on a case by case basis (some PPP cases)
- approvals limited to negligible risk assessed on a case by case basis (BP professional uses)
- approvals limited to socio/economic considerations (PPP to fight a serious danger to plant health; BP professional uses when a substance is needed to prevent or control serious dangers to human health, animal health or the environment or measures would lead to disproportionate negative effects on society).

The derogations in the PPP and BP Regulations differ in their scope (exposure vs. risk because of exposure respectively, and socio-economic considerations vs. danger to plant health respectively), but also if they apply sequentially or are assessed in an integrated way, leading to differences in the implementation (see Figure 1 for more details). These differences have consequences for the approval of substances, and hence to the availability of PPP or BP, which is then expected to impact several sectors.

The regulatory consequences in the PPP and BP Regulations also differ with respect to the allowed residues. While in the PPP legislation residues (MRLs) of substances identified as EDs will be lowered to the analytical zero, the BP Regulation foresees that a treated article shall not be placed on the EU market unless all active substances contained in the biocidal products that it was treated with or incorporates are approved. These provisions are applicable to commodities and products produced in the EU but also to those imported from non-EU countries. As a consequence the provisions may also have impacts on international trade with consequences for the internal market.

1.6. Evaluations

Neither the PPP nor the BP Regulations, adopted in 2009 and 2012 respectively have so far been subject to an ex-post evaluation. However, preparations for the evaluation of Regulation

(EC) No 1107/2009 have started under the REFIT[39] programme. Regulation (EC) No 1107/2009 in its Article 82 provides for the issuance of a report which should cover, inter alia, the application of the criteria for approval as set out in Annex II (which includes the provisions on EDs) and their impacts on agriculture, human health, and environment.

2. WHY SHOULD THE EU ACT?

Defining scientific criteria for the identification of EDs is a legal obligation for the European Commission, set out in the PPP and BP Regulations, which were both adopted through the ordinary legislative procedure. The endocrine properties of an active substance to be used in PPP and BP need to be assessed for its approval. Since this approval process is done at EU level, EU action is needed for setting the criteria.

Scientific criteria to identify substances which have endocrine disrupting properties are expected to contribute to a more informed regulatory decision making which considers current scientific knowledge. This implies a regulatory decision making which considers in addition to the adverse effects (WHAT question) also the endocrine mode of action (HOW question). Knowledge on the endocrine mode of action is relatively recent and it may further accumulate in the future.

Setting *harmonised* criteria under the PPP and BP legislation will ensure a consistent level of protection of human health and the environment. A coherent approach with respect to EDs under the PPP and BP legislation will also allow legal coherence and certainty, as well as regulatory consistency and predictability. This is in particular important as some chemical substances (currently around 38 substances[40], considering only the biocides already assessed under the review programme) fall under both pieces of legislations.

3. WHAT OBJECTIVES SHOULD BE ACHIEVED?

Scientific criteria to identify EDs need to be presented in order to fulfil legal obligations set in the PPP and BP Regulations, with the aim of maintaining the high level of protection of human health and the environment and to provide consistency in these levels of protection across both sets of legislation.

The general objectives within the Treaty guide the present impact assessment, as they are the legal basis for both the PPP and BP Regulations:

- ensuring a high level of protection to human health, animal health and the environment;
- strengthening the functioning of the internal market.

For the PPP Regulation the two objectives mentioned above should be considered while improving agricultural production (see Article 1 of Regulation (EC) No 1107/2009).

The compliance with international obligations, notably under the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) agreements under the World Trade Organisation are also important considerations.

[39] Annex II: REFIT Initiatives. Annex to Commission Work Programme 2016; No time for business as usual. Retrieved from: http://ec.europa.eu/atwork/pdf/cwp_2016_annex_ii_en.pdf

[40] Some examples are benzoic acid, bifenthrin, bromadiolone, capric acid, clothianidin, copper hydroxide, cypermethrin, cyproconazole, dazomet, deltamethrin

The following specific objectives for PPP and BP Regulations have also been considered:

- providing for legal clarity, predictability and coherence in the identification of EDs;
- providing for scientific criteria that are operational in terms of regulatory decision-making;
- offering possibility to apply these criteria across the PPP and BP Regulations.

4. WHAT ARE THE OPTIONS TO ACHIEVE THE OBJECTIVES?

As explained in previous sections, the European Commission is legally required to establish scientific criteria to identify substances with endocrine disrupting properties in the context of the PPP and BP Regulations. Four options, including the current baseline (interim criteria), have been developed. The four options are based on hazard, and consider scientific knowledge.

The regulatory consequences (i.e. implementation) of the scientific criteria to identify EDs are already set under the PPP and BP Regulations and are driving the potential impacts of the criteria (see Sections 1 for more details). The regulatory consequences differ in terms of scope and implementation, adding complexity to the impact assessment. In order to address this complexity, a 2nd set of options was developed and presented in the roadmap. Consequently, two separate sets of options were considered along two aspects:

- Aspect I: setting scientific criteria to identify EDs based on hazard under the PPP and BP Regulations;
- Aspect II: implementation of the ED criteria / approach to regulatory decision making.

The options for each aspect are described below and analysed separately. These analyses are not aimed at concluding on any preferred option for setting scientific criteria to identify endocrine disruptors, but at providing additional information to decision makers on the potential implications of these different options under the PPP and BP Regulations.

4.1. Aspect I: Setting scientific criteria to identify EDs based on hazard under the PPP and BP Regulations

All the options considered under this aspect (with exception of the baseline) are based on hazard and on the WHO/IPCS definition, for which there is a wide scientific consensus. They have been all presented in the Roadmap and are representing different views of Member States and stakeholders. These views are explained in the sub-sections below.

4.1.1. Option 1: No policy change (baseline).

No scientific criteria are specified and the interim criteria set in the PPP and BP Regulations continue to apply. The interim criteria are based on classification of substances: suspected of being carcinogenic and/or suspected of being toxic to reproduction (C2 and/or R2 according to Regulation (EC) No 1272/2008[41], respectively).

[41] 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

The majority of the respondents to the public consultation that was carried out in the context of the impact assessment did not support Option 1 as it may fail to identify the correct EDs. There is scientific consensus that the interim criteria set in the PPP and BP Regulations are not correctly identifying EDs because they are unable to detect an ED mode of action. The interim criteria may detect "false positives" (the interim criteria identify EDs even when no ED mode of action is present) and "false negatives" (substances which have ED mode of action which cause potential adverse effects are not identified by the interim criteria).

4.1.2. Option 2: WHO/IPCS definition to identify EDs

The aim of this option is to identify, based on hazard elements, substances which meet the WHO/IPCS definition (2002). EDs are identified as substances:

a) Which show an adverse effect. An adverse effect is defined according to the definition of WHO/IPCS (2009)[42];

b) and where there is experimental evidence based on international agreed study protocols[43] (*in vivo* studies), possibly supported with other information (e.g. (Q)SAR, analogue and category approaches) that the substance has the capacity to cause endocrine-mediated adverse effects in humans or endocrine-mediated adverse effects relevant at the population level on animal species living in the environment. However:

- This evidence needs to occur in the absence of other toxic effects, or if occurring together with other toxic effects, the endocrine-mediated adverse effects should not be a non-specific secondary consequence of other toxic effects;
- where there is information demonstrating that the effects are clearly not relevant for humans and not relevant at population level to species living in the environment, then the substance should not be considered an ED.

As mentioned before, there is a wide scientific consensus on the WHO/IPCS definition for identifying endocrine disruptors. This was confirmed in the "BfR consensus statement" published on 4 May 2016[44].

However, scientists, MS and stakeholders are divided on whether this definition alone would be the best option in the context of the PPP and BP Regulations.

Some of them (most endocrinologists, some MS, health/environmental/consumers NGOs) consider that this option is the most appropriate as it would correctly identify EDs.

Others (most toxicologists, some MS, industry and third countries) consider that this option would not correctly identify EDs of actual concern under the current PPP Regulation, i.e. would not correctly assess which EDs pose an ***actual risk*** to human health and the environment because the current derogations under the PPP Regulation are mainly hazard

[42] An adverse effect is "*a change in the morphology, physiology, growth, development, reproduction, or, life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences"* (WHO/IPCS (2009)

[43] The EFSA Opinion on EDs indicated that a reasonable complete suite of standardised assays for testing EDs is currently (or will soon be) available only for vertebrate species. See footnote 33 in EFSA Scientific Committee; Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132. [84 pp.] doi: 10.2903/j.efsa.2013.3132.

[44] "Scientific principles for the identification of endocrine disrupting chemicals – a consensus statement Outcome of an international expert meeting organized by the German Federal Institute for Risk Assessment (BfR)" Retrieved from http://www.bfr.bund.de/cm/349/scientific-principles-for-the-identification-of-endocrine-disrupting-chemicals-a-consensus-statement.pdf

based. They believe that many active substances would no longer be approved although they can be used safely, i.e. they would only produce an adverse effect at unrealistic high exposure. They believe that only a subset of the identified EDs should be regulated under the current hazard based "cut-off" criteria set in the PPP, i.e. those substances which produce an adverse effect at realistic doses of exposure. Some of these diverging opinions are also reflected in the public consultation report.

4.1.3. Option 3: WHO/IPCS definition to identify EDs and introduction of additional categories based on the different strength of evidence for fulfilling the WHO/IPCS definition.

The aim of this option is to identify, based on hazard elements, substances which meet the WHO/IPCS definition, and to introduce additional categories based on the strength of the evidence. For the purpose of this impact assessment 3 categories are evaluated, as follows:

- Category I: EDs (as defined in Option 2).
- Category II: Suspected EDs, which means substances where there is some evidence that endocrine-mediated adverse effects can be produced on humans or on populations living in the environment, but where the evidence is not sufficiently strong or convincing enough to place the substance in Category I.
- Category III: Endocrine active substances, which means substances for which there is some *in vitro or in vivo* evidence indicating an interference with the endocrine system (endocrine activity) but without evidence of an adverse effect in intact organisms.

Regulatory consequences are defined in the PPP and BP Regulations for EDs (Category I), while no regulatory consequences are defined in these Regulations for suspected EDs or endocrine active substances (Categories II and III). Therefore, EDs under Option 2 and under Option 3 Category I are identical in terms of substances identified and the impacts related to their regulatory consequences are expected to be the same.

Scientists, MS and stakeholders are divided on whether this option would positively contribute to more efficacy and operability of the criteria. Most endocrinologists, some MS, health/environmental/consumers NGOs are generally in favour of this option considering that:

- the classification system would be consistent with classification under CLP regulation;
- additional categories would bring further clarity and easier classification by assessors;
- downstream users would better plan the substances to use in their products.

Most toxicologists, some MS and industry are generally against this option considering that it would raise confusion on whether all categories should be subject to regulatory consequences, while the uncertainties on taking regulatory action exclusively based on identification of a substance as an ED are already higher than usual. They believe that:

- additional categories with no specific regulatory consequences would reduce clarity and predictability;
- harmonized classification is competence of CLP regulation and not of sectorial legislation;
- additional categories are likely to lead to "blacklisting" of substances which may negatively affect innovation.

Some of these views have also been expressed in the public consultation. The views expressed in the context of Option 2 (see above) need to be also considered.

4.1.4. Option 4: WHO/IPCS definition to identify EDs and inclusion of potency as an element of hazard characterisation.

The aim of this option is to identify, based on hazard elements and in the regulatory context of the PPP and BP Regulations, substances which meet the WHO/IPCS definition and to prioritise the substances of greater concern. A prioritisation of substances is supported by farmers, the chemical industry and some EU MS. Third countries are expected to favour this option with respect to options 1 to 3. Therefore, this option was included in the Roadmap and considered in the impact assessment.

Under the PPP and the BP Regulations, if a substance is identified as an ED it will not be approved unless certain derogations apply. If a substance is not identified as an ED, it will undergo a full risk assessment focused on potential adverse effects and based on comprehensive data requirements (see Figure 1). Under this regulatory context, a prioritisation of substances of greater concern via hazard characterisation may be considered for the substances which would fall under the "hazard cut off criteria" leading to a non-approval of these substances unless derogations apply, while substances not falling under these "cut off criteria" would still be subject to a full risk assessment and only approved if considered not having adverse effects on human health, animal health or the environment. Thus, Option 4 would identify, based on hazard elements, substances which meet the WHO/IPCS definition and which have a stronger potency, being potency one of the elements of hazard characterisation.

Potency is part of hazard characterization and not of hazard identification; however it is neither a full hazard characterisation (hazard characterisation includes e.g. potency, severity, irreversibility) nor a risk assessment (risk assessment is hazard characterisation + exposure assessment). Potency is an inherent characteristic of a chemical substance. It is a scientific measurement (i.e. based on experiments) of the substance's ability to produce an (adverse) effect. In other words, the higher the potency of a substance, the lower the dose needed to produce a certain adverse effect. For instance artificial sweeteners are more potent than sugar to sweeten a cup of tea, since only a few drops are needed instead of a spoon. Another example is cyanide and table salt: both can be toxic but cyanide is far more toxic than salt.

Potency may be considered in several ways. One way would be setting a dose threshold necessary to achieve an adverse effect. For the purpose of this impact assessment potency has been defined as a threshold value based on the STOT-RE Cat 1[45] trigger values from the Regulation (EC) No 1272/2008 (see Section 5).

Considering in particular the regulatory context of the PPP Regulation (i.e. derogations based mainly on hazard) the diverging views of scientists, stakeholders and MS regarding this option are summarized below.

Most endocrinologists, some MS, health/environmental/consumers NGOs believe that:

- potency should not be part of the criteria for identification of EDs because it is part of hazard characterisation;
- considering potency in the criteria to identify EDs might reduce protection of human health and environment because EDs are suspected to produce adverse effects at low doses (i.e. EDs are suspected to act via non-monotonic dose-response curves, i.e. a safety threshold might not be identified for EDs);

[45] Specific Target Organ Toxicity - Repeated Exposure

Most toxicologists, some MS, industry and third countries believe that:

- EDs are chemicals which can be treated like any other chemicals because the available evidence does not confirm the existence of non-monotonic dose-response curves for EDs. This implies that safety thresholds can be set for EDs like for any other chemical and that regulatory decisions can be based on risk considerations.
- if risk considerations cannot be taken into account in the regulatory decision making because derogations are based mainly on hazard, it would be unscientific not to prioritize the most hazardous substances based on scientific information. The consideration of potency would be a scientific way to achieve this prioritisation.

Recent scientific reports[25,46] state that assessment of risks from ED on human health and the environment would require consideration of dose-response relationships (which includes potency considerations), exposure assessment, and risk characterisation.

There is scientific consensus that Option 4 would not identify correctly all EDs, but that potency should be used when assessing risks of EDs on human health and wildlife. Scientists agree that potency should not be considered at the step of hazard identification, but at the step of hazard characterization needed for a risk assessment of ED. This was confirmed in the "BfR consensus statement" published on the BfR website the 4 May 2016[46] (see Box 1 for more details) but has not yet been published in a scientific peer reviewed journal (the process for publication is currently on-going).

4.2. Aspect II: Implementation of the ED criteria / approach to regulatory decision making

The regulatory consequences (i.e. implementation) of the criteria to identify EDs are already set under the PPP and BP Regulations and are driving the impacts. In addition, the regulatory consequences differ in terms of scope and implementation, adding complexity to the impact assessment. For analytical purposes it was considered important to address this complexity and thus the options presented in the Roadmap were designed in order to address the difference in the derogations between the PPP and the BP Regulations.

As a consequence a very comprehensive range of options was developed which covers the entire spectrum of potential policy choices: these include the baseline (current provisions in the BP and PPP Regulations), the possibility to modify an annex of the PPP Regulation under regulatory procedure with scrutiny, and the possibility to modify the PPP Regulation under ordinary legislative procedure. The inclusion of such a wide spectrum of options has been done for analytical purposes and greater transparency, in order to allow greater comparability of the evidence gathered throughout the analysis and facilitate the identification of the most proportionate and fit for purpose policy choice.

Some Member States and all third countries replying to the public consultation support an option that will identify EDs and take regulatory decisions based on risk assessment.

[46] Expert conference on endocrine disruptors organised by the Federal Institute for Risk Assessment (BfR) and held in Berlin on 11 and 12 April 2016:
http://www.bfr.bund.de/en/press_information/2016/13/breakthrough_in_the_scientific_discussion_of_endocrine_disruptors-197254.html
The statement indicated potency is part of hazard identification. However, the assessment of the corresponding risks on human health and wildlife would further require consideration of dose-response relationships, including potency, exposure assessment, and risk characterization, including susceptible sub-populations, severity and reversibility of effects.

4.2.1. Option A: No policy change (baseline).

The regulatory consequences under the PPP and BP Regulations remain unchanged. This means that the decision making in the PPP sector is, including the derogations, mainly based on hazard while the decision making in the BP sector considers more risk and socio economic elements (except for consumers).

A decision taken based on hazard means that a substance is not-approved based on its inherent properties, while a decision based on risk considers the use of the substance and if there is actually exposure to this substance which leads to a risk. [47]

This baseline option (Option A) implicitly applies when evaluating the impacts of the options for setting scientific criteria (Aspect I) because it represents the current regulatory framework.

Most endocrinologists, some MS, health/environmental/consumers NGOs call for EU criteria to assess EDs purely based on hazard. Most toxicologists, some MS, industry, farmers and third countries disagree with hazard-based ED criteria and call for EU criteria to assess EDs which consider risk.

4.2.2. Option B: Adjustment of the PPP derogations in light of current scientific knowledge.

Option B only applies to the PPP Regulation and takes into account scientific knowledge which is based on scientific consensus. The option aims at updating the derogations foreseen in the PPP legislation while maintaining the essentially hazard-based decision making. It would contribute to increased operability of the derogations currently laid down in the PPPR and would allow implementing the criteria in a consistent manner across the PPP Regulation and the BP Regulation. See below and Figure 2 for more details.

The derogations to the non-approval of active substances, currently mainly hazard-based, would be updated in light of current scientific knowledge (e.g. recent scientific opinions of EFSA[48], Scientific Committee SCCS[49], expert meeting in Berlin[46]) to derogations which consider risk components. While the general hazard approach for EDs would be maintained, the derogations would be based on a stronger risk component compared to the current regulatory situation.

The European Commission is empowered to amend non-essential elements of the Annexes in Regulation (EC) No 1107/2009 taking into account current scientific and technological knowledge via Regulatory Procedure with Scrutiny (RPS) (cf. Article 78 of Regulation (EC) No 1107/2009). This option is therefore feasible within the remit of the mandate of the Commission as it does not imply changes by ordinary legislative procedure to the basic act.

By updating the PPP derogations to take into account current scientific knowledge, there would also be a higher alignment of the PPP Regulation to the BP Regulation (see also Section 1.5 and Annex 8 for further details on the exact working of the derogations under the

[47] For instance, a knife – a dangerous object per se - would be banned completely if the decision is taken based on hazard, while it would be allowed for certain uses or restricted (e.g. not allowed for small children) if the decision is taken based on risk.

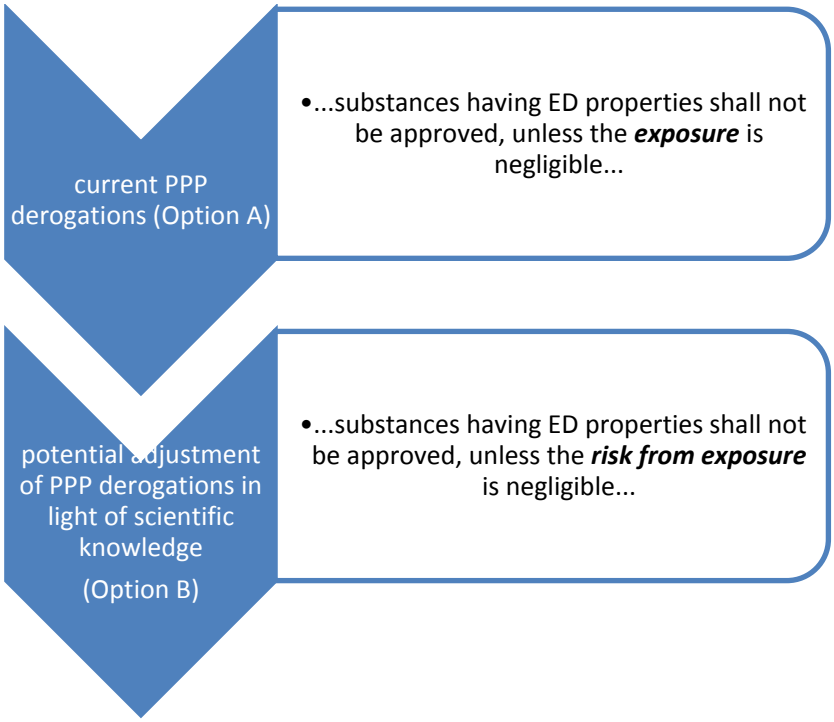
[48] The EFSA Scientific Opinion 2013 indicated that safe doses/concentrations of EDs can be established and that severity, irreversibility and potency should be evaluated in relation to degree, timing and duration of exposure, i.e. using risk assessment. EFSA also stated that EDs can be treated like most other substances of concern for human health and the environment, i.e. be subject to risk assessment and not only to hazard assessment.

[49] The Scientific Committee on Consumer Safety (SCCS) supports the use of risk assessment to assess EDs for decision making (Memorandum 2014)

PPP and BP Regulations). Such alignment would provide for more harmonisation of the implementation of the criteria. Thus, this option represents a potential contribution to a clearer and simpler regulatory environment and of an easier implementation of the criteria. It would also contribute to achieving one of the objectives of Better Regulation which is effectiveness of EU action.

Third countries replying to the public consultation support this option because it will identify EDs and take regulatory decisions based on a hazard approach which considers derogations based on science and consideration of risk elements, as requested by international obligations (notably Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT)). Chemical industry, farmers, and some MS are in favour of decision making which considers risk.

Figure 2 Potential adjustment of derogations under the PPP Regulation in light of current scientific knowledge (Option B)



4.2.3. Option C: Alignment of the PPP with the BP Regulation by introducing further socio-economic considerations.

Option C only applies to the PPP Regulation, as it implies an amendment of the PPP Regulation to introduce measures similar to those in the BP Regulation as regards the derogations for non-approval of substances in case this would have a disproportionate negative impact on society (Art 5.2. of the BP Regulation).

This option would require a modification via ordinary legislative procedure of the current PPP Regulation. At a preliminary stage of the analysis it was anticipated that this option goes beyond the mandate given to the Commission for the identification of ED criteria and that it should be discarded. Nevertheless, the option was still considered relevant for analytical purposes and to support the analysis of potential future policy choices. As a consequence, it was maintained for the analysis but not further discussed in the main report. Moreover, it was part of the roadmap which was considered as the basis of this impact assessment.

5. WHAT ARE THE IMPACTS OF THE DIFFERENT POLICY OPTIONS AND WHO WILL BE AFFECTED?

5.1. Methodology applied for assessing the impacts

Once the criteria to identify EDs are set based scientific considerations, they will be applied subsequently to the regulatory process for the approval or renewal of approval of active substances falling under the PPP and BP Regulations (no derogations for SMEs are foreseen in the Regulations). The impacts are driven by the regulatory consequences foreseen for the substances which are identified as EDs. Regarding the international dimension, the impacts need to be assessed considering provisions set in international law, such as customary international law and treaties ratified by the EU.

Due to this situation, the impacts have been assessed in a two-step procedure as described in the subsections below.

5.1.1. Step 1: Number of substances identified as ED – the screening study

In a first instance, the **number of substances which would be identified as EDs** under the various options has been estimated via a screening study performed by an external contractor (Specific Contract SANTE/2015/E3/001). The study was based on a scientific method developed by the Joint Research Centre (JRC). The JRC monitored and assisted the screening process performed by the contractor. The methodology, the results of the screening, and the contractor's details will be published once the screening is finalised, which is expected by end June 2016.

The screening study served as a case study and constitutes the basis for the assessment of the impacts on different policy areas. It resulted in a quantifiable estimation regarding how many and which chemical substances used in PPP and BP may be identified as EDs under Options 1 to 4. It also gave an estimate of the extent of the overlap between the options allowing a comparison of the options. Further, both the method and the experience applying it might be used at a later state as a starting point for practical guidance to apply the criteria.

However, the results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [Regulation (EC) No 1107/2009 on plant protection products and Regulation (EU) No 528/2012 on biocidal products] and in no way prejudge future decisions on active substances to be taken pursuant to these two Regulations. The results of the study cannot be used for regulatory purposes because for identifying a substance as ED for taking regulatory decisions a more in depth assessment in line with the provisions of the respective Regulations would be required.

5.1.2. Step 2: Direct and indirect impacts in different policy areas

Building on the results of the screening study (i.e. the chemical substances identified as ED under each of the Options 1 to 4) and the regulatory consequences foreseen in the PPP and BP Regulations (non-approval of active substances unless the derogations apply), the direct and indirect impacts in different policy areas have been assessed. The policy areas covered in the assessment were human health, environment, economic operators, users, MS and third countries.

For assessing these impacts and because they are multifactorial, the evidence of the screening study was complemented with additional information. However, the availability of reliable

and sound data to assess the impacts on agriculture, trade, health and environment was scarce and highly variable. Also the identification of plausible and reliable case studies to be used for assessing the impacts was difficult. In particular:

- Basic agricultural/trade data were either not available, not ready, or not easy to use (e.g. information on uses of active substances per crop and per pest were not available for all EU MS; yield decreases in crop production due to the absence of a PPP - crucial for any estimation of agricultural and end consumers impacts - could only be estimated with significant uncertainties; extrapolation from case studies based on few Member States to the whole EU was not considered appropriate due to e.g. differences in climate conditions; some agronomic impacts cannot be quantified for example resistance to target organisms).
- Regarding health data, no active substance identified in the options can be linked directly to hormone related diseases and disorders because of the acknowledged limitations of the reviewed health studies. Also, studies trying to quantify the health cost associated to EDs' exposure rely upon controversial assumptions and models adapted from other sectors. Further, due to the already high protection of health in the PPP and BP legislations (no use of substances that pose a serious health or environmental concern would be authorised), a comparison between Option A and Option B (approaches to regulatory decision making) would be difficult.
- Assessing environmental impacts, e.g. on biodiversity/ecosystems, is also difficult, in particular because evidence to link environmental data to particular active substances is in general not possible, as confirmed by the recent study on benefits of chemical legislation (RPA, 2015)[50].

The preliminary assessment of the evidence concluded that it would not be possible to quantify impacts, as data would neither be of sufficient quality nor reflect reality due to the high level of uncertainties and assumptions made. In addition, some approaches to estimate impacts would - as a consequence of the variable data availability in the different areas – create a strong imbalance between the assessments of the areas. Thus, under consideration of the Better Regulation Guidelines and in light of the complexity of the areas and the potential impacts (including key impacts listed in Tool #16), as well as the evidence and data available, a **Multi-Criteria Analysis (MCA**, Better Regulation Guidelines' Tool #55[51]) was considered as the most appropriate analytical method to compare and rank the options against the areas considered because:

- it is useful when impacts cannot be fully quantified or monetised;
- it allows impacts to be reconciled with policy objectives;
- it can capture distributional impacts (e.g. in terms of stakeholder types);
- it enables to judge the pros and cons of options along the criteria chosen for the comparison;

[50] Risk and Policy Analysts (RPA) et al. 2015. Study on the Calculation of the Benefits of Chemical Legislation on Human Health and the Environment, Final report for DG Environment, March 2016, Loddon, Norfolk, UK

[51] The analytical methods listed in Tool #55 are: Cost Benefit Analysis (CBA), Least Cost Analysis (LCA), Multi-Criteria Analysis (MCA), Cost-Effectiveness Analysis (CEA), Counterfactual Analysis, and SWOT Analysis. Cost-Benefit Analysis, Least Cost Analysis and Cost-Effectiveness Analysis were discarded because robust assumptions for quantifying and monetising the impacts were not available. The Counterfactual analysis was discarded as it is more appropriate for evaluations as it looks at what would have happened in the absence of an intervention. The SWOT analysis was discarded as it is not an analytical method per se, but it is used to identify Strengths, Weaknesses, Opportunities and Threats in relation to a project/organisation.

- it allows the selected criteria to determine the results obtained by assigning weights to them.

Although a MCA is complex and might be difficult to communicate, it has also many advantages over informal judgement. Advantages are in particular that performance scores and weights are explicit and developed according to established techniques; that a sensitivity analysis can be performed, highlighting how the weights assigned to MCA-criteria and changes in performance of the options influence the final result; and that the scores and weights used provides an audit trail.

The performance scores applied in the MCA methodology of this impact assessment for Options 1 to 4 (i.e. the assessment of the impacts for each of the MCA-criteria) are based on the results of the screening combined with the additional evidence available in each of the dimensions analysed (e.g. human health, agriculture, trade). It is assumed that Options 1 to 4 are applied under the current PPP and BP Regulations (Option A).

In order to assess the potential impacts of Options B and C (Option C was discarded but kept for methodological reasons, see Section 4.2.3), a 2nd MCA was carried out which compares qualitatively the current regulatory framework with potential different regulatory decision making. Thus, the MCA was carried out in a step-wise approach, as there were two sets of options with the aim to simplify the already very complex analysis:

- Step 1: the MCA methodology applied to Options 1 to 4 (Aspect I)
- Step 2: the MCA methodology applied to Options A to C (Aspect II)

The same MCA parameters (criteria, weights, performance assessment methods, etc.) were used for both steps.

The MCA-methodology is detailed in Annex 6 and includes a sensitivity analysis which considers different scenarios based on the availability of evidence, different priority setting (weight) to the different dimensions (e.g. giving a higher weight / priority to human health), and/or different performance of the options. In the sub-sections below the key steps of the MCA are summarised.

5.1.3. MCA methodology: selection of the MCA-criteria

The MCA-criteria need to be operational so that they assess how well each option meets the objectives expressed by the MCA-criteria. The number of MCA-criteria should be kept as low as is consistent with making a well-founded decision.

The MCA-criteria were developed as the first MCA-step by the procedure summarised in this section and in more detail in Annex 6:

1) The MCA-criteria were designed so that effectiveness, efficiency and coherence of each option can be assessed, by following Tool #8 of the Better Regulation Guidelines (see below). In particular:
    a) Link with the objectives (effectiveness): the MCA-criteria were selected considering the objectives described in Section 3 and which are: 1) ensuring of high level of protection of human health, animal health and the environment; and 2) strengthening the functioning of the internal marked while improving agricultural production. Criteria on the social and environmental impacts are linked to the first objective, whereas criteria on the economic, effectiveness and coherence impacts are linked to the second objective. Further, the compliance with international obligations and specific objectives were also considered (see Section 3).

b) Areas with significant impacts (efficiency): the MCA-criteria were selected to cover the areas were significant impacts could be expected. This was done by following Tool #16 – "Identification/screening of impacts" for identifying the key economic, social and environmental impacts.

c) Consistency with other EU legislation (coherence): the MCA-criteria selected include consideration of international treaties that the EU needs to abide by (WTO and Codex Alimentarius) or the coherence between PPP and BP legislation.

Table 1: MCA-criteria listed by dimension and by impacts they address

Impacts		Dimensions and MCA-criteria
EFFECTIVENESS & COHERENCE		**EFFECTIVENESS & COHERENCE**
		Legal certainty and proportionality:
		Operability for regulatory decision making:
		Coherence between BP and PPP legislation:
		Compliance with international obligations of the EU:
EFFICIENCY	Economic	**SECTORIAL COMPETITIVENESS: EU AGRICULTURE**
		Number of PPP affected:
		Crops affected:
		Existence of alternatives / risk of resistance of pests:
		SECTORIAL COMPETITIVENESS: PPP, BP AND RELATED INDUSTRIES
		Functioning of the single market:
		Innovation and research:
		SME's:
		INTERNATIONAL TRADE
		Import of food:
		Import of feed:
		Import of treated articles:
	Social	**HUMAN HEALTH**
		Hormone related diseases and disorders:
		Transmissible diseases caused by lack of appropriate disinfectants or insecticides:
		Food safety:
	Environment	**ENVIRONMENT**
		Chemical quality of water:
		Wildlife vertebrate populations:
		Animal welfare:

2) The availability of evidence was crucial for the selection of MCA-criteria in order to be able to use the criteria to assess the performance of the options. As mentioned before, the data availability was highly variable, with some fields benefiting from more detailed data while others being characterised by the prevalence of qualitative data or the lack of data (see Table 2).

3) The MCA-criteria were assessed against a range of qualities: completeness, redundancy, operationality and mutual independence.

4) The MCA-criteria were checked against the Public Consultation Report to ensure that all relevant potential impacts mentioned by stakeholders are covered.

5) The MCA-criteria were discussed with the members of the Impact Assessment Steering Group (IASG) at the meeting of 1st February 2016, in order to ensure that all relevant potential impacts are covered.

5.1.4. MCA methodology: assessment of the options and sensitivity analysis

In a second MCA-step, the performance of the options was assessed for each of the MCA-criteria. The performances reflect the impacts expected for each criterion.

The assessment of the performance (impacts) was based on the outcome of the screening study (number and, where possible, identity of AS identified as EDs under each option). Additional evidence was also considered to the extent possible for the analysis of the impacts and for assessing the performance of the options under the current regulatory framework (Option A). A summary of the evidence used for each criterion is given in Table 2 and described in more detail in the respective Annexes.

Some of the impacts (MCA-criteria for EU agriculture and international trade) could be assessed based on case studies which were based on the substance-specific outcome of the screening study (identity of the substance) and additional evidence. For other criteria, where less evidence was available, a more descriptive approach had to be followed so that the evidence compiled via the screening study played a more prominent role because of the assumptions taken during the assessment of the potential impacts. Assumptions played also a prominent role when assessing the potential impacts of Options B and C (Option C was discarded but kept for methodological reasons, see Section 4.2.3). The reason for this is that the comparison of the impacts of these options with those under the current regulatory framework (Option A) could only be done qualitatively. Exact evidence could only be collected once the regulatory process is finalised for each substance, which usually takes 2 to 3 years and is therefore not possible to be assessed in the context of this impact assessment.

The impacts described in Sections 5.3 and 5.4 translate into the performance of the options and have been structured the same way as the dimensions used for the MCA:

- Achievement of effectiveness and coherence (Annex 8)
- Human Health-Hormone related diseases and disorders (Annex 9)
- Human Health-Transmissible diseases and food safety (Annex 10)
- Environment (Annex 11)
- Sectorial competitiveness: EU agriculture (Annex 12 and 13)
- Sectorial competitiveness: PPP, BP and related industries (Annex 14)
- International Trade (Annex 15)

Table 2: Description and underlying evidence for the MCA-criteria listed by dimension

MCA-CRITERIA	ADDITIONAL EVIDENCE CONSIDERED WHEN ASSESSING PERFORMANCE OF THE OPTIONS IN THE MCA	DESCRIPTION AND ASSUMPTIONS OF THE MCA-CRITERIA
EFFECTIVENESS & COHERENCE		
Legal certainty and proportionality: *degree to which legal certainty is ensured*	current experience implementing the PPP and BP Regulations and their derogations.	Legal certainty would in principle be achieved by all options. However, the application of case-by-case derogations is expected to lead to more uncertainty to applicants and stakeholders. The introduction of categories may decrease legal certainty as AS placed under Category II or III have no regulatory consequences under the PPP and BP Regulations.
Operability for regulatory decision making: *additional efforts required to public authorities and applicants resulting from implementing derogations and a revision of categories*	current experience implementing the PPP and BP Regulations and their derogations.	The application of derogations for approving substances identified as EDs would decrease operability for regulatory decision making. Additional burden may be expected because of the application of case-by-case derogations.
Coherence between BP and PPP legislation	current experience implementing the PPP and BP Regulations and their derogations as some substances fall under both legislations.	The application of case-by-case derogations (currently different between BP and PPP and currently clearer and easier to implement under BP), is expected to lead to less coherence between the PPP and BP Regulation. An alignment of derogations is assumed to lead to higher coherence and better implementation.
Compliance with international obligations: *compliance with international obligations (WTO and Codex Alimentarius)*	Provisions of - The Agreement on Technical Barriers to Trade (TBT Agreement) - The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).	It is assumed that the more the implementation of criteria is based on risk rather than hazard, the more compliant is the EU with its international obligations.
HUMAN HEALTH		
Hormone related diseases and disorders (potentially ED related diseases and disorders): *health risks potentially related to hormonal axes (EATS)*	- No evidence available to establish a causal link between currently approved AS and potentially ED related diseases. - Incidence of potentially ED related diseases in the EU based on literature review and data from Eurostat, OECD, and WHO. - Current experience implementing the PPP and BP Regulations and their derogations.	All options based on the WHO definition are considered to be equally protective. Option 1 is considered not fit for purpose as not able to identify an ED mode of action. i) An active substance is only approved following a risk assessment. As a consequence, it can be assumed that no harmful or unacceptable effects on human health are expected for approved substances. It can be assumed that human health is protected regardless the number of AS identified as ED. ii) exposure zero scenario: it is assumed that only a hazard based approach can protect human health. Thus, it is assumed that any exposure to an AS with ED properties is harmful and the longer the list of *relevant* AS with ED properties, the higher the protection of human health.
Transmissible diseases: health risks caused by lack of appropriate disinfectants (e.g. in hospital settings) or insecticides (e.g. mosquito borne public health treats)	- Expert advice on transmissible diseases was provided by the European Centre for Disease Prevention and Control (ECDC). - Current experience implementing the BP Regulation and its derogations.	It can be assumed that the expected impact is proportional to the number of BP identified as ED as there is a need for a wide spectrum of disinfectants (there is no single universal disinfectant) and insecticides to control transmissible diseases
Food safety: *risk of contamination of food (e.g. by mycotoxins)*	- The Rapid Alert System for Food and Feed (RASFF) data - EFSA database on Collection on	The impact on food safety with regards to mycotoxins includes large elements of uncertainty. It can be assumed that the likelihood of having an impact on health will be higher if less PPP relevant for the control of fungi

MCA-CRITERIA	ADDITIONAL EVIDENCE CONSIDERED WHEN ASSESSING PERFORMANCE OF THE OPTIONS IN THE MCA	DESCRIPTION AND ASSUMPTIONS OF THE MCA-CRITERIA
	Contaminant Occurrence Data - No detailed data is available on the monetary impact of mycotoxins in the EU.	producing mycotoxins are available.
ENVIRONMENT		
Chemical quality of water: *contamination of ground, surface, and drinking water with ED chemicals used as PPP or BP*	No direct evidence available to establish a link between the use of PPP and BP and chemical quality of water. This criterion assumes that the quality of the water is inversely proportional to the number of active substances present in it, irrespectively of their levels. It aims at zero exposure from active substances.	It is assumed that the higher the number of AS removed from the market or restricted, the higher the likelihood of an improvement in the chemical status of water.
Wildlife vertebrate populations: *decrease of wildlife vertebrate populations because of ED mediated adverse effects*	No direct evidence available to establish a link between the use of PPP and BP and the adverse effect on vertebrate populations.	All options based on the WHO definition are considered to be equally protective. Option 1 is considered not fit for purpose as not able to identify an ED mode of action. It is assumed that a decision making based on risk assessment is equally protective for wildlife populations as a decision making based on hazard. Differently, the inclusion of socio-economic considerations may consider a risk/benefit analysis and, therefore, it is assumed to protect the environment to a lesser extent. Exposure zero scenario: it is assumed that only a hazard based approach can protect environment. Thus, it is assumed that any exposure to an AS with ED properties is harmful and the longer the list of relevant AS with ED properties, the higher the protection of environment
Animal welfare: *number of animal tests needed*	Number of tests required in the application dossiers.	All the options perform the same, no matter how many substances they identify as ED. It is however assumed that the inclusion of additional categories under option 3 might trigger additional animal testing, as companies or authorities would wish to verify whether the chemicals classified as Category II or III are actual EDs or not.
SECTORIAL COMPETITIVENESS: EU AGRICULTURE		
Number of PPP affected: *number of PPP authorised at national level that will be affected as a consequence of the non-approval of affected AS identified as EDs*	Data on authorised PPP from 8 MS collected via PPPAMS but evidence is lacking in order to quantitatively assess the impacts in terms of yield losses of the potential disappearance of one single substance.	After an AS is approved under the PPP Regulation, MS can authorise products containing this AS. Consequently, if an AS is no longer approved, the PPPs containing this AS will no longer be authorised. Data to assess this, at AS level, were available from 8 MS and were used as case studies. It is assumed that the higher the number of PPP that will disappear from the market, the higher the negative impacts on EU agriculture.
Crops affected: *number of crops affected by the disappearance of certain AS*	Data on authorised PPP uses on crops from 8 MS collected via PPPAMS	After an AS is approved under the PPP Regulation, MS can authorise products containing this AS which are used on specific crops against specific pests. Data to assess this, at AS level, were available from 8 MS and were used as case studies. It is assumed that the longer the list of crops affected, the higher the negative impacts on EU agriculture.
Existence of alternatives / risk of resistance of pests: *number of PPP alternatives existing for each crop / risk of appearance of resistance in pests resulting from a lower number of available PPP*	Eurostat data concerning statistics on pesticides (Regulation (EC) No 1185/2009).	The data available in the context of Regulation (EC) No 1185/2009 were used to analyse the percentage of AS (in terms of sales) affected per chemical class and per major group. It is assumed that the higher the percentage of a chemical class affected, the lower the number of alternatives existing. For some crops, only one particular AS is

MCA-CRITERIA	ADDITIONAL EVIDENCE CONSIDERED WHEN ASSESSING PERFORMANCE OF THE OPTIONS IN THE MCA	DESCRIPTION AND ASSUMPTIONS OF THE MCA-CRITERIA
		effective/efficient and therefore its loss might lead to higher impacts for the crop production than the data shown in the assessment but the level of detail and of reliability of additional data at the disposal of the Commission did not allow for such a detailed analysis.
SECTORIAL COMPETITIVENESS: PPP, BP AND RELATED INDUSTRIES		
Functioning of the single market (in particular when exceptions apply):	Current experience implementing the PPP and BP Regulations and their derogations, in particular the effect on national authorisations and mutual recognitions.	Derogations may be applied at MS level where it is necessary and subject to specific conditions that only applies in some MS and not in others. Thus, it can be assumed that the higher the number of AS removed from the market or approved under restricted conditions, the more specific national conditions would apply, which consequently would impact negatively on the functioning of the single market.
Innovation and research: *change of innovation, research, and technical development in PPP and BP industry, pesticide application industry, food industry, others*	General information available on the costs to develop and market PPP and BP, but evidence is lacking in order to quantitatively assess the impacts on innovation and research.	Considering the current drivers for innovation and the market structure, it can be assumed that the non-approval of an AS will probably not trigger substantial innovation.
SME's: *Burden to SMEs*	- Eurostat data on the size of farms, both in terms of hectares and full-time equivalent jobs per holding, in the EU. All agricultural holdings qualify as SMEs. - No data available on SMEs operating in the BP sector. - Not data available on SMEs operating in the PPP industry sector	It is assumed that the higher the impacts on farmers, the higher the impacts on SMEs, as all farmers are SMEs – see also impacts for agriculture. Any increase in costs and demand of staff is assumed to negatively affect the market position of SMEs because larger firms have greater financial capacity and are better able to e.g. spread risks. SMEs have in general smaller portfolios of active substances than larger companies and therefore they are relatively more vulnerable to the withdrawal of AS identified as ED.
INTERNATIONAL TRADE		
Import of food: *volume of imports of food potentially affected by lowering the MRLs at the limit of determination (LOD).*	- The EU Pesticide Database on MRLs (at AS and crop basis). - COMEXT trade databases from Eurostat for volumes and value of imports of crops from third countries, but evidence is lacking in order to quantitatively assess the impacts on third countries' economies of the possible trade disruption resulting from lowered MRLs	The PPP Regulation provides that for AS identified as ED, the MRLs in products imported to the EU is set at the default level (no risk assessment). This implies that some MRLs already set (information available via the EU Pesticide database) will need to be lowered to the default value, i.e. to the limit of determination (LOD). This MCA criterion was evaluated based on information available. For each AS identified as ED and for a sample of the more relevant crops imported in the EU (COMEXT database), it was evaluated how many MRLs would be lowered to the LOD for a crop. It can be assumed that the higher the number of MRLs lowered, the worse the impacts on trade. Also, the higher the value of imports of impacted crops, the worse the impacts on trade.
Import of feed: *volume of imports of feed potentially affected by lowering the MRLs at the LOD*		
Import of treated articles: *volume of imports of goods which may be affected as a consequence of implementing the BP Regulation in relation to treated articles*	Eurostat COMEXT data used to analyse the country of origin, value and volume of textiles imported to the EU	With the non-approval of a BP, it is assumed that manufacturers and importers have to make an effort to adapt to the new requirements. It can therefore be assumed that the more AS identified as ED used in treated articles, the higher the volume of imports may be affected.

5.2. Direct impacts on the number of PPP and BP active substances falling under Options 1 to 4

For determining whether an active substance would be identified as ED under each of the options, a screening study was performed by an external contractor. This study provides evidence regarding which substances and how many of the substances used in PPP and BP may be identified as EDs under each of Options 1 to 4. Please refer to Annex 3 for a method description, Annex 4 for the list of substances screened and Annex 5 for the detailed results of the screening study.

The screening study was carried out in the context of this impact assessment to evaluate the impacts associated to options for criteria to identify endocrine disruptors under the regulations on plant protection products and biocidal products. The screening was based on available evidence (no additional testing) and needed to be carried out in a limited time. The screening methodology was developed for the purpose of the screening exercise.

The results of the screening therefore do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [Regulation (EC) No 1107/2009 on plant protection products and Regulation (EU) No 528/2012 on biocidal products] and in no way prejudge future decisions on active substances to be taken pursuant to these two Regulations. It would thus be erroneous to consider that the substances identified in the screening are considered as endocrine disruptors within the meaning of the EU legislation.

The screening was based on hazard classification according to Regulation (EC) No 1272/2008, scientific data available in regulatory assessment reports[52], and information from databases[53] focusing on endocrine effects and including non-regulatory scientific studies (see Annex 3 for a method description). The methodology used was developed by the Joint Research Centre (JRC, European Commission) and was based on the WHO/IPCS definition of an ED and international guidance on assessment of EDs (2012 OECD technical guidance on assessment of EDs[54]). Considering the internationally validated testing methods available[55], the methodology only focused on the estrogenic, androgenic, thyroidal and steroidogenic modalities of the endocrine system (EATS modalities) and on population-relevant effects in animal vertebrate species.

The screening of chemical substances used in PPP or BP resulted in the same number of active substances identified as EDs under Option 2 and Option 3 Category I, while the number of substances identified under Option 4 is a subset of these (see Table 2 and Figure 2). This trend was expected since it is related to the design of the options and the method used for the screening, however the results indicate the magnitude of the difference between the options and which substances or substance groups are likely to be affected. This information was not available before performing the screening study.

[52] EFSA conclusions, Member State (MS) Draft Assessment Reports, MS Competent Authority Reports, REACH restriction dossiers, Support documents for identification of SVHC and opinions of the SCCS.

[53] JRC's Endocrine Active Substances Information System, TEDX, SIN list, ToxCast, EDSP WoE analyses and targeted literature searching

[54] OECD Guidance document on standadised test guidelines for evaluating chemicals for endocrine disruption. No. 150. Retrieved from: http://www.oecd.org/chemicalsafety/testing/oecdguidancedocumentonstandardisedtestguidelinesforevaluatingchemicalsforendocrinedisruption.htm

[55] EFSA Scientific Committee; Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132. [84 pp.] doi: 10.2903/j.efsa.2013.3132.

All **PPP active substances** that are currently on the market were screened, with some exceptions (such as the exclusion of micro-organisms) which are explained in Annex 4. In total, 347 PPP active substances were screened.

For PPP, Option 1 (interim criteria) identifies almost twice as many substances than Option 2 or Option 3 Category I, but only a small overlap (5 substances) exists between them. A total of 37 substances are identified under Option 1 as ED, but they are not overlapping with the substances identified under options 2, 3 Category I, or 4. Consequently they are considered to be **false positives** because they are identified as EDs under Option 1 without appearing to have ED properties under Options 2 to 4. This is because the approach followed for Option 1 and Options 2, 3 Category I, and 4 differ: while the interim criteria are based on categorisation of substances as suspected of being carcinogenic (C2) or suspected of being toxic for reproduction (R2), Options 2 to 4 are based on implementation of the WHO definition of EDs (adverse effects, mode of action and causal link).

Table 3. Number of active substances used in PPP or BP identified as EDs under the screening study[56] preformed for this impact assessment (substances identified as ED and classified as C1 or R1, thus falling under the "cut-off" criteria, are not included in the PPP numbers). In total, 347 PPP and 98 BP were screened.

	NUMBER OF SUBSTANCES IDENTIFIED AS EDS				
	OPTION 1	OPTION 2 / OPTION 3 CAT I	OPTION 3 CAT II	OPTION 3 CAT III	OPTION 4[57]
Active substances used in PPP	42	26	82	45	11
Active substances used in BP	16	5	26	8	2

The results also show that Option 1 (interim criteria) did not identify all active substances that were considered ED under Options 2, 3 Category I, or 4. These 21 substances are **false negatives** because substances identified as ED using the WHO definition are not identified under Option 1 (however this identification is only the 1st step in regulatory decision making). This result confirms that Option 1 is not effective to identify all substances with endocrine-properties. However, it should be kept in mind that most of the adverse effects caused by these "false negatives" would be addressed via the "standard" risk assessment needed in any case under the PPP and BP Regulations, which is focused on potential adverse effects (WHAT question), being the mode of action (HOW question) known or not.

It should be noted that the number of substances identified under Option 1 is based on *harmonised* CLP[58] classification as suspected of being carcinogenic (C2) or suspected of being toxic for reproduction (R2) and in addition on proposals for such classification by the EFSA which are more recent than the *harmonised* classification. This further increased the number of substances classified as C2 or R2 and therefore as EDs under Option 1.

[56] The screening study includes substances falling under REACH, Cosmetics Regulation, and Water Framework Directive (see Annex 4). The results of the screening of these substances were neither available nor relevant in the context of this impact assessment report. They will be published in the report of the screening study.

[57] In the screening, potency-based STOT-RE Cat 1 trigger values from the Regulation (EC) No 1272/2008 were used as cut-off criteria to evaluate potency. The most sensitive endocrine specific endpoint was compared to the potency cut-off values taken from the STOT-RE, according to the route of exposure (oral, dermal, inhalation). The doses were time-adjusted to a 90-day study. The same value was used for all species and no adjustment for different sizes (body weights) or life spans was done.

[58] Regulation (EC) No 1272/2008

In order to avoid "double-counting" from a regulatory perspective and with respect to potential impacts, substances identified in the screening as EDs and already falling under one of the "cut-off" criteria (R1, C1, and persistent/toxic and bio-accumulative substances), are identified separately (see Annex 5). Although this confirms that some EDs are already regulated via the consideration of the adverse effects, they have been excluded from the analysis of the impacts in the different areas (in particular agriculture and trade).

A total of 98 **BP active substances** were screened. The BP substances selected for the screening were linked to the availability of data at EU level, which is related to the on-going review programme of existing biocidal substances on the market and resulted in different percentages of product groups screened, for instance only 17% of active substances used in disinfectants were screened compared to 52% of the pest control substances. Thus, any result of the screening of BP substances should be cautiously interpreted for the potential impact on all product types on the market. Nevertheless, the overall trend (see Table 3) that Option 1 identifies more substances (16 substances) than Options 2 and 3 Category I (5 substances) is confirmed also for BP, as well as the fact that Option 4 identifies a subset of Option 2 and Option 3 Category I.

The number of false positives and false negatives show the same trend for BP as for PPP. A total of 13 substances are identified under Option 1 for BP but not under Option 2 and 3 Cat I (false positives). The interim criteria failed to identify two substances that have endocrine modes of actions (false negatives) that were identified as EDs under Option 2 and 3 Cat I.

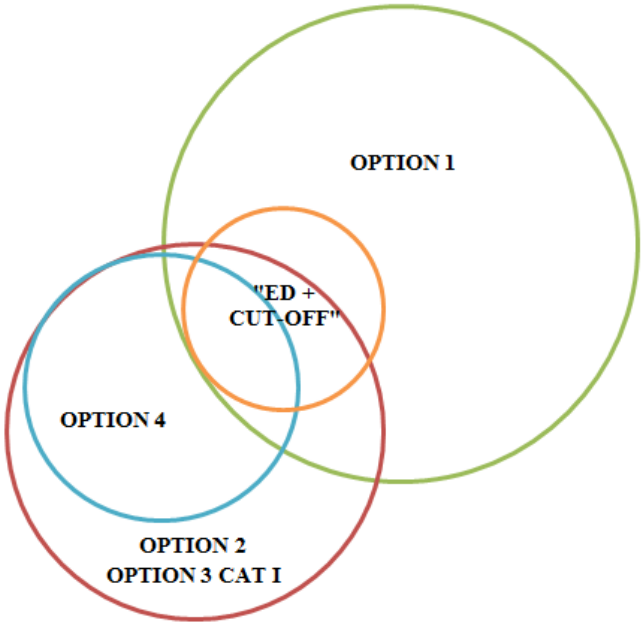


Figure 3. Relation between the chemical substances used in PPP identified as EDs under Option 1, Option 2 and Option 3 Category I, and Option 4. The circle "ED + cut off" represents substances that are identified as ED and also classified as C1 or R1 and therefore falling under the cut-off criteria in the PPP Regulation.

Table 4. False positives and false negatives identified for Option 1 by the screening.

	PPP	BP
False positives (identified under Option 1 but not under Options 2 to 4)	37	13
False negatives (identified under Options 2 to 4 but not under Option 1)	21	2

5.3. Direct and indirect impacts in different policy areas expected after implementing the scientific criteria in the current regulatory PPP and BP Regulations (Aspect I)

Once the new scientific criteria are defined, they will be applied in the context of the review or renewal of approval programmes foreseen in the PPP and BP Regulations for active substances. As a consequence, they are expected to impact the number of active substances which are on the market to be used in PPP and BP. This will then lead to impacts on several areas in particular human health, environment, sectorial competitiveness including agriculture, and trade, as summarised below.

- The health of the general population, consumers, and workers would be affected directly or indirectly via the occurrence of PPP and BP or their metabolites in food or in the environment, by the availability of PPP or BP (e.g. disinfectants), by the availability of certain products for which production PPP or BP may not be longer available, or by the variation in costs for products including agricultural commodities.
- Economic operators may also be affected. Besides the chemical industry, impacts are also expected for downstream users of PPP and BP (e.g. food operators, farmers, health facilities) because of availability of PPP and BP. Consumers and international trade may also be affected.
- Potential impacts of the different options on legal certainty, proportionality and operability for regulatory decision making, coherence between the PPP and the BP legislation, as well as the coherence with international treaties and/or obligations, were also considered in the assessment.

The potential impacts are summarised in the subsections below, which reflect the dimensions identified to perform the Multi Criteria Analysis (MCA) (see Table 1). More detailed discussion on the respective impacts can be found in the respective Annexes.

5.3.1. Achievement of effectiveness and coherence (Annex 8)

The criteria to define EDs will be applied in the framework of the current PPP and BP Regulations. The effectiveness of the options to fulfil the objectives of these Regulations was assessed considering legal certainty and operability, while coherence was assessed considering the coherence between the PPP and BP Regulations and the compliance with international obligations of the EU (WTO and Codex Alimentarius).

Legal certainty would in principle be achieved by all options. However, the case-by-case assessment of derogations for the approval decision process of substances identified as EDs would decrease legal certainty for all involved parties and also decrease **operability** regarding regulatory decision making.

The introduction of categories (Option 3, WHO definition with categories), may decrease legal certainty because the current legislation for PPP and BP does not foresee specific provisions regarding the application of categories for ED substances. It is likely that MS and

stakeholders may interpret differently regulatory consequences for substances placed under Category II or III, which would decrease legal certainty for operators. Further, substances falling under Categories II and III may be "black listed".

In addition, using categories similar to those used for classification under Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP Regulation) may lead to confusion. It may be misinterpreted that substances categorised under the criteria to identify EDs as EDs Category II or EDs Category III are classified as such under the CLP, while this would not be the case. The criteria to identify EDs were mandated by the co-legislators only for PPP and BP. It may be confusing with respect to other overarching pieces of EU legislation (CLP), and thus negatively affect legal certainty and operability, in particular because the categories foreseen under Option 3 (Cat I, II and III) do not follow the same rationale as those used in the CLP Regulation.

Summarising, the more substances identified under an option which is implemented under the current legal framework (Option A), the more likely the derogations would be applied and legal certainty would therefore be decreased. Therefore and based on the results of the screening, the options would perform 4>2>1>3. With respect to operability, it can be expected that the more substances are identified as EDs, the more case-by-case derogations are expected which would lead to higher operability difficulties and additional burden, implying that the options rank 4 > 2/3 > 1.

Coherence between the PPP and BP legislation on the implementation of the ED criteria is not achieved under the current regulatory decision making (Option A) because the current derogations differ in these two pieces of legislation for approval of substances identified as EDs. This is particularly important as some chemical substances (currently 38) fall under both the PPP and BP legislation. The more substances identified, the more cases for derogations are likely to arise, and the less the coherence between the PPP and BP Regulations is obtained. Thus, the options would perform this way: 4>2/3>1.

Compliance with international obligations (e.g. those under the WTO-Sanitary and Phytosanitary (SPS) agreement and Codex Alimentarius) was also considered. The issue of the assumed non-compliance of options to set ED criteria based on hazard (Option A for PPP) has been raised increasingly by WTO Members at every Technical Barriers to Trade (TBT) and SPS Committee meeting since October 2013. In the public consultation, six public authorities and six governments from non-EU countries gave their comments. One of the main issues they stressed was the potential impact on trade triggered by ED criteria based on hazard alone, whereas the SPS agreement lays down that measures have to be based on risk assessment.

Options 1, 2 and 3 are all based on the identification of hazard. However, Option 4 will perform comparatively better than the others in terms of compliance with WTO rules as it goes one step further in the direction of risk assessment by including potency as one element of hazard characterization. This implies a ranking of options 4 > 2/3/1.

5.3.2. Human health (Annexes 9 and 10)

Protection of human health is a Treaty objective (Art 168.1) and a key objective for both the PPP and BP Regulations. In the context of this impact assessment, impacts and evidence regarding hormone related diseases were analysed, but also impacts on transmissible diseases caused by lack of appropriate disinfectants or insecticides and food safety (in particular contamination by mycotoxins).

In the public consultation, concerns regarding food safety and public health were raised by public authorities, professional associations, and NGOs. Some EU MS (France, Denmark, Sweden), health, environmental and consumer NGOs call for EU criteria to identify EDs based on hazard that would also include additional categories based on the different strength of evidence for fulfilling the WHO/IPCS definition (Option 3). On the other hand, some EU MS (Germany, UK) support risk assessment (Option B, see Section 5.4) or Option 4 (WHO definition and inclusion of potency).

The association between incidence of certain human diseases and exposure to EDs have been raised in some international reports (WHO-UNEP, 2012[59]) or stakeholder statements (Endocrine Society, 2009[60], 2015[61]). Evidence, including EU data, is scattered and its interpretation difficult. The evidence available which aims at demonstrating effects of ED, is often linked to substances which are already banned in the EU. Epidemiological information, including cohort studies and systematic reviews, suggests that a causal link between the exposure to PPP and certain human diseases is not proven or not applicable to the regulatory situation in the EU with respect to PPP and BP (EFSA[62]; "AgriCan"[63]). Also the recent RPA study[64] stresses that health outcomes are often the results of the synergies of multiple factors. For long latency diseases a number of assumptions is required which seriously limits the value of any indicator trying to measure the contribution of chemicals legislation in lowering exposures.

Estimates on costs of diseases related to exposure to EDs which were recently published should be taken with caution. There are concerns over the validity of these estimates and the methods used to calculate them, which are linked to the scattered evidence. Moreover performing a Cost of Illness (CoI) analysis is always very challenging (Annex 9).

Further, it needs to be acknowledged that science is still evolving and that controversy between scientists still exists regarding some key aspects which are not relevant for the identification of EDs but are relevant for the assessment of EDs. This controversy is also reflected in recent meetings and events, for instance the "meeting with the former Chief Scientific Advisor of the European Commission Ms Ann Glover" (2013)[65], the conference "EDs: criteria for identification and related impacts" (1st June 2015, Brussels)[66], and the "Expert Meeting to Reach Scientific Consensus on EDs" (April 2016, Berlin, chaired by the German Federal Institute for Risk Assessment).

Summarising, the evidence related to **endocrine mediated diseases** and associated costs shows that under the existing EU regulatory framework with respect to PPP and BP robust

[59] World Health Organization (WHO) 2012. State of the science of Endocrine Disrupting Chemicals 2012. Summary for Decision-Makers. Ed. Bergman Å., Heindel, J.J., Jobling S., Kidd, K.A., and Zoeller R.T. Retrieved from http://www.unep.org/pdf/WHO_HSE_PHE_IHE_2013.1_eng.pdf

[60] Diamanti-Kandarakis E. et al. 2009 Endocrine-Disrupting Chemicals: An Endocrine Society Scientific Statement. Endocrine Reviews 30(4):293-342, doi:10.1210/er.2009-0002, available on: https://www.endocrine.org/endocrine-press/scientific-statements

[61] Gore, A.C., et al. 2015. EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals. Endocrine Reviews 36 (6) doi.org/10.1210/er.2015-1010

[62] European Food Safety Authority. 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 8(6):1637. [90 pp.]. doi:10.2903/j.efsa.2010.1637

[63] Levêque-Morlais, N., et al. 2015. The AGRIculture and CANcer (AGRICAN) cohort study: enrolment and causes of death for the 2005–2009 period. International Archives of Occupational and Environmental Health. 88 (1): 61-73. DOI 10.1007/s00420-014-0933-x

[64] Risk and Policy Analysts (RPA) et al. 2015. Study on the Calculation of the Benefits of Chemical Legislation on Human Health and the Environment, Final report for DG Environment, March 2016, Loddon, Norfolk, UK

[65] European Commission. 2013. Minutes of the expert meeting on endocrine disruptors. Retrieved from: http://sciences.blogs.liberation.fr/files/glover-u-s-perturbateurs-endocriniens.pdf

[66] European Commission. 2015. Conference "Endocrine disruptors: criteria for identification and related impacts". Retrieved from: http://ec.europa.eu/health/endocrine_disruptors/events/ev_20150416_en.htm

conclusions cannot be drawn on the link between exposure to EDs and increased incidence of endocrine mediated diseases. Nevertheless, protection of human health remains the highest priority as it is a main objective in the PPP and BP Regulations, and thus guides this impact assessment. Protection of human health was therefore analysed under consideration of the current regulatory framework of the PPP and BP Regulations.

The EU authorisation system for PPP and BP is based on prior approval (a "positive list"), i.e. substances are deemed hazardous until proven otherwise.30 This also applies to the assessment of **adverse effects linked to EDs.** Most of the adverse effects associated with endocrine disruption are covered by the "standard" risk assessment carried out for a substance even if this substance is not identified as an ED (for example, reproductive adverse effects). This is confirmed by the high number of PPP commonly associated with the endocrine mediated diseases which have already been banned for years in the EU (see Table 3 in Annex 9). It is also confirmed by the fact that Member States could not find an agreement on whether it would be appropriate under REACH Regulation to identify some substances as EDs for their adverse effect human health: several Member States in fact argue that the *very same* adverse effects triggering the identification as EDs of those substances are already considered via the classification as substances toxic for reproduction. These Member States clearly argue that identification as EDs would mean *double-counting* the same effects with no added in a regulatory context.

The substances identified under the ED criteria defined in Options 1 to 4, under the current PPP and BP Regulations (Option A), may be approved subject to conditions if the foreseen derogations apply. However, in case a substance is not identified as an ED under any of these criteria, it still goes through a "standard" risk assessment, which includes assessment of human health (see Figure 1). A substance with endocrine disrupting properties, whether identified as an ED or not, would only be approved if it has no harmful or unacceptable effects on human health. As a consequence, even if Option 2, 3 and 4 identify a different number of EDs, it can be assumed that the approval procedure of the substance will act as a safety net and ensure that human health is protected to the same extent for any of these options. This assumption can be also applied to "false negatives", i.e. substances which are not identified as ED under Options 1 or 4 but are identified as ED under Option 2 or Option 3 Category 1. However, Option 1 fails to detect some modalities, e.g. thyroid modality. Although these "false negative" substances would be covered by the "standard" risk assessment under the PPP and BP Regulations, nevertheless Option 1 can be considered as not fit for purpose to detect ED because some modalities are not covered. In addition, Option 1 identifies “false positives”, i.e. substances with no endocrine mode of action. These substances would be removed from the market (unless derogations apply) although they are not EDs according to the WHO/IPCS definition. This might in turn have negative impacts on human health because of higher risks of occurrence of mycotoxins and transmissible diseases, while not identifying the correct EDs. Therefore, with respect to endocrine mediated diseases the options are considered to perform as follows: 2/3/4>1.

In addition, a sensitivity analysis which includes a variation of the performance of the options was performed. The MCA-scenario "aim: exposure zero" assessed the performance of the options based on a different assumption which only aims at minimizing exposure: the higher the number of active substances identified as EDs, the better the performance of the option for human health with respect to exposure (without consideration of any risk assessment). As a consequence, within this scenario, the options perform as 2/3 > 4 > 1 only based on exposure considerations.

Transmissible diseases can be passed from person to person or from a host/product to a person. This can occur by direct contact, by food or through a vector (for example mosquitos).

Disinfectants are extensively used in hospitals or other health care setting to prevent and control diseases. Disinfectants are also extensively used in the food industry to ensure the microbial safety of food products. Insecticides are used to control insects which transmit human diseases. In the screening of biocidal active substances one of the 44 included disinfectants (Iodine) and one of the 49 the included pest control substances (Cypermethrin) was identified as an ED. However, the results of the screening should be very cautiously interpreted as it is not possible to judge how representative the screening results are for biocides. For example, the screening did cover only 44 of 266 disinfectants. In addition, not only the number of substances but also which substances are important to consider, as they may target different disease agents. The results indicate that the different options may results in different numbers of disinfectants or insecticides identified as ED.

The case of iodine (used as disinfectant) is interesting. In the screening it is identified as ED under Options 2, Option 3 Category I and Option 4. Iodine is a physiologically essential element and it is required for the synthesis of the thyroid hormones. This means that both iodine deficiency as well as excess iodine can affect thyroid hormone levels. This substance was identified in the screening as an ED, since it can produce adverse effects via an endocrine mode of action. At the doses used as disinfectant, it would unlikely pose any risk to human health and the environment. However, if identification as an ED was confirmed in a formal assessment, it would be regulated as an ED under the BP Regulation.

Although the BP Regulation provides the possibility of applying derogations for the approval of an ED substance, it can be assumed that the number of disinfectants or substances available to control vectors[67] may decrease for professional users, even if derogations may be granted. Nonetheless several disinfectants remain available on the market, this may have a health impacts as there is a need for a wide spectrum of disinfectants (there is no single universal disinfectant which kills all pathogenic micro-organisms). Critical impacts may in particular occur if key substances would not be available and no appropriate alternatives could be found or developed. Based on the current information it cannot be excluded neither properly estimated whether non-approval of key biocidal substances for transmissible diseases will occur. Notwithstanding the high uncertainties it can be assumed that the impacts would be associated to the number of biocides that would be identified as ED. Therefore, it can be assumed that, with respect to transmissible diseases, an option would perform worse if it identifies a higher number of EDs, i.e. options perform as follows: 4>2/3>1.

Food safety of agricultural products or derived products may be at risk of **contamination by mycotoxins**. Mycotoxins are dangerous substances produced during storage or plant growth by fungi species (moulds). They are one of the most important categories of biologically produced natural toxins, including some which are EDs like zearalenone found on several foods and feeds in temperate regions worldwide.[68] To protect humans and animals from the dangerous effects of mycotoxins (e.g. liver cancer), the European Commission has set maximum levels in food and feed products.

PPP are used on certain crops in order to limit the growth of fungi and consequently the contamination by mycotoxins. Other methods to reduce the presence of mycotoxins are crop rotation (growing different crops on a field in different years) and using resistant plant varieties.

[67] A vector is an organism, often an invertebrate arthropod, that transmits diseases (it transmits a pathogen from reservoir to host).

[68] Zinedine, A. et al. 2007. Review on the toxicity, occurrence, metabolism, detoxification, regulations and intake of zearalenone: an oestrogenic mycotoxin. Food Chem Toxicolo 2007; 45(1):1-18. Retrieved from: http://www.ncbi.nlm.nih.gov/pubmed/17045381

The screening of PPP for endocrine disrupting properties resulted in a varying number of PPP identified under the four options (see Annex 5). In all the options PPP were identified belonging to the group of azoles (for example, cyproconazole, tebuconazole, tetraconazole, see Table 3 in Annex 5). This group of fungicides is considered to be important for mycotoxin control in the EU. Depending on the option, the group of azoles would be impacted between 5% and 35%. Option 4 identified both the lowest number of PPP as EDs and the lowest number of substances belonging to the group of azoles (see Figure 3 and Table 3 in Annex 5). An analysis of the identified substances under each option points out that substances in the same group of PPP remain available to manage fungi (see Annex 5, Table 2 analysing the outcome of screening for groups of PPP). However, it is unclear whether these alternatives are equally effective to control the fungi producing mycotoxins and whether the efficacy will be reduced in the short term because of the development of resistance (see Annex 13). So, it is not possible to quantify to which extent the loss of one or more PPP, including substances belonging to the group of azoles, would lead to higher levels of contamination of crops and consequently higher levels of mycotoxins in food and feed in the future as many factors influence the occurrence of mycotoxins. Notwithstanding the uncertainties it could be assumed that the likelihood of having an impact on health will be probably higher if an option results in less PPP active substances available on the market belonging to a group of PPP relevant for the control of fungi producing mycotoxins. This implies that Option 4 appears relatively the best option in relation to control mycotoxin contamination of food and feed, followed by Option 2 and Option 3, i.e. the options perform 4 > 2/3 > 1.

5.3.3. Environment (Annex 11)

In general terms, the use of chemicals may have environmental effects. In addition, human health might be affected via environmental exposure. Animal welfare (animal testing) is also considered in this chapter. It was a concern for several respondents to the public consultation who specifically called for the development and use of methods that do not rely on animal testing in order to produce safety data.

A recent study carried out for the European Commission[69], concluded that it was not possible to identify robust and reliable environmental impact indicators in relation to ecosystem services or species level effects. The indicators that could be developed for the environment were limited inter alia because of the lack of monitoring data.

For the purpose of this impact assessment, exposure via water (groundwater, drinking water and surface water) was considered, as well as the potential effects on vertebrate populations. In addition, animal welfare, in the context of animal testing required for regulatory purposes, was considered in line with Tool # 16 of the Better Regulation Guidelines.

Regarding the MCA-criterion **"*chemical* quality of groundwater, drinking water and surface water"**, the assessment was carried out under the assumption that any potential presence of active substance is to be avoided and that the chemical quality of the water is inversely proportional to the amount of any active substance potentially present in it. Under this assumption, it could be concluded that the higher the number of substances removed from the market or restricted, the higher the likelihood that the chemical status of the water improves. The options would therefore perform: 1>2/3>4. However, it should be noted that this approach does not take into account the fact that for groundwater, strict thresholds

[69] RPA et al. 2015. Study on the Calculation of the Benefits of Chemical Legislation on Human Health and the Environment, Final report for DG Environment, March 2016, Loddon, Norfolk, UK

already apply and that for surface water, levels of chemicals below certain thresholds would actually pose no risk to aquatic organisms.

In order to carry out a sensitivity analysis which includes a variation of the performance of the options, the MCA-scenario "aim: exposure zero" was developed. It assessed the performance of the options based on an assumption that aims at minimizing exposure: the higher the number of active substances identified as EDs, the better the performance of the option for the environment with respect to exposure (without consideration of any risk assessment). As a consequence, within this scenario, the options perform 1>2/3>4 only based on exposure considerations.

Decline in some **wildlife vertebrate populations** might be at least partially due to exposure to EDs in the environment. However, a number of other factors including overexploitation, loss of habitat and climate change are also likely to be contributing causes to this decline.

PPP and BP are the most "data rich" regulated product groups in the EU. A detailed list of data requirements has to be submitted by the applicant before any approval of the active substance or authorisation of a product containing the approved substances can be considered. These core data requirements include testing of several non-target species, cover several ecological compartments and, include assessment of reproductive effects. It can thus be assumed that effects on wildlife species, in terms of potential reproductive effects which may be relevant for population effects, are assessed. Tests which cover endocrine disrupting endpoints have been added recently to the data requirements. Moreover, evidence shows that most substances generally linked to ED effects have already been banned in the EU or have been approved subject to strict conditions in recent years, reflecting the regulatory system in place in the EU and its focus, inter alia, on protecting the environment. As a consequence, it can be assumed that wildlife vertebrate populations are equally protected by the standard risk assessment foreseen under the PPP and BP Regulations, irrespectively of how many substances are identified as ED under different options of the criteria. However, Option 1 fails to detect some modalities, e.g. thyroid modality. Although these "false negative" substances would be covered by the "standard" risk assessment under the PPP and BP Regulations, nevertheless Option 1 can be considered as not fit for purpose to detect ED because some modalities are not covered. The performance of options for wildlife vertebrate populations is therefore: 2/3/4 > 1.

In order to carry out a sensitivity analysis which includes a variation of the performance of the options, the MCA-scenario "aim: exposure zero" was developed. It assessed the performance of the options based on an assumption that aims at minimizing exposure: the higher the number of active substances identified as EDs, the better the performance of the option for the environment with respect to exposure (without consideration of any risk assessment). As a consequence, within this scenario, the options perform 2/3 > 4 > 1 only based on exposure considerations.

In terms of **animal welfare**, all options rank the same, irrespective of the number of substances they identify as ED. However, Option 3 with the inclusion of additional categories, might trigger additional animal testing by third parties which would want to verify if the chemicals, classified in Category II or III, are EDs or not. This would not be in line with the objectives of Directive 2010/63/EU on the protection of animals used for scientific purposes. The ranking of the options is therefore considered to be 1/2/4>3.

5.3.4. Sectorial competitiveness: EU agriculture (Annexes 12 and 13)

Agriculture plays a critical role in the EU, providing food security, high quality food and also generating jobs in the farming, food and related sectors. The use of PPP plays an important role in agricultural production, and the availability of sufficient tools to control pests and weeds is crucial to farmers. Farmers are usually agricultural holdings with less than 250 employees and can therefore qualify as SMEs.

In their answers to the public consultation, farmers generally expressed concerns about the yield losses that would result from the potential disappearance of key PPP, the development of resistance that might occur (if only a few similar types of PPP remain available) and expressed their preference for a more proportionate decision making concerning EDs that would include elements of risks (Option B, see Section 5.4).

The current legislative framework foresees a non-approval of active substances identified as EDs used in PPP, unless derogations apply. Thus, an impact on the number of PPP available to farmers is expected as a consequence of the non-approval of active substances identified as ED. This impact will also have consequences on the cultivation of crops for which some PPP may no longer be available, and the number of available alternatives to fight a given pest or disease. This latter aspect is important from an agricultural point of view, as recognised by on-going international activities focusing on this topic, carried out by the European and Mediterranean Plant Protection Organisation (EPPO)[70] or the Food and Agriculture Organisation of the United Nations (FAO)[71]. A reduction in the number of active substances with a different mode of action is expected to increase the risk of development of resistance in pests and diseases, since the exclusive reliance on a single active substance and the lack of diversity of available control measures are agronomic factors which increase the risk of resistance (EPPO, 2015).[72] Resistance may decrease the efficacy of a whole chemical group of PPP, leaving farmers with insufficient alternatives to tackle plant health problems.

Considering the three MCA-criteria chosen for assessing impacts on agriculture, it appears in the case studies carried out to assess the performance of the options that Option 4 would have the lowest impact. Option 1 and Option 2/3 Category I perform differently depending on the criterion chosen and, for PPP authorised and crops affected, the MS analysed. Intuitively, one would think that the higher the number of actives substances identified as ED, the higher the number of PPP authorisations and the number of crops that would be affected. Such an assumption would lead to Option 1 (the one identifying the highest number of active substances as ED) being the one performing the worst. However, the evidence available for the 8 MS which provided data did not confirm this in most of the cases. In almost all the 8 MS analysed, Option 1 is the second best performing option and has less impact in terms of PPP and crops affected than Options 2/3 Category I. Thus, as a result of the case studies the options perform 4>1>2/3.

The availability of alternatives and the risk of developing resistance was analysed based on the data available under Regulation (EC) No 1185/2009 concerning statistics on pesticides. In a first step, the chemical classes that would be affected by the potential non approval of the active substances identified as endocrine disruptors (EDs) under the different options were analysed in terms of percentage of active substances that would be affected per chemical class

[70] EPPO activities on resistance to plant protection products. Retrieved from: https://www.eppo.int/PPPRODUCTS/resistance/resistance.htm

[71] For instance FAO Guidelines on Prevention and Management of Pesticide Resistance. International Code of Conduct on the Distribution and Use of Pesticides. September 2012.

[72] EPPO 2015. PP 1/213 (4) Resistance risk analysis. Bulletin OEPP/EPPO Bulletin (2015) 45 (3), 371–387 ISSN 0250-8052. DOI: 10.1111/epp.12246.

and major group (e.g. herbicides, fungicides, and insecticides). It is assumed that the higher the percentage of chemical class affected, the lower the number of alternatives existing. Similar calculations were performed for the volumes of sales of these active substances. As a result of the analyses, Option 2/3 Category I is expected to have less impact than Option 1. Overall, the options perform this way: 4 > 2/3 >1.

5.3.5. Sectorial competitiveness: PPP, BP, and related industries (Annex 14)

Sectorial competitiveness is particularly important in the context of the current EU priorities: boosting jobs, growth and investment. This applies to the various sectors involved, e.g. producers of raw materials, formulators of PPP and BP, downstream users (e.g. farmers, food processors, the paint and coating industry, healthcare facilities like hospitals), related industries (application equipment), and consumers. Sectorial competitiveness has been assessed considering in particular the impact on research and innovation, the burden to SMEs and the functioning of the single market.

Before analysing the impacts it is important to refer to the general discussion about the impact of stricter rules on innovation. Many companies and industry organizations consider stricter rules as having a negative impact on innovation and competitiveness as it diverts personnel and resources away from R&D and production activities. On the other hand, it is argued that regulation can have a positive effect on innovation and growth: for example, requirements could promote innovation by encouraging the replacement of hazardous chemicals with more sustainable alternatives. Both views were expressed by respondents in the public consultation. In their answers to the public consultation, industry representatives generally expressed their preference for a decision making concerning EDs based on risk (Option B, see Section 5.4) as they believe that further elements of hazard characterisation (severity, (ir)reversibility, potency and lead toxicity) should be included in the criteria (potency is included in Option 4).

Competitiveness and innovation in companies in the supply chain is driven by a wide range of factors (energy prices, labour costs and productivity, infrastructure, taxation, regulatory environment etc.). It is stressed that setting criteria for EDs is just one issue that may affect the innovative capacity or competitiveness of EU companies. Information is lacking in order to compare the size of the impact of setting EDs in relation to those other factors impacting competitiveness and innovation. Also should be considered that in general, not linked to the setting of criteria for EDs, a decrease of the number of active substances and BP and PPP available on the market in the EU has taken or is still taking place.

The criteria for EDs may lead to additional costs and increase the time it takes to put PPP and BP on the market as more tests and data may be required to evaluate whether a chemical for which an endocrine mode of action is determined can be considered an ED. It is expected that setting the ED criteria would imply that some substances incorporated in PPP or BP will be non-approved or approved under more restrictive conditions. Taking into account the current drivers for innovation (energy prices, labour costs and productivity, infrastructure, taxation, regulatory environment etc.) and the market structure (for instance, multinationals focus their R&D on growth markets), this may not necessarily trigger substantial **innovation** for replacing these by alternative substances for use in PPP and BP or alternative techniques. For downstream users and formulators it is difficult to judge whether the proposals will lead to additional innovation because of the many factors involved. For example, many major industrial sectors are relying on the use of BP. This market is segmented and consists of highly diverse group of enterprises that may respond differently. It will also depend on the substance in question. For key substances in the supply chain probably quicker increased R&D will occur. It is important to note that replacing a chemical in an article or a mixture can

imply that companies need to change their technologies or processes. It can also imply to establish new relations with suppliers.

With respect to the functioning of the **single market**, the derogations foreseen in the PPP and BP Regulations are expected to create new complexity (specific conditions that would apply in each MS and the interpretation and the enforcement of those conditions). As a consequence, the availability of PPP and BP to downstream users (farmers, professional users, health care sector and food chain producers, industry, etc.) may differ between MS, creating an unequal playing field for downstream users.

SMEs play an important role both in the PPP and BP sector, as well as in downstream and related industries. In general it can be concluded that any increase in costs and demand in human resources would negatively affect the market position of SMEs because SMEs are less able than larger firms to accommodate such costs and additional demand in personal resources and expertise. Moreover, SMEs in general have less active substances in their portfolio than larger companies, therefore making them more vulnerable to the non-approval of substances identified as ED. This could lead to a reduction of SMEs, to even further concentration in the BP and PPP-sector and to less competition.

To sum up, the impacts on all aspects on sectorial competitiveness are related to the number of substances identified as ED. Therefore the options would perform this way: 4>2/3>1.

5.3.6. International trade (Annex 15)

Trade is essential to economic growth and job creation in the EU. Around two thirds of EU imports are raw materials, intermediary goods and components needed for companies' production processes. Imports on food, feed, and treated articles are the three commodity groups used as MCA-criteria for trade in this impact assessment. These groups cover many products imported to the EU and are essential for food security and important to a wide range of trading partners. While impacts on food and feed imports are mainly related to PPPs, impacts on treated articles are mainly related to BP.

Exporters to the EU have to comply with the food and feed safety standards of the EU. An active substance identified as an ED may lead to impacts on trade as the allowed Maximum Residue Levels (MRLs) of the substance in products imported in the EU would have to be lowered to the limit of determination (LOD) in accordance with point 3.6.5 of Annex II of Regulation (EC) No 1107/2009. In practice, this means that many of the active substances for which the MRLs are lowered cannot be used in the production of food or feed in third countries.

In the public consultation, third countries raised concern over the potentially significant trade implications of setting criteria to identify EDs based on hazard, and asked for a risk-based approach to be taken (Option B, see Section 5.4). They reminded the European Commission that any decision on EDs needs to respect the principles of the WTO (notably Article 5 of the SPS agreement). The topic of setting ED criteria by the different options has raised attention in the WTO Technical Barriers to Trade (TBT) and Sanitary and PhytoSanitary (SPS) Committees since 2013, where an increasing number of WTO Members are taking the floor to express concerns.

Examples of countries and crops that may be affected are wine from Chile, bananas from Latin America, soybeans imported for the production of feed, as well as citrus fruit from South Africa, to name just a few.

It is difficult to quantify precisely the potential impacts on trade. However, an analysis was carried out by using the screening results (see Section 5.2 and Annex 5) and then quantitatively assessing the number of MRLs that would be lowered to LOD for a selection of the most valuable imported crops under the four options. Data from the EU Pesticide Database on MRLs and Eurostat COMEXT trade databases were used to carry out the analysis. To determine how the options rank against each other it is assumed that the more MRLs lowered for a certain crop, the greater negative impact. Furthermore, the higher the value of imports expected to be affected, the worse an option performs. Therefore, the analysis of trade impacts can be considered as set of case studies which is based on the identity of substances identified under each option, and the MRLs which would be consequently lowered for a number of imported crops. For BPs, textiles have been selected as case study in order to illustrate potential impacts.

For the most **imported food crops** in terms of value, Option 4 consistently has the least impacts on trade. Looking beyond the best performing option, it is clear that all other options will have significant negative impacts on trade but it is highly dependent on the crop, e.g. citrus fruits will be more heavily impacted under Option 2/3 Category I, while wheat and barley is more impacted by Option 1. The overall performance is therefore 4 > 2 / 3 / 1.

The most impacted food crops in absolute terms would be tomatoes under Option 1 with 17 MRLs lowered. This represents 12 % of the total number of MRLs for tomatoes. Another crop highly impacted by Option 1 is barley with 15 MRLs lowered (13% of the MRLs set). Crops with high expected impacts under Option 2/3 Category I are wine and pears with 15 MRLs lowered. This represents 11% and 12% of the MRLs set, respectively.

The EU is highly dependent on **imports of feed**, and an increase in feed costs could weaken the competitiveness of the EU livestock sector. A trade disruption could amplify the current EU protein deficit for the livestock sector and the need for alternative sources. The analysis focused on four imported products mainly used for feed; soybeans, maize, rapeseed and cottonseed. Option 4 would have the least negative impacts, followed by Option 2/3 Cat I, with Option 1 having the most negative impacts on trade. The performance is 4 > 2 / 3 > 1

In the BP Regulation, an article containing a BP ("**treated article**") shall not be placed on the EU market unless all active substances that it incorporates are approved in the EU. This is expected to have consequences on imported products. Textiles are used as a case study to analyse the potential impacts because 80% of the textile articles used in the EU are imported, mainly from Asia. Textiles could be treated to prevent growth of mould during storage and transport or to create special functions, such as anti-odour in sportswear. One impact of non-approval of a biocidal active substance could be higher prices of treated articles as a limited number of companies would be able to supply treated articles of the same quality. Another possible impact may be the removal of certain treated articles from the EU market because of the lack of alternatives. The impact of the options are assumed to be correlated with the number of AS identified as ED, thus, Option 4 performs better than Option 2/3 Cat I which performs better than Option 1.The performance is 4 > 2 / 3 > 1.

5.4. Direct and indirect impacts in different policy areas expected under consideration of different implementation of the ED criteria and different approaches to regulatory decision making (Aspect II)

The regulatory consequences (i.e. implementation) of the criteria to identify EDs are already set under the PPP and BP Regulations and are driving the impacts of the criteria, as detailed in Section 5.3.

Because the regulatory consequences differ in terms of scope and implementation under the PPP and BP Regulations, adding complexity to the impact assessment, a second set of options was developed (Aspect II). This set of options under Aspect II considers in particular the implementation of the ED criteria into the PPP and BP Regulations and their different approaches to regulatory decision making. For methodological reasons the options developed cover the entire spectrum of potential policy choices and address the difference in the current derogations between the PPP and the BP Regulations. Two options were developed in addition to the current provisions in the BP and PPP Regulations (Option A): the possibility to modify an annex of the PPP Regulation under regulatory procedure with scrutiny (Option B), and the possibility to modify the PPP Regulation under ordinary legislative procedure (Option C). Obviously, Options B and C are not relevant for the BP Regulation.

At a preliminary stage of the impact assessment it was anticipated that Option C should be discarded, nevertheless it was maintained for the analysis of the impacts for methodological reasons (see Section 4.2.3 and Annexes 6 and 7). The impacts discussed in this section only refer to Option B compared to Option A, and are only applicable to the PPP Regulation as mentioned above (see also Section 4.2.2).

The impacts are expected to cover the same areas as those discussed under Section 5.3, which addresses the implementation of the criteria to identify EDs under the current regulatory framework. In the current section addressing the options under Aspect II, it was evaluated if potential changes to regulatory decision making would lead to the same, more or less impact for the different areas. Therefore, the comparison of Options B or C with the current regulatory framework (Option A) could only be done qualitatively, as robust evidence on the outcome of regulatory decision making takes usually 2 to 3 years for each substance evaluated, which is outside the timeframe for this impact assessment.

Option B, i.e. taking regulatory decisions based on risk assessment, is supported by some Member States and all third countries replying to the public consultation. Industry and farmers also indicated to support a regulatory decision making based on risk considerations.

5.4.1. Achievement of effectiveness and coherence (Annex 8)

The effectiveness of the options to fulfil the objectives of these Regulations was assessed considering legal certainty and operability, while coherence was assessed considering the coherence between the PPP and BP Regulations and the compliance with international obligations of the EU (WTO and Codex Alimentarius). It was assumed that clearer derogations based on current scientific knowledge (Option B) would increase legal certainty and lead to higher operability because of less controversial discussions during the regulatory decision making foreseen under the PPP Regulation. As a consequence, for both criteria the options are ranked B > A.

Coherence between the PPP and BP legislation on the implementation of the ED criteria is not achieved under Option A (no changes to the regulatory decision making), as the current derogations differ in these two pieces of legislation for approval of substances identified as EDs. An alignment of the PPP derogations to the BP derogations (Option B) would ensure more coherence between these two pieces of legislation in terms of consideration of risk, and would ensure that the criteria to identify EDs would be implemented consistently. This is particularly important as some chemical substances (currently 38) fall under both the PPP and BP legislation. Thus, the options would perform B > A.

Compliance with international obligations (e.g. those under the WTO-Sanitary and Phytosanitary (SPS) agreement and Codex Alimentarius) was also considered. The issue of

the assumed non-compliance of options to set ED criteria based on hazard (Option A for PPP) has been raised increasingly by WTO Members at every Technical Barriers to Trade (TBT) and SPS Committee meeting since October 2013. In the public consultation, six public authorities and six governments from non-EU countries gave their comments. One of the main issues they stressed was the potential impact on trade triggered by ED criteria based on hazard alone, whereas the SPS agreement lays down that measures have to be based on risk assessment. In Option A, the decision making is mainly based on hazard, while Option B considers the inclusion of further elements of risk assessment in the derogations of the PPP Regulation. Therefore, the options regarding decision making would perform B > A.

5.4.2. Human health (Annexes 9 and 10)

Protection of human health is a Treaty objective (Art 168.1) and a key objective for both the PPP and BP Regulations. In the context of this impact assessment, impacts and evidence regarding hormone related diseases were analysed, but also impacts on food safety (in particular contamination by mycotoxins). Potential impacts on transmissible diseases are not considered relevant in this section because they are only related to the availability of BP, which are not relevant as explained in Section 5.4.

In the public consultation, concerns regarding food safety and public health were raised by public authorities, professional associations, and NGOs. Some EU MS (Germany, UK) support risk assessment (Option B).

Potential impacts on human health are described in detail in Section 5.3.2. Summarising, the evidence related to **endocrine mediated diseases** and associated costs shows that under the existing EU regulatory framework with respect to PPP and BP robust conclusions cannot be drawn on the link between exposure to EDs and increased incidence of endocrine mediated diseases. Protection of human health was therefore analysed under consideration of the current regulatory framework of the PPP and BP Regulations. The EU authorisation system for PPP and BP is based on prior approval (a "positive list"). This implies that most of the adverse effects associated with endocrine disruption are covered by the "standard" risk assessment carried out for a substance even if this substance is not identified as an ED (for example, reproductive adverse effects). This is confirmed by the high number of PPP commonly associated with the endocrine mediated diseases which have already been banned for years in the EU (see Table 3 in Annex 9).This is also confirmed by the fact that Member States could not find an agreement on whether it would be appropriate under REACH Regulation to identify some substances as EDs for their adverse effect human health.

Recent available Scientific Opinions from EU Agencies and Scientific Committees regarding EDs argue in favour of the use of risk assessment decision making in order to maximise available information to protect human health compared to decision making that is based on hazard alone. Also recent WHO reports (2014[73], 2015[74]) recommend to identify risks from exposure to EDs. Considering that the current rules (i.e. the risk assessment step following identification or non-identification of a substance as an ED) ensure that authorised products do not have unacceptable effects on the health of humans, it can be assumed that Option A and B have the same impact with regard to potential adverse effects caused by exposure to EDs. As a consequence, with respect to endocrine mediated diseases, the options A and B perform the same: A/ B.

[73] WHO 2014. Identification of risks from exposure to EDCs at the country level.
[74] WHO. 2015. Identification of risks of EDCs: overview of existing practices and steps ahead. Report of a meeting in Bonn, Germany 7-8 July 2014

In order to carry out a sensitivity analysis which includes a variation of the performance of the options, the MCA-scenario "aim: exposure zero" was developed. It assessed the performance of the options based on a different assumption which only aims at minimizing exposure: the higher the number of active substances identified as EDs, the better the performance of the option for human health with respect to exposure (without consideration of any risk assessment). The assessment to evaluate the options under Aspect II was based on the number of correctly identified ED substances which will not be approved. As Option A would take from the market (non-approval) more substances identified as EDs than Options B, it is assumed that it would perform the best in a scenario only based on exposure considerations.

Food safety of agricultural products or derived products may be at risk of contamination by mycotoxins. Mycotoxins are one of the most important categories of biologically produced natural toxins, including some which are EDs like zearalenone found on several foods and feeds in temperate regions worldwide.[75] PPP are used to limit the growth of fungi and consequently the contamination by mycotoxins.

The screening of PPP for endocrine disrupting properties resulted in a varying number of PPP identified under the four options (see Section 5.3.2. and Annex 5). In all the options PPP were identified belonging to the group of azoles, a group of fungicides considered important for mycotoxin control in the EU. The group of azoles would be impacted between 5% and 35%. Notwithstanding the uncertainties it could be assumed that the likelihood of having an impact on health will be probably higher if an option results in less PPP active substances available on the market belonging to a group of PPP relevant for the control of fungi producing mycotoxins. This implies that Option B (which considers derogations based on risk) performs better than Option A (which considers derogations based mainly on hazard).

5.4.3. Environment (Annex 11)

In general terms, the use of chemicals may have environmental effects. In addition, human health might be affected via environmental exposure. Animal welfare (animal testing) is also considered in this chapter. It was a concern for several respondents to the public consultation who specifically called for the development and use of methods that do not rely on animal testing in order to produce safety data.

A recent study carried out for the European Commission[76], concluded that it was not possible to identify robust and reliable environmental impact indicators in relation to ecosystem services or species level effects. The indicators that could be developed for the environment were limited inter alia because of the lack of monitoring data. For the purpose of this impact assessment, exposure via water (groundwater, drinking water and surface water), the potential effects on vertebrate populations and animal welfare, in the context of animal testing required for regulatory purposes, was considered.

Potential impacts on **chemical quality of groundwater, drinking water and surface water** were evaluated assuming that any potential presence of active substance is to be avoided and that the chemical quality of the water is inversely proportional to the amount of any active substance potentially present in it. Under this assumption, it could be concluded that the higher the number of substances removed from the market or restricted, the higher the

[75] Zinedine, A. et al. 2007. Review on the toxicity, occurrence, metabolism, detoxification, regulations and intake of zearalenone: an oestrogenic mycotoxin. Food Chem Toxicolo 2007; 45(1):1-18. Retrieved from: http://www.ncbi.nlm.nih.gov/pubmed/17045381

[76] RPA et al. 2015. Study on the Calculation of the Benefits of Chemical Legislation on Human Health and the Environment, Final report for DG Environment, March 2016, Loddon, Norfolk, UK

likelihood that the chemical status of the water improves. However, this approach does not take into account the fact that for groundwater, strict thresholds already apply and that for surface water, levels of chemicals below certain thresholds would actually pose no risk to aquatic organisms. Options A and B are considered to rate equally assuming that both would lead to chemical qualities which fulfil the strict thresholds provided under the PPP Regulation and would not pose a risk to organisms.

In order to carry out a sensitivity analysis which includes a variation of the performance of the options, the MCA-scenario "aim: exposure zero" was developed. This scenario aims at minimizing exposure and considers that the higher the number of active substances identified as EDs, the better the performance of the option for the environment with respect to exposure (without consideration of any risk assessment). The assessment was based on the number of correctly identified ED substances which will not be approved. As Option A would take from the market (non-approval) more substances identified as EDs than Options B, it is assumed that it would perform the best based on exposure considerations only.

Decline in some **wildlife vertebrate populations** might be at least partially due to exposure to EDs in the environment. However, a number of other factors including overexploitation, loss of habitat and climate change are also likely to be contributing causes to this decline.

PPP and BP are the most "data rich" regulated product groups in the EU. A detailed list of data requirements has to be submitted by the applicant before any approval of the active substance or authorisation of a product containing the approved substances can be considered. These core data requirements include testing of several non-target species, cover several ecological compartments and, include assessment of reproductive effects. It can thus be assumed that effects on wildlife species, in terms of potential reproductive effects which may be relevant for population effects, are assessed. Tests which cover endocrine disrupting endpoints have been added recently to the data requirements. Moreover, evidence shows that most substances generally linked to ED effects have already been banned in the EU or have been approved subject to strict conditions in recent years, reflecting the regulatory system in place in the EU and its focus, inter alia, on protecting the environment. As a consequence, it can be assumed that wildlife vertebrate populations are equally protected by the standard risk assessment foreseen under the PPP and BP Regulations, irrespectively of how many substances are identified as ED under different options of the criteria. Recent available Scientific Opinions from EU Agencies and Scientific Committees regarding EDs support the use of risk assessment decision making in order to maximise available information compared to decision making that is based on hazard alone. Therefore, Options A and B have the same impact with regard to potential adverse effects caused by exposure to EDs.

In addition, under the MCA-scenario "aim: exposure zero" which assesses the performance of the options aiming at minimizing exposure, it is assumed that Option A would take from the market (non-approval) more substances identified as EDs than Options B. Thus, Option A performs the best with respect to exposure only.

In terms of **animal welfare**, no difference is expected in terms of the number of required animal tests for Options A and B because the data requirements under the PPP and BP Regulations are already set.

5.4.4. Sectorial competitiveness: EU agriculture (Annexes 12 and 13)

Agriculture plays a critical role in the EU, providing food security, high quality food and also generating jobs in the farming, food and related sectors. The use of PPP plays an important role in agricultural production, and the availability of sufficient tools to control pests and

weeds is crucial to farmers. Farmers are usually agricultural holdings with less than 250 employees and can therefore qualify as SMEs.

In their answers to the public consultation, farmers generally expressed concerns about the yield losses that would result from the potential disappearance of key PPP, the development of resistance that might occur (if only a few similar types of PPP remain available) and expressed their preference for a more proportionate decision making concerning EDs that would include elements of risks (Option B).

The current legislative framework foresees a non-approval of active substances identified as EDs used in PPP, unless derogations apply and MS agree with the derogations. Thus, an impact on the number of PPP available to farmers is expected as a consequence of the non-approval of active substances identified as ED. This impact will also have consequences on the cultivation of crops for which some PPP may no longer be available, and the number of available alternatives to fight a given pest or disease, as described more in detail in Section 5.3.4.

Considering the three MCA-criteria chosen for assessing impacts on agriculture and with respect to Aspect II, all options applied under the current legislative framework in the PPP sector (Option A) may lead to an impact on agriculture (see for more details Section 5.3.4). These impacts depend on the option chosen. Option B would allow decision making based on derogations which consider risk elements and would thus have less impact on agriculture than Option A. Thus, the options would perform this way for all MCA-criteria related to EU agriculture: B>A.

5.4.5. Sectorial competitiveness: PPP, BP, and related industries (Annex 14)

Sectorial competitiveness is particularly important in the context of the current EU priorities: boosting jobs, growth and investment. This applies to the various sectors involved, e.g. producers of raw materials, formulators of PPP and BP, downstream users (e.g. farmers, food processors, the paint and coating industry, healthcare facilities like hospitals), related industries (application equipment), and consumers. Sectorial competitiveness has been assessed considering in particular the impact on research and innovation, the burden to SMEs and the functioning of the single market. In their answers to the public consultation, industry representatives generally expressed their preference for a decision making concerning EDs based on risk (Option B).

Competitiveness and innovation in companies in the supply chain is driven by a wide range of factors (energy prices, labour costs and productivity, infrastructure, taxation, regulatory environment etc.) which are discussed more in detail in Section 5.3.5. In general, not linked exclusively to the setting of criteria for EDs, a decrease of the number of active substances and BP and PPP available on the market in the EU has taken or is still taking place.

The criteria for EDs may lead to additional costs and increase the time it takes to put PPP and BP on the market and would imply that some substances incorporated in PPP or BP will be non-approved or approved under more restrictive conditions. Taking into account the current drivers for innovation (energy prices, labour costs and productivity, infrastructure, taxation, regulatory environment etc.) and the market structure (for instance, multinationals focus their R&D on growth markets), this may not necessarily trigger substantial **innovation**. For downstream users and formulators it is difficult to judge whether the proposals will lead to additional innovation because of the many factors involved. Many major industrial sectors are relying on the use of BP. This market is segmented and consists of highly diverse group of enterprises that may respond differently. For key substances in the supply chain probably

quicker increased R&D will occur. It is important to note that replacing a chemical in an article or a mixture can imply that companies need to change their technologies or processes. It can also imply to establish new relations with suppliers.

With respect to the functioning of the **single market**, the derogations foreseen in the PPP and BP Regulations are expected to create new complexity (specific conditions that would apply in each MS and the interpretation and the enforcement of those conditions). As a consequence, the availability of PPP and BP to downstream users (farmers, professional users, health care sector and food chain producers, industry, etc.) may differ between MS, creating an unequal playing field for downstream users.

SMEs play an important role both in the PPP and BP sector, as well as in downstream and related industries. In general it can be concluded that any increase in costs and demand in human resources would negatively affect the market position of SMEs because SMEs are less able than larger firms to accommodate such costs and additional demand in personal resources and expertise. Moreover, SMEs in general have less active substances in their portfolio than larger companies, therefore making them more vulnerable to the non-approval of substances identified as ED. This could lead to a reduction of SMEs, to even further concentration in the BP and PPP-sector and to less competition.

To sum up, the impacts on all aspects on sectorial competitiveness are related to the number of substances identified as ED which is leading to the non-approval of substances unless derogations apply. Therefore, Option B which considered derogations based on risk elements, is expected to have less impacts than Option A (derogations based mainly on hazard),

5.4.6. International trade (Annex 15)

Trade is essential to economic growth and job creation in the EU. Around two thirds of EU imports are raw materials, intermediary goods and components needed for companies' production processes. Imports on food, feed, and treated articles are the three commodity groups used as MCA-criteria for trade in this impact assessment. These groups cover many products imported to the EU and are essential for food security and important to a wide range of trading partners. While impacts on food and feed imports are mainly related to PPPs, impacts on treated articles are mainly related to BP. Treated articles are not assessed because Option B is not applicable for the BP Regulation (see Section 5.4).

Exporters to the EU have to comply with the food and feed safety standards of the EU. An active substance identified as an ED may lead to impacts on trade as the allowed Maximum Residue Levels (MRLs) of the substance in products imported in the EU would have to be lowered to the limit of determination (LOD) in accordance with point 3.6.5 of Annex II of Regulation (EC) No 1107/2009. In practice, this means that many of the active substances for which the MRLs are lowered cannot be used in the production of food or feed in third countries.

In the public consultation, third countries raised concern over the potentially significant trade implications of setting criteria to identify EDs based on hazard, and asked for a risk-based approach to be taken (Option B). They reminded the European Commission that any decision on EDs needs to respect the principles of the WTO (notably Article 5 of the SPS agreement). The topic of setting ED criteria by the different options has raised attention in the WTO Technical Barriers to Trade (TBT) and Sanitary and PhytoSanitary (SPS) Committees since 2013, where an increasing number of WTO Members are taking the floor to express concerns.

Examples of countries and crops that may be affected are wine from Chile, bananas from Latin America, soybeans imported for the production of feed, as well as citrus fruit from South Africa, to name just a few.

It is difficult to quantify precisely the potential impacts on trade. An analysis was carried out by using the screening results and then quantitatively assessing the number of MRLs that would be lowered to LOD for a selection of the most valuable imported crops under the four options (see Section 5.3.6 for a more detailed description).

Depending on the option for the criteria chosen, food imports are expected to be affected in different extent under the current PPP Regulation (see Section 5.3.6). Also feed imports will be affected in a similar way than food. Since the EU is highly dependent on imports of feed, an increase in feed costs could weaken the competitiveness of the EU livestock sector. A trade disruption could amplify the current EU protein deficit for the livestock sector and the need for alternative sources. For both food and feed imports, Option B would take into account elements of risk in the foreseen derogations and would thus have less impact than Option A. The options are thus performing as B>A.

6. HOW DO THE OPTIONS COMPARE?

This section is not concluding on any preferred option for setting scientific criteria to identify endocrine disruptors, but aims compiling the information on the potential implications of these different options under the PPP and BP Regulations.

Under Section 6.1 Options 1 to 4 (Aspect I: setting scientific criteria to identify EDs) were compared via an MCA which included a sensitivity analysis under consideration of different weight scenarios (ranging from either equally distributed weight to giving different weights to different policy areas). The comparison of Options 1 to 4 implies that the current regulatory decision making applies (Option A of Aspect II). For more details please refer to Section 5.1 and Annex 6.

Under Section 6.2, the independent analysis carried out for the options of Aspect II (implementing ED criteria / approach to regulatory decision making) is presented, which is a MCA with the same criteria and scenarios for the sensitivity analysis as for the options under Aspect I. For reasons related to the MCA-methodology and in order to maintain consistency between the two MCAs, Option C was maintained for the analysis of the impacts although at a preliminary stage of the impact assessment it was discarded (see Section 4.2.3 and Annexes 6 and 7).

Under Section 6.3 a final summary discussion on the options is given.

6.1. Policy ranking of Options 1 to 4 for setting scientific criteria to identify EDs under the current regulatory decision making (Aspect I) - MCA results

Option 4 ranks consistently as the best in the MCA, followed by Option 2. Option 1 scores consistently the worst (see Annex 7).

Options 2 to 4 are all based on the WHO definition, which is currently recognised by most scientists. These options offer the same high level of protection to human health regarding EDs for PPP and BP under the current Regulations. Option 3 adds additional categories to the WHO definition, which seem to be difficult to implement in the current PPP and BP legislation and may add additional burden to administration and businesses, with uncertain benefits. Compared to the other options, Option 4 prioritises some substances based on some

elements of hazard characterisation and as a consequence minimises the socio-economic impacts on, for example, agriculture and trade.

Option 1 is the baseline (interim criteria) and not considered fit for purpose as it is based on classification and not based on science regarding EDs. Option 1 results in the incorrect identification of substances as EDs, i.e. it is likely to identify a certain number of false positives. Option 1 would also fail to identify some substances which would be identified as ED under Options 2 to 4 (false negatives), however the adverse effects caused by these substances are expected to be covered by the "standard" risk assessment under the PPP and BP Regulations. Further, the Commission has been mandated to replace Option 1 in the PPP and BP regulations, and it has been shown clearly in the public consultation that this option is not supported by any of the stakeholders.

The policy ranking remains the same throughout the sensitivity analysis, which considers different weights ("priorities") for MCA-criteria and different assessment of the performance of the options (see Annex 6 and 7 for more details).

6.2. Policy ranking of the options related to different implementation of the ED criteria and different approaches to regulatory decision making (Aspect II) – MCA results

Option A represents the current regulatory decision making in place, i.e. the PPP and BP Regulations .The additional options discussed under Aspect II are only applicable to the PPP Regulation (please refer to Section 4.2 for more details). For reasons related to the MCA-methodology and in order to maintain consistency between the two MCA, Option C was maintained for the analysis of the impacts although at a preliminary stage of the impact assessment it was anticipated that it should be discarded (see Section 4.2.3 and Annexes 6 and 7).

The MCA policy ranking clearly identifies Option C (alignment of PPP with BP regarding socio-economic considerations) as the best option, followed by Option B (adjustment of the PPP derogations in light of current scientific knowledge). However, as mentioned before, Option C was discarded at a preliminary stage and only kept for methodological reasons, which as a consequence implies that Option B is consistently ranked as the best policy option compared to A.

Option B corresponds to an adjustment of the derogations foreseen under the PPP Regulation in light of current scientific knowledge and would align the PPP with the BP Regulation with respect to the foreseen derogations. Recently, EU Panels of experts like those of the EFSA[25] and the Scientific Committee for Consumer Safety[26] stated that decisions regarding EDs should be based on risk assessments in order to make the best use of the available information with the aim of protecting human health. Amendments in light of scientific evidence of non-essential elements of the act are foreseen in Article 78 of the PPP Regulation and can be done with measures adopted in accordance with the regulatory procedure with scrutiny.

An alignment of the derogations between the PPP and BP legislation would be better received in the context of international obligations (such as WTO and Codex Alimentarius) which the EU must respect when exercising its powers. In accordance with these international obligations any draft legal proposals on setting criteria to identify EDs need to be notified to WTO under the prescribed procedures to allow third countries to comment.

The policy ranking remains the same throughout the sensitivity analysis, which considers different weights ("priorities") for MCA-criteria and different assessment of the performance of the options (see Annex 6 and 7 for more details).

6.3. Summary

This section is not concluding on any preferred option for setting scientific criteria to identify endocrine disruptors, but aims compiling the information on the potential implications of these different options under the PPP and BP Regulations.

The options considered in this impact assessment for setting scientific criteria to identify EDs under the current PPP and BP Regulations are Option 1 (interim criteria), Option 2 (WHO definition), Option 3 (WHO definition + categories), and Option 4 (WHO definition + potency). In addition, Option B (adjustment of the PPP derogations in light of current scientific knowledge, Aspect II) is considered.

However, given the scientific (fit for purpose) and legal implementation aspects discussed in the previous section, Option 1 is not considered to be a viable alternative at the present time. It is also the option which ranks worse in the MCA. Thus, the range of options which could be selected for the setting the criteria to identify EDs is reduced – with no particular ranking order – to 2, 3, and 4 under the current PPP and BP Regulations. In addition, Option B (adjustment of the PPP derogations in light of current scientific knowledge, Aspect II) could be considered in combination with any of these options.

All options offer the same high level of protection to human health regarding EDs under the current PPP and BP Regulations because they are all based on the WHO definition (currently recognised by most scientists) and because the Regulations are based on a prior approval system and on a highly comprehensive set of data requirements. Indeed, as explained earlier, under the PPP and BP Regulations, no active substance – whether its mode of action is known or not – would be authorised in the EU if an unacceptable risk of causing adverse effects to human health or the environment is identified.

On **Options 2 and 3** there is agreement amongst the various Member States, scientists and stakeholders that the two options would, from a scientific point of view, correctly identify EDs. Both options, implemented under the current PPP and BP Regulations, will have the highest impacts on sectorial competitiveness, agriculture, and trade.

The implementation of **Option 3** may be challenging in the context of the PPP and BP legislation, which are not designed for "categories", i.e. they do not foresee any regulatory consequences for the additional categories. Option 3 may lead to legal uncertainty, unpredictability and lack of operability because MS and stakeholders may interpret differently regulatory consequences for substances placed under Category II or III. It may be also misinterpreted that substances categorised as Category II or Category III are classified as such under Regulation (EC) No 1272/2008 (Classification, Labelling, Packaging), while this would not be the case. For these reasons, Option 3 may also reduce harmonisation in the single market. Further, Option 3 is expected to lead to additional animal testing, which would not be in line with the objectives of Directive 2010/63/EU on the protection of animals used for scientific purposes. Indeed, this option may encourage economic players to find substitutes for substances “suspected EDs” (Category II) and “endocrine active substances” (Category III) or may lead to the need of confirmation of the substance as an ED and thus, following further animal testing, to a transfer to a different Category. Finally, option 3 may lead to "black listing" of substances falling under Categories II and III and may then impose additional burden to economic sectors.

Option 4 is contested by some Member States, some stakeholders and some scientists because the less potent EDs would not be identified as EDs (although these substances are expected to fall under the "normal" risk assessment and would be regulated based on the assessment of the potential adverse effects). In light of a very recent scientific consensus

paper (see "BfR consensus statement" referred to in Sections 1.2.1 and 4.1.4), potency should not be considered in the identification of endocrine disruptors. This implies that Option 4, although fully taken into account in the assessment, should no longer be considered a feasible option for the scientific criteria to identify endocrine disruptors under the PPP and BP Regulations. Further, the way potency is considered may still be subject to a political decision (e.g. on whether or not to fix a cut-off and eventually at which level). Although Option 4 is expected to lead to fewer impacts compared to options 2 and 3 because it would allow a prioritisation of substances, if applied under the current legislative framework it would not be in line with international obligations because of the decision making based mainly on hazard under the PPP Regulation.

Option B, in combination with any of the other options, is based on science because the derogations would be based on a scientific consideration of risk applied on a case-by-case basis[77], while the hazard based approach in the PPP Regulation is maintained. This option would also be in line with international obligations. Based on the previous paragraphs, Option B in combination with Option 2 (WHO definition) is expected to reach the widest consensus amongst scientists, Member States and stakeholders because the criteria for identification of EDs are based on the WHO definition and the derogations under the PPP Regulation would be adjusted to current scientific knowledge (based on 2013-2015 Scientific Opinions by EU Agencies/Scientific Committees and the "BfR consensus statement" published in May 2016). Further, the adjustment of the derogations under the PPP Regulation would provide more clarity/operability and would allow implementing the criteria consistently across the PPPR and the BPR.

7. HOW WOULD IMPACTS BE MONITORED AND EVALUATED?

The legal acts which will be presented as a consequence of this impact assessment are secondary legislation under Regulation (EC) No 1107/2009 and Regulation (EU) No 528/2012. Monitoring and evaluation of secondary legislation shall not be carried out per se, but should be done in the context of the primary legislation. Regarding the implementation of the criteria, sufficient time should be allowed in order to evaluate the regulatory consequence.

In terms of effects on human health or the environment, it needs to be considered that either positive or negative effects related to EDs will only be visible on the medium or even long term. As a consequence, sufficient time would need to be allocated in order to be able to see any effects via monitoring.

The data used in this impact assessment for agriculture and trade, could be used also in future to evaluate impacts on these areas. In addition, other monitoring data are currently collected or will be collected over the coming years. All these data could be used to monitor and evaluate, for instance, exposure levels to EDs and impacts on different sectors. In particular, the data collected under the following pieces of legislation, EU initiatives and other sources could be considered in order to evaluate the impact of the legislation:

- Data concerning human health collected by EUROSTAT or through registries (e.g. Cancer registries, rare disease registries), for instance those described in Section 1.1. of Annex 9 of this impact assessment.

[77] Risk assessment is one of the pillars of the precautionary principle: Communication from the Commission on the precautionary principle /* COM/2000/0001 final */

- Data on workplace health and occupational health collected as follow up to Commission Recommendation 2003/670/EC[78] and activities related to this (e.g. Commission exercise to establish a list of occupational diseases for a pilot study, with the objective of overcoming certain discrepancies linked to the diversity of occupational diseases' systems across the EU; European opinion polls on occupational safety and health at work carried out by the European Agency for Safety and Health at Work[79]).
- To address the lack of information about exposure of citizen to chemicals, Horizon 2020 Societal Challenge 1 has published a call in the work programme 2016-2017 for a joint European programme on HBM[80] (the European Human Biomonitoring Initiative – EHBMI). The goals of the programme are to coordinate existing HBM initiatives in Europe, to establish a single European reference hub, and to build capacity and understanding of the nature and level of chemical exposure of EU citizens and the associated potential health risks. A strong EU-wide evidence base of comparable and validated exposure and health data for sound policy-making at EU and national level is expected to be established.
- Pesticides residues analysis data collected under the coordinated multiannual union control and national control programs to ensure compliance with the maximum residue levels in food, summarised in the annual EFSA scientific reports on pesticides residues in food.
- EU water basins are monitored under the Water Framework Directive for priority chemical substances and could be used to determine the presence of certain substances in the environment.
- In addition, the 'Information Platform for Chemical Monitoring' (IPCheM)[81] designed and implemented by the European Commission, offers a single access point to chemical monitoring data collections managed by and available to European Commission bodies, MS, international and national organisations and researchers.
- Data collected under Regulation (EC) 1185/2009 (pesticide statistics) by MS and transmitted to the European Commission (Eurostat) could be used to improve understanding of exposure to certain active substances.
- In future, data collected via the PPP Application Management System, currently developed by the European Commission and expected to be fully operational in the near future.
- Trade data, e.g. COMEXT databases (Eurostat).
- Data from the audits carried out by the European Commission (DG SANTE) in the MS for the purpose of verifying the implementation and enforcement of the rules on pesticides, including emergency authorisations, marketing and use, formulation analysis and sustainable uses.

[78] Commission Recommendation 2003/670/EC of 19 September 2003 concerning the European schedule of occupational diseases, OJ L 238, 25.9.2003, p.28

[79] Information about the European opinion polls on safety and health at work can be found on the EU-OSHA website. Retrieved from: https://osha.europa.eu/en/surveys-and-statistics-osh/european-opinion-polls-safety-and-health-work

[80] Horizon 2020 Societal Challenge 1 call in the work programme 2016-2017 for a joint European programme on HBM (the European Human Biomonitoring Initiative – EHBMI).

[81] European Commission. JRC. Information Platform for Chemical Monitoring Data (IPCheM). Retrieved from: https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html

- Feedback received from stakeholders and MS authorities on the implementation of Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005.

In case the data collected through the above sources shows that further data might be needed to determine the impact of the initiative, the European Commission might decide to carry out an impact check or a specific evaluation to check the long term impacts of the criteria in the PPP and BP regulatory framework. However, it is still premature to affirm whether this specific assessment on the criteria will be needed as the necessity would derive from the strength and completeness of the data collected.

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