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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.7.2007  
SEC(2007) 955

**COMMISSION STAFF WORKING DOCUMENT**

*Annex to the*

**COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE  
EUROPEAN PARLIAMENT AND THE EUROPEAN ECONOMIC AND SOCIAL  
COMMITTEE**

**On the implementation of the Community Strategy for dioxins, furans and  
polychlorinated biphenyls (COM(2001) 593) – Second progress report**

[COM(2007) 396 final]

## COMMISSION STAFF WORKING DOCUMENT

This Commission Staff Working Paper is an Annex to the second Communication on the developments under the Community Strategy for dioxins, furans and polychlorinated biphenyls in the areas of environment and feed and food, covering the period 2004-2006. While the Communication gives a summarised record of the developments, this document contains more detailed and technical descriptions of the progress in the various areas of relevance to these substances.

### **1. 1. DEVELOPMENTS IN THE ENVIRONMENTAL FIELD**

#### **1.1. Introduction**

A major development during the period 2004-2006 was the adoption of Regulation (EC) No 850/2004 on persistent organic pollutants<sup>1</sup> (POP Regulation). The Regulation aims at implementing the Community's obligations under two international agreements: the UNEP Stockholm Convention on Persistent Organic Pollutants and The Protocol to the 1979 UN-ECE Convention on Long-Range Trans-boundary Air Pollution on Persistent Organic Pollutants.

The POP Regulation covers 16 POPs, among them dioxins, furans and PCBs. They are listed in Annex III to the Regulation which refers to so-called unintentionally released POPs. Since PCBs may also be intentionally produced, they are in addition listed in Annex I covering substances subject to prohibitions. The objective of the Regulation relating to unintentionally released POPs is "*minimising with a view to eliminating where feasible as soon as possible, releases of such substances, and by establishing provisions regarding waste consisting of, containing or contaminated by any of these substances*". This aim concurs with the objectives of the Dioxin Strategy, and the activities under the Dioxin Strategy have therefore been closely co-ordinated with those developed under the POP Regulation.

This section describes briefly the developments under the POP Regulation, as well as activities in other areas covered by the Dioxin Strategy, *i.e.* relating to emissions, water, soil, waste, information to the public, monitoring and studies on EU 10.

#### **1.2. Community Implementation Plan under the Regulation on persistent organic pollutants**

Under the Stockholm Convention and the POP Regulation, Member States are requested to draw up National Implementation Plans. For unintentionally released POPs, they shall develop and maintain release inventories and set up national action plans designed to identify, characterise and minimise the releases of the substances as part of their National Implementation Plan. Both the release inventories and the action plans are regarded as essential tools for cost-effective and continuing reduction of the releases of dioxins, furans and PCBs. National Implementation Plans have already been adopted by some Member States while others are in the process of preparing them<sup>2</sup>. The Commission has developed a

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<sup>1</sup> Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC, OJ L 158, 30.4.2004.

<sup>2</sup> <http://www.pops.int/documents/implementation/nips/submissions/default.htm>

corresponding Community Implementation Plan published in March 2007<sup>3</sup>, which covers measures to be taken at EU level. Apart from general support activities like research, monitoring and information exchange, the areas that are of highest relevance for the substances covered by the Dioxin Strategy are the actions to reduce the emissions of unintentionally produced POPs and the actions for the management of waste.

### 1.3. Emissions

To help defining actions to reduce unintentionally released POPs at Community level for the Implementation Plan under the POP Regulation, an assessment was made in 2006 to identify major remaining sources and the extent to which they can usefully be addressed at EU level<sup>4</sup>. This assessment took account of National Implementation Plans as far as they are currently available and was the basis for a broad consultation with Member States, experts and stakeholders.

It was found that there are still high uncertainties to the estimates of emissions of dioxins, furans and PCBs to the environment due to lack of data. Based on the data available, it is however concluded that the largest sources for dioxin and furan emissions to air in the EU are residential combustion and open burning of waste. Among the industrial point sources, the iron and steel industry is believed to contribute with a major share.

With regard to *industrial sources*, emissions to the environment are addressed under the Integrated Pollution Prevention and Control (IPPC) Directive<sup>5</sup> and the Waste Incineration Directive<sup>6</sup>. The former requires Member States to establish permit conditions based on the Best Available Techniques (BAT) for a wide variety of industry sectors, and the latter sets maximum permissible limit values for releases of dioxins and furans. An appropriate framework is therefore already in place, but the Community Implementation Plan highlights the need for proper implementation of the existing legislation and the importance of including extensive information on the prevention of the formation and control of POP releases in the review of the BAT reference documents (BREFs).

The BREFs are the result of an exchange of information on BAT for various sectors<sup>7</sup> organised by the Commission under the IPPC Directive. They include information on dioxin related prevention and control measures if relevant. They are intended to assist licensing authorities and companies in determining BAT as an essential element of permits issued for the operation of industrial installations subject to the IPPC Directive.

At the end of 2006 the last six of a series of 32 BREFs were finalised. For some earlier adopted BREFs a review to take into account new developments has already started, e.g. for the cement and lime, pulp and paper and iron and steel sectors. A review of the BREF for the ferrous and non-ferrous metals sector is planned to start in 2007. For the review of the iron and steel BREF, the outcome of a study finalised in 2005 on the monitoring of dioxin

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<sup>3</sup> SEC (2007) 341.

<sup>4</sup> Study called "Identification, assessment and prioritisation of EU measures to reduce releases of unintentionally produced/released POPs". <http://ec.europa.eu/environment/dioxin/index.htm>

<sup>5</sup> Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control, OJ L 257, 10.10.1996, p. 26.

<sup>6</sup> Directive 2000/76/EC of the European Parliament and of the Council 4 December 2000 on the incineration of waste, OJ L 332, 28.12.2000, p. 91.

<sup>7</sup> <http://eippcb.jrc.es/pages/FActivities.htm>

emissions from the metal industry will be taken into account<sup>8</sup>. The study concluded that big variations exist in the way dioxin emissions are monitored in the Member States and that there is a need to improve the measurement of dioxins emitted by this sector.

As regards *domestic sources*, such as open burning of waste and residential heating with wood and coal, it was confirmed by the assessment that they are becoming increasingly important. It was estimated that domestic sources might contribute with as much as 45 % of total dioxin emissions to air in the EU, although there are significant uncertainties to this estimate, and obviously large differences between Member States. Domestic sources are small but numerous and difficult to regulate. Since there is a lack of awareness among the public of the risks associated with domestic burning, campaigns to inform the public could help avoiding emissions from these sources. Some Member States have carried out or are planning to launch such awareness raising campaigns. The Commission intends to compile available information in this area and organise a workshop during 2007-2008 to promote exchange of information and experiences among different stakeholders, e.g. competent authorities at different levels, environmental NGOs and international organisations.

In the area of release inventories, the Commission, represented by the Joint Research Centre, is contributing to the work on reviewing and updating the UNEP (United Nations Environment Programme) standardized toolkit for the identification and quantification of dioxin and furan releases, which is conducted under the Stockholm Convention.

#### 1.4. Water

For implementation of the Water Framework Directive (WFD)<sup>9</sup>, and in particular Article 16 on strategies against water pollution, the Council and Parliament designated a first list of 33 'priority substances' for EU action under the WFD in 2001<sup>10</sup>. These substances include pesticides, heavy metals and other dangerous chemical substances, which have been identified as posing a particular risk to animal and plant life in the aquatic environment and to human health. In July 2006 the Commission adopted a draft Directive establishing environmental quality standards for 41 substances including the 33 priority substances and a further eight substances covered by existing legislation on dangerous substances in water<sup>11</sup>.

Dioxins, furans and PCBs are not part of the initial list of priority substances, given that they are considered to be historic pollutants and that existing emission control as well as marketing and use restrictions provide sufficient protection<sup>12</sup>. However, according to Article 16(4) of the WFD, the list of priority substances is to be revised every four years. If new monitoring data on dioxins, furans and PCBs would reveal that there are still risks of exposure to or via the

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<sup>8</sup> [http://ec.europa.eu/environment/ipcc/ipcc\\_studies.htm](http://ec.europa.eu/environment/ipcc/ipcc_studies.htm)

<sup>9</sup> Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L 327, 22.12.2000, p. 1.

<sup>10</sup> Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC. OJ L 331, 15.12.2001, p. 1.

<sup>11</sup> COM(2006)397 final. Proposal for Directive of the European Parliament and of the Council on environmental quality standards in the field of water policy and amending Directive 2000/60/EC. The proposal is accompanied by a Communication (COM(2006)398 final) on integrated prevention and control of chemical pollution of surface waters in the European Union.

<sup>12</sup> European Commission. "Study on the Prioritisation of substances dangerous to the aquatic environment", June 1999. ISBN 92-828-7981-X. Available at [http://europa.eu.int/comm/environment/water/water-dangersub/pri\\_substances.htm](http://europa.eu.int/comm/environment/water/water-dangersub/pri_substances.htm)

aquatic environment in EU Member States and/or that there are still significant point or diffuse sources connected with the aquatic environment where emission control is insufficient, the inclusion of these substances in the list of priority substances for Community level action could be considered. The Commission aims to review the priority substances list in 2008, and make proposals if appropriate.

As regards other main pollutants of concern, each individual Member State is required under the WFD to establish quality standards and emission controls for any substance that is identified as significant in that Member State. Member States have submitted their first reports on pressures and impacts in 2005 according to Article 5 of the Directive, and these reports should give an indication of which substances are relevant at national level, including PCBs, dioxins and furans. The information will be used for the revision of the priority substances list.

### **1.5. Soil**

As regards the identification and remediation of sites contaminated by dangerous substances, the Commission adopted in September 2006 a proposal for a Thematic Strategy on Soil Protection<sup>13</sup>. This Strategy contains a proposal for a framework Directive on the protection of soil. This proposal requires Member States to prevent soil contamination, to make an inventory of contaminated sites (including sites contaminated by POPs) and to remediate the sites identified. Member States are also required to take measures to raise awareness on and promote the transfer of knowledge and experience for a sustainable use of soil. This can include an exchange of information on the best available technologies for the remediation of POP-contaminated sites.

### **1.6. Waste**

The POP Regulation lays down stringent rules on waste containing or consisting of POP substances, including dioxins, furans and PCBs. As a general rule, POP waste should be disposed of without delay in such a way that the POP content is destroyed or irreversibly transformed into substances which do not exhibit POP characteristics.

If the POP concentrations are below a certain limit, waste may however be otherwise disposed of or recovered in accordance with the relevant Community legislation. In July 2006 a Regulation<sup>14</sup> was adopted in which those low concentration limits are defined. In the case of dioxins and furans, the concentration limit applicable is 15 µg/kg<sup>15</sup> and for PCBs<sup>16</sup> the limit is 50 mg/kg. The limit values were set based on an assessment made in a comprehensive study published in 2005<sup>17</sup>.

In exceptional cases certain POP waste with higher concentrations can also be managed in other ways than destruction or irreversible destruction if the method is considered to be a

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<sup>13</sup> COM (2006)232 final.

<sup>14</sup> Council Regulation (EC) No 1195/2006 of 18 July 2006 amending Annex IV to Regulation (EC) No 850/2004 on persistent organic pollutants, OJ L 217, 8.8.2006, p. 1..

<sup>15</sup> The concentration limit is expressed in toxic equivalent concentration (TEQ) using the 1998 World Health Organisation toxic equivalency factors (TEFs) as specified in the Regulation.

<sup>16</sup> Where applicable, the calculation methods laid down in European standards EN 12766-1 and EN 12766-2 shall be applied.

<sup>17</sup> Study to facilitate the implementation of certain waste related provisions of the Regulation on Persistent Organic Pollutants, [http://ec.europa.eu/environment/waste/studies/pdf/pops\\_waste\\_full\\_report.pdf](http://ec.europa.eu/environment/waste/studies/pdf/pops_waste_full_report.pdf)

better environmental option<sup>18</sup>. Eligible operations are permanent storage in safe, deep, underground hard rock formations, salt mines or a landfill site for hazardous waste. The Council adopted in February 2007 a Regulation<sup>19</sup> that restricts the dioxin and furan concentration of solidified or partly stabilised waste going to surface landfills for hazardous waste to 5 mg/kg and the PCB concentration to 50 mg/kg.

### **1.7. Communication to the public**

In the framework of the IPPC Directive, industrial emissions have to be reported to the European Pollutant Emission Register (EPER) and are then made publicly available at a website<sup>20</sup>. Comprehensive data on emissions from individual installations in the EU has been published at the website in 2004 (data reported for 2001) and 2006 (data reported for 2004).

In January 2006, a Regulation<sup>21</sup> was adopted to introduce a more ambitious register, the European Pollutant Release and Transfer Register (E-PRTR). The first reporting (with emission data from 2007) under this new register will be published in 2009. The emission threshold for reporting on dioxins and furans has been reduced compared to EPER by the factor of 10 to 0.1 g I-TEQ (toxic equivalents)<sup>22</sup> per year. It can therefore be expected that more data on emissions of dioxins and furans, especially in the metal industry sector, will be available from the year 2009 onwards<sup>23</sup>. In addition to dioxins and furans, reporting is also required for PCBs. The new register will also cover releases to land and off-site transfers of waste. In the medium to long term it is planned to include the releases of POPs and other pollutants from diffuse sources, e.g. road traffic, agriculture, domestic heating, shipping and aviation.

### **1.8. Monitoring**

Harmonised monitoring of dioxins, furans and PCBs in the environment does not exist at EU level at present. However, according to the Stockholm Convention arrangements to obtain comparable monitoring data for POPs should be established. A technical working group, including representatives from the EU, has therefore been established by UNEP to evaluate existing monitoring programmes and to develop elements for a global monitoring plan. A first evaluation based on monitoring data for air and human exposure (blood or breast milk) will be presented to the Stockholm Convention secretariat in June 2008. This first evaluation report will provide the baseline for future evaluations.

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<sup>18</sup> To be demonstrated by the holder of the waste and authorised by the competent authorities.

<sup>19</sup> Council Regulation (EC) No 172/2007 of 16 February 2007 amending Annex V to Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants, OJ L 55, 23.2.2007, p. 1.

<sup>20</sup> <http://eper.ec.europa.eu/>

<sup>21</sup> Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register, OJ L 33, 4.2.2006, p.1.

<sup>22</sup> International toxic equivalents scheme. A toxic equivalency value is calculated by evaluating the relative toxicity of the individual dioxin and furan compared to the most toxic one. The TEQ values can then be summed up to a total sum. The I-TEQ scheme covers dioxins and furans, but not dioxin-like PCBs.

<sup>23</sup> Report "Preparatory work for new dioxin measurement requirements for the European metal industry", page 86, see [http://ec.europa.eu/environment/ippc/ippc\\_studies.htm](http://ec.europa.eu/environment/ippc/ippc_studies.htm)

## **1.9. Dioxin situation in the EU 10**

In view of lack of information with regard to dioxin, furan and PCB levels in EU 10, the Council stressed in its Conclusions on the Dioxin Strategy of December 2001 the need to involve the then accession countries at an early stage and to compile an inventory of sources and levels of contamination of the environment and human exposure.

Two major studies were therefore carried out in the period 2002-2005 to investigate the situation in these countries that have since become full members of the European Union. The study reports contain a large amount of data on emissions (dioxins and furans) and levels in the environment and humans (dioxins, furans and PCBs)<sup>24</sup>. The situation in this part of Europe is compared with the one in EU 15 as far as it is possible with the data available.

The results were discussed at a workshop organised in Brussels in February 2005<sup>25</sup>. At a very general level, it could be stated that the situation in EU 10 is comparable to the one in EU 15. Overall, emissions to air, environmental contamination and human exposure are at about the same levels. Releases to water and land are estimated to be significantly lower. Uncertainties of the estimates are in general high and low comparability of data makes it difficult to draw firm conclusions. The workshop identified implementation of existing legislation and increased attention to small domestic sources as priorities for the future.

## **2. DEVELOPMENTS IN THE AREA OF FEED AND FOOD**

### **2.1. Integrated approach**

The Dioxin Strategy describes an integrated approach to legislation on feed and food to reduce the presence of dioxins, furans and PCBs throughout the food chain. This integrated approach consists of three pillars:

- (1) The establishment of strict but feasible maximum levels in feed and food taking into account the results obtained in lowering the presence of dioxins in the environment.
- (2) The establishment of action levels to trigger action when levels in feed or food are found clearly above background level. These action levels have an early warning function.
- (3) The establishment of target levels to be achieved over time so as to bring the exposure of the majority of the European population within the limits recommended by the Scientific Committee on Food.

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<sup>24</sup> In addition to EU 10, the studies also cover EU-2 and Turkey.

<sup>25</sup> Study reports and workshop documents can be found at [http://ec.europa.eu/environment/dioxin/index.htm#enlarged\\_eu](http://ec.europa.eu/environment/dioxin/index.htm#enlarged_eu)



### 2.1.1. First pillar: maximum levels

Maximum levels as first pillar have been established at Community level for all feed materials, feedingstuffs and food of animal origin<sup>26</sup>, with only some minor exceptions.

The maximum levels for the sum of dioxins and furans were established in 2001 and were applicable from 1 July 2002 onwards. They are expressed in "WHO equivalents", as determined by the World Health Organisation (WHO) in 1998<sup>27</sup> and are upperbound concentrations (all values of the different congeners less than the limit of quantification are equal to the limit of quantification).

The maximum levels have been established at a strict but feasible level, while taking account of background contamination. These maximum levels should prevent unacceptably high exposure levels in animals and the human population, as well as the distribution of feedingstuffs and foodstuffs with an unacceptably high contamination

For feed materials and feedingstuffs the levels are on a product basis relative to a feedingstuff with 12% moisture content. For foodstuffs, the maximum levels are on a fat basis with the exception of fish and fishery products, which are on a wet weight basis. For the foodstuffs on which the maximum level is expressed on a fat basis, the maximum level is not applicable for foods containing < 1% fat.

From a toxicological point of view, any maximum level should apply to the sum of dioxins, furans and dioxin-like PCBs. In 2001 however, maximum levels were set only for dioxins and furans and not for dioxin-like PCBs, given the very limited data available at that time on the occurrence of dioxin-like PCBs in food and feed.

Legislation provided therefore that, in the light of new data on the presence of dioxin-like PCBs, the maximum levels should be reviewed with the aim of including the dioxin-like PCBs. Since 2001, an active approach has been followed to generate and collect data on the presence of dioxin-like PCBs in feed and food.

Therefore, in 2006 maximum levels for the sum of dioxins, furans and dioxin-like PCBs in feed and food have been established<sup>28</sup>. In order to ensure a smooth transition, it was found appropriate to maintain for a temporary period the already existing maximum levels for

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<sup>26</sup> Feed: Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 (OJ L140, 30.5.2002, p. 10) on undesirable substances in animal feed as last amended by Directive 2006/77/EC of 29 September 2006 (OJ L 271, 30.9.2006, p. 53).

Food: Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. (OJ L 364, 19.12. 2006, p. 5). Regulation replacing and repealing Commission Regulation (EC) No 466/2001 setting maximum levels for certain contaminants (OJ L 77, 16.3.2001, p.1) as last amended by Regulation (EC) No 199/2006 (OJ L32, 4.2.2006, p. 32)

<sup>27</sup> WHO-TEFs for human risk assessment based on the conclusions of the WHO meeting in Stockholm, Sweden, 15-18 June 1997 (Van den Berg et al., (1998) Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and for Wildlife. Environmental Health Perspectives, 106 (12), 775).

<sup>28</sup> Commission Directive 2006/13/EC of 3 February 2006 amending Annexes I and II to Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed as regards dioxins and dioxin-like PCBs (OJ L 32, 4.2.2006, p. 44) for feed; and Commission Regulation (EC) 199/2006 of 3 February 2006 amending Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs as regards dioxins and dioxin-like PCBs (OJ L32, 4.2.2006, p. 34) for food. The latter has been replaced Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in food. (OJ L364, 20.12.2006, p. 5)

dioxins and furans, in addition to new proposed maximum levels for the sum of dioxins, furans and dioxin-like PCBs. These newly set maximum levels for the sum of dioxins, furans and dioxin-like PCBs apply since 4 November 2006

For feedingstuffs, given the regular findings of high levels of dioxins (and dioxin-like PCBs) in trace elements, maximum levels have now also been set for this category of feed additives for dioxins and furans and for the sum of dioxins, furans and dioxin-like PCBs.

In order to ensure that all operators in the food and feed chain continue to make efforts and to take all the necessary measures to reduce the presence of dioxins, furans and dioxin-like PCBs in feed and food, a revision is foreseen with the aim to set lower levels by the year 2008, in particular as regards marine oil for human consumption, fish oil, fish meal and fish feed for animal feeding.

### 2.1.2. *Second pillar: action levels*

There must be permanent monitoring of the presence of dioxins, furans and PCBs in feed and food across the EU. Whenever there is an abnormal increase in the levels of these compounds, sources and/or pathways of contamination have to be identified. In order to determine what constitutes an abnormally increased level, action levels are set to prompt competent authorities and operators to identify sources and pathways of contamination and to take measures to eliminate them.

Action levels for dioxins and furans in foodstuffs, feed materials and feedingstuffs were set by Commission Recommendation 2002/201/EC of 4 March 2002 on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs<sup>29</sup>. Given that the sources of dioxins and dioxin-like PCBs are different, it was appropriate to maintain the action levels set for dioxins and furans in 2002 and to establish separate action levels for dioxin-like PCBs in 2006 simultaneously with the setting of maximum levels for the sum of dioxins, furans and dioxin-like PCBs.

Specific action levels for dioxins, furans and dioxin-like PCBs in *food* have been established by Commission Recommendation 2006/88/EC of 6 February 2006 on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs<sup>30</sup>.

Directive 2002/32/EC provides for the possibility to set action levels. The action levels for dioxins, furans and dioxin-like PCBs in *feed* have therefore been transferred to Annex II to Directive 2002/32/EC by Commission Directive 2006/13/EC amending Directive 2002/32/EC of the European Parliament and of the Council.

### 2.1.3. *Third pillar: target levels*

The third pillar of the measures concerns the future establishment of target levels, foreseen to be done in 2008. These target levels would be the levels to be achieved in feed and food in order to bring the exposure of the large majority of the European population below the Tolerable Weekly Intake recommended by the Scientific Committee on Food. Target levels will act as the driving force for measures, which are necessary to further reduce emissions into the environment.

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<sup>29</sup> OJ L 67, 9.3.2002, p. 69

<sup>30</sup> OJ L 42, 14.2.2006, p. 26

With increasing decline of emissions, the distribution of the contamination levels for the different feed and food groups will shift towards lower levels and will come closer to the target levels. However, for the time being, it is difficult to foresee accurately the impact of environmental measures on the levels in the different feed materials and in the different foodstuffs of animal origin. Accordingly, no numerical target levels can yet be set with reasonable scientific certainty.

## **2.2. Method of analysis and monitoring**

### *2.2.1. Method of analysis*

With regard to sampling and methods of analysis, requirements for the determination of the levels of dioxins, furans and dioxin-like PCBs in food and feed have been recently established in Community legislation in order to ensure that laboratories use methods of analysis with comparable levels of performance providing reliable results.

Commission Directive 2002/70/EC of 26 July 2002 establishing requirements for the determination of levels of dioxins and dioxin-like PCBs in feedingstuffs<sup>31</sup> is currently under revision in view of the newly set maximum levels for the sum of dioxins, furans and dioxin-like PCBs. Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs<sup>32</sup> takes already into account the newly set maximum levels for the sum of dioxins, furans and dioxin-like PCBs.

Monitoring for the presence of dioxins, furans and dioxin-like PCBs in feed and food can be performed by a strategy involving a screening method in order to select those samples with levels of dioxins, furans and dioxin-like PCBs that are less than 25% below or exceed the level of interest (maximum level). The concentration in those samples with significant levels needs to be determined/confirmed by a confirmatory method.

Screening methods (GC/MS, cell based such as CALUX and kit based bioassays) are methods that are used to detect the presence of dioxins, furans and dioxin-like PCBs at the level of interest. These methods have a capacity for a high sample throughput and are used to sift large numbers of samples for potential positives. They are specifically designed to avoid false negatives (< 1%).

Confirmatory methods (HRGC/HRMS) are methods that provide full or complementary information enabling the dioxins, furans and dioxin-like PCBs to be identified and quantified unequivocally at the level of interest.

The recently established network of a Community Reference Laboratory (CRL) with national reference laboratories (NRL) for dioxins, furans and PCBs in feed and food will further improve the analytical performance of official laboratories analysing those substances in feed and food.

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<sup>31</sup> OJ L 209, 6.8.2002, p. 15. Directive as amended by Commission Directive 2005/7/EC of 27 January 2005 (OJ L27, 29.1.2005, p. 41)

<sup>32</sup> OJ L 364, 20.12.2006, p. 32. Regulation replacing Directive 2002/69/EC of 26 July 2002 lays down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs (OJ L209, 6.8.2002, p. 5).

### 2.2.2. Monitoring

Extensive monitoring on dioxins, furans and dioxin-like PCBs in feed and food continues to be important in order to identify contamination of the feed and food chain in an early stage, as new sources continue to be identified. Indeed, all contamination incidents mentioned have been identified through monitoring in feed and food. Only the Belgian PCB/dioxin contamination incident was identified through animal health problems in chickens. However, it should not be overlooked that the above-mentioned incident has been at the very origin of the current monitoring and control system and at the review of the Rapid Alert System for Feed and Food.

In addition to the co-ordinated official control programs including the topic of dioxins in feed and food (targeted control), also specific monitoring programmes on background levels of dioxins, furans and dioxin-like PCBs in feed and food have been established (time trends).

Commission Recommendation 2004/704/EC of 11 October 2004 on the monitoring of background levels of dioxins and dioxin-like PCBs in *feedingstuffs*<sup>33</sup> recommends to the Member States minimum frequency of samples to be analysed yearly (1500 in total) for the different categories of feedingstuffs as well the format of reporting of the results for the monitoring of the background presence of dioxins, furans and dioxin-like PCBs in feedingstuffs. An updated recommendation based upon the experiences gained is in preparation.

Commission Recommendation 2004/705/EC of 11 October 2004 on the monitoring of background levels of dioxins and dioxin-like PCBs in *foodstuffs*<sup>34</sup> recommends to the Member States minimum frequency of samples to be analysed yearly (1500 in total) for the different categories of foodstuffs as well the format of reporting of the results for the monitoring of the background presence of dioxins, furans and dioxin-like PCBs in foodstuffs. This recommendation has been replaced by Commission Recommendation 2006/794/EC of 16 November 2006 on the monitoring of background levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs<sup>35</sup> taking into account the experiences gained by the monitoring programme provided for by Recommendation 2004/705/EC.

## 2.3. Specific issues

### 2.3.1. Derogation for fish from the Baltic Sea region sold in Finland and Sweden

A temporary derogation until 31 December 2006 to the maximum level applicable for fish was foreseen for Finland and Sweden for their local production and local consumption of fish originating from the Baltic region, on the condition that the vulnerable groups of the population (e.g. women of childbearing age) are advised not to eat it or to a very limited extent. The derogation has been extended by Commission Regulation (EC) 2006/199 until 31 December 2011 for a limited number of fish species (*i.e.* herring, salmon, char, trout, river lamprey, roe of vendace). Also other Baltic States such as Estonia, Latvia and Lithuania could in the future benefit from such a derogation, but this derogation will be granted only after demonstration of fulfilment of the same conditions required as for Finland and Sweden.

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<sup>33</sup> OJ L 321, 22.10.2004, p. 38

<sup>34</sup> OJ L 321, 22.10.2004, p. 45

<sup>35</sup> OJ L 322, 22.11.2006, p. 24

### 2.3.2. Evaluation of the control of dioxins in fish from the Baltic region

The Food and Veterinary Office (FVO) has between September 2005 and June 2006 carried out a series of missions on the controls on dioxins in fish originating in the Baltic region and covered all eight Member States on the Baltic Sea coast. A summary of the main findings and conclusions made in the mission series has been compiled in an overview report.

As follow-up to the findings, a working group has been established composed of experts from the 8 Member States from the Baltic region to:

- compare analytical results and examine the differences;
- achieve common conclusions as regards the dioxin, furan and dioxin-like PCB contamination level in a certain fish species from a certain age, size and geographical region and in particular as regards compliance with the maximum levels established in Commission Regulation (EC) 1881/2006;
- conclude on common risk management measures to ensure that fish placed on the market in the EU complies with the maximum levels as established by Commission Regulation (EC) 1881/2006 (without prejudice to the application of the derogation for Finland and Sweden) and to ensure the harmonised application of these risk management measures by all Member States.

### 2.3.3. Progress on non-dioxin-like PCBs

The Scientific Panel on Contaminants in the Food Chain of European Food Safety Authority (CONTAM Panel) has on 8 November 2005 adopted on request from the Commission an opinion related to the presence of non-dioxin-like PCBs (NDL-PCB) in feed and food<sup>36</sup>.

The CONTAM Panel concluded that no health based guidance value for humans can be established for NDL-PCBs because simultaneous exposure to NDL-PCB and dioxin-like compounds hampers the interpretation of results of the toxicological and epidemiological studies, and the database on effects of individual NDL-PCB congeners is rather limited. There are however indications that subtle developmental effects, being caused by NDL-PCB, dioxin-like PCB, or dioxins and furans alone, or in combination, may occur at maternal body burden that are only slighter higher than those expected from the average daily intake in European countries. Because some individuals and some European sub-populations may be exposed to considerably higher average intakes, a continued effort to lower the levels of NDL-PCB in food is warranted.

Data on occurrence of NDL-PCB in food and feed have been reported in different ways for example as the sum of three congeners (PCB 138, 153 and 180), as the sum of six PCB congeners (PCB 28, 52, 101, 138, 153, 180) often referred to as indicator PCB, or as the sum of seven (sum of six indicator PCB plus PCB 11). The Panel decided to use the sum of the six indicator PCB as the basis for the evaluation because these congeners are appropriate indicators for different PCB patterns in various sample matrices and are most suitable for a

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[http://www.efsa.europa.eu/etc/medialib/efsa/science/contam/contam\\_opinions/1229.Par.0003.File.dat/contam\\_op\\_ej284\\_ndl-pcb\\_en1.pdf](http://www.efsa.europa.eu/etc/medialib/efsa/science/contam/contam_opinions/1229.Par.0003.File.dat/contam_op_ej284_ndl-pcb_en1.pdf)

risk assessment of NDL-PCB on the basis of the available data. The Panel noted that the sum of the six indicator PCB represents about 50 % of total NDL-PCB in food.

Due to different sources of contamination, different places of origin of the feed and food commodities, as well as different production methods and circumstances, definite relationships between NDL-PCB and the sum of dioxins, furans and dioxin-like PCBs are only found occasionally in specific well-defined contamination cases or in geographically defined sampling areas.

Usually, samples containing high levels of NDL-PCB will also contain high levels of dioxin-like PCBs, dioxins and furans. In these circumstances risk management measures to reduce dioxin-like PCBs, dioxins and furans, will probably also protect consumers from elevated NDL-PCB exposure. In specific situations, such as contamination with lower chlorinated PCB mixtures, where levels of NDL-PCB could be high, but levels of dioxins, furans and dioxin-like PCBs could be low, measures to reduce the latter will not guarantee protection of the population against products with high levels of NDL-PCBs.

Currently discussions are ongoing for the setting of regulatory levels for non-dioxin-like PCBs in feed and food.

#### 2.3.4. *Re-evaluation of WHO-TEFs*

In June 2005 a WHO-IPCS (International Programme on Chemical Safety) expert meeting was held in Geneva during which the toxic equivalency factors (TEFs) for dioxin like compounds, including some polychlorinated biphenyls, were re-evaluated<sup>37</sup>. Several changes to the WHO-1998-TEF values were decided.

Current legislation on maximum levels and action levels for dioxins and furans and sum for dioxins, furans and dioxin-like PCBs in feed and food are expressed in WHO-TEQ<sup>38</sup> values (“WHO-1998-TEF”)

It has been decided<sup>39</sup>:

- to maintain the current maximum and action levels in feed and food, expressed in WHO-TEQ with the TEF values as determined by WHO in 1998.
- that the Commission services take care to re-calculate all available congener-specific occurrence data with the new TEF values (“WHO-2005-TEF”) and compare the TEQ values obtained by making use of the WHO-2005-TEF with the TEQ values obtained by making use of the WHO-1998-TEF (current situation).
- to use the TEQ values obtained by making use of the WHO-2005-TEF for the review of the maximum and action levels in feed and food foreseen by 31 December 2008. In this review, also the significance of the contribution of the mono-ortho PCBs to the total TEQ will be assessed.

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<sup>37</sup> The 2005 World Health Organization Reevaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Van den Berg et al, *Tox. Sci.* 93(2), 223-241 (2006).

<sup>38</sup> The WHO toxic equivalents scheme covers dioxins, furans and dioxin-like PCBs.

<sup>39</sup> Report of the Standing Committee on the Food Chain and Animal Health, section Toxicological Safety of the Food Chain, 6 October 2006, [http://ec.europa.eu/food/committees/regulatory/scfcah/toxic/summary22\\_en.pdf](http://ec.europa.eu/food/committees/regulatory/scfcah/toxic/summary22_en.pdf)

- that the revised maximum and action levels, and the established target levels following the review foreseen by 31 December 2008, refer to TEQ values obtained by making use of the WHO-2005-TEF.

### 3. RESEARCH AND LIFE PROJECTS

Under the Sixth Research Framework Programme (2002–2006), several projects with links to dioxins, furans and PCBs in the food chain and the effects on human health, including for the unborn child, were funded. Examples are the Network of Excellence CASCADE (Chemicals as contaminants in the food chain; a network for research, risk assessment and education - [www.cascadenet.org](http://www.cascadenet.org)), the Integrated project NEWGENERIS (Effects of maternal exposure to certain compounds, including dioxins and PCBs - [www.newgeneris.org](http://www.newgeneris.org)), and the Specific Targeted Research Projects PIONEER (Influence of endocrine disrupters on puberty onset - <http://cascade.projectcoordinator.net/~pioneer>), DEVNERTOX (Neurotoxic effects of mixtures of PCBs and heavy metals - [www.imm.ki.se/devnertox](http://www.imm.ki.se/devnertox)) and ATHON (assessment of the toxicity and hazard of non-dioxin-like PCBs - [www.athon-net.eu](http://www.athon-net.eu)). The project ENVIRISK (Assessing the risks of environmental stressors: Contribution to the development of integrated methodology - <http://envirisk.nilu.no>) aims at developing a framework for the assessment of the relationships between exposure to selected pollutants, including dioxins and PCBs, and human health. The objectives of the DROPS project (Development of macro and sectoral economic models aiming to evaluate the role of public health externalities on society - [www.nilu.no/DROPS](http://www.nilu.no/DROPS)) is to develop a framework for evaluating the costs to society for public health problems linked to exposure to certain pollutants, including dioxins and PCBs. The Integrated Project PHIME studies the influence of POPs on osteoporosis using DDE and PCB-153 as indicators ([www.phime.org](http://www.phime.org)).

In the Fifth Framework Programme of Research (1998-2002), a number of projects were funded dealing with human and wildlife impacts of PCBs and related chemical compounds. These projects have recently ended and the final reports are available at [http://ec.europa.eu/research/quality-of-life/ka4/ka4\\_reports\\_en.html](http://ec.europa.eu/research/quality-of-life/ka4/ka4_reports_en.html).

Research on dioxins, furans and PCBs has also been undertaken by the Joint Research Centre of the Commission in the areas of soil, water, ambient air and emission factors for domestic heating with coal<sup>40</sup>.

Projects on PCB transformer decontamination, material recycling of PCB containing waste and remediation of PCB contaminated soils have been funded under the financial instrument for the environment (LIFE)<sup>41</sup>.

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<sup>40</sup> For a full list including references, see <http://ec.europa.eu/environment/dioxin/index.htm>

<sup>41</sup> <http://ec.europa.eu/environment/life/project/projectsbythemes.htm>