# Commission Regulation (EU) No 1259/2011 of 2 December 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs in foodstuffs (Text with EEA relevance)

## COMMISSION REGULATION (EU) No 1259/2011

## of 2 December 2011

## amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs in foodstuffs

## (Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[(1)], and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs[(2)] sets maximum levels for dioxins and dioxin-like PCBs in a range of foodstuffs.

(2) Dioxins belong to a group of 75 polychlorinated dibenzo-p-dioxin (PCDD) congeners and 135 polychlorinated dibenzofuran (PCDF) congeners, of which 17 are of toxicological concern. Polychlorinated biphenyls (PCBs) are a group of 209 different congeners which can be divided into two groups according to their toxicological properties: 12 congeners exhibit toxicological properties similar to dioxins and are therefore often referred to as 'dioxin-like PCBs' (DL-PCB). The other PCBs do not exhibit dioxin-like toxicity but have a different toxicological profile and are referred to as 'non dioxin-like PCB' (NDL-PCB).

(3) Each congener of dioxins or DL-PCBs exhibits a different level of toxicity. In order to be able to sum up the toxicity of these different congeners, the concept of toxic equivalency factors (TEFs) was introduced to facilitate risk assessment and regulatory control. As a result the analytical results relating to all the individual dioxin and dioxin-like PCB congeners of toxicological concern are expressed in terms of a quantifiable unit, namely the TCDD toxic equivalent (TEQ).

(4) The World Health Organisation (WHO) held an expert workshop on 28 to 30 June 2005 concerning the TEF values, agreed by WHO in 1998. A number of TEF values were changed, notably for PCBs, octachlorinated congeners and pentachlorinated furans. The data on the effect of the new TEF values and the recent occurrence are compiled in the European Food Safety Authority's (EFSA) scientific report 'Results of the monitoring of dioxin levels in food and feed'[(3)]. Therefore, it is appropriate to review the maximum levels of PCBs taking into account these new data.

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Regulation (EU) No 1259/2011. (See end of Document for details)*

(5) The Scientific Panel on Contaminants in the Food Chain of the EFSA on a request from the Commission has adopted an opinion on the presence of NDL-PCBs in feed and food[(4)].

(6) The sum of the six marker or indicator PCBs (PCB 28, 52, 101, 138, 153 and 180) comprises about half of the amount of total NDL-PCB present in feed and food. That sum is considered as an appropriate marker for occurrence and human exposure to NDL-PCB and therefore should be set as a maximum level.

(7) Maximum levels have been established taking into account recent occurrence data compiled in the EFSA scientific report 'Results of the monitoring of non dioxin-like PCBs in food and feed'[(5)]. Although it is possible to achieve lower limits of quantification (LOQ), it can be observed that a considerable number of laboratories apply an LOQ of 1 μg/kg fat or even 2 μg/kg fat. Expressing the analytical result as an upperbound level would result in some cases in a level close to the maximum level if very strict maximum levels would be established, even if no PCBs have been quantified. It was also acknowledged that for certain food categories the data were not very extensive. Therefore, it would be appropriate to review the maximum levels in 3 years time, based upon a more extensive database obtained with a method of analysis with sufficient sensitivity for quantifying low levels.

(8) Derogations have been granted to Finland and Sweden to place on the market fish originating in the Baltic region and intended for consumption in their territory with dioxin levels higher than the maximum levels established for dioxins and the sum of dioxins and DL-PCBs in fish. Those Member States have fulfilled the conditions as regards the provision of information to consumers on dietary recommendations. Every year they communicate to the Commission the results of their monitoring of the levels of dioxins in fish from the Baltic region and the measures to reduce human exposure to dioxins from the Baltic region.

(9) On the basis of the results of monitoring of levels of dioxins and DL-PCBs carried out by Finland and Sweden, the derogation granted could be limited to certain fish species. Given the persistent presence of dioxins and PCBs in the environment and consequently in fish it is appropriate to grant this derogation without a time limit.

(10) As regards wild caught salmon, Latvia has requested a similar derogation as that granted to Finland and Sweden. To that end, Latvia has demonstrated that human exposure to dioxins and DL-PCBs in its territory is not higher than the highest average level in any of the Member States and that it has a system in place to ensure that consumers are fully informed of dietary recommendations with regard to restrictions on the consumption of fish from the Baltic region by identified vulnerable sections of the population in order to avoid potential health risks. Furthermore, monitoring of the levels of dioxins and DL-PCBs in fish from the Baltic region should be carried out and the results and measures that have been taken to reduce human exposure to dioxins and DL-PCBs from fish from the Baltic region should be reported to the Commission. The necessary measures have been put in place ensuring that fish and fish products not complying with EU maximum levels for PCBs are not marketed in other Member States.

(11) Given that the contamination pattern of NDL-PCBs in fish from the Baltic region show similarities with the contamination of dioxins and DL-PCBs and given that also NDL-PCBs are very persistent in the environment, it is appropriate to grant a similar derogation as regards the presence of NDL-PCBs as for dioxins and DL-PCBs in fish from the Baltic region.

(12) EFSA has been requested to provide scientific opinion as regards the presence of dioxins and dioxin-like PCBs in sheep and deer liver and the appropriateness to establish maximum levels for dioxins and PCBs in liver and derived products on product basis rather than on a fat basis, as is currently the case. Therefore, the provisions on liver and derived products should be reviewed in particular the provisions as regards sheep and deer liver once the EFSA opinion is available. In the meantime it is appropriate to set the maximum level for dioxins and PCBs on a fat basis.

(13) Foods with less than 1 % fat were until now excluded from the maximum level for dioxins and DL-PCBs, given that those foods are generally minor contributors to the human exposure. However, there have been cases with food containing less than 1 % fat but with very high levels of dioxins and DL-PCBs in the fat. Therefore, it is appropriate to apply the maximum level to such foods, but on a product basis. Taking into account that a maximum level is established on product basis for certain low fat containing foods, it is appropriate to apply a maximum level on product basis for foods containing less than 2 % fat.

(14) In the light of the monitoring data for dioxins and DL-PCBs in foods for infants and young children it is appropriate to set specific lower maximum levels for dioxins and DL-PCBs in foods for infants and young children. The Federal Institute for Risk Assessment from Germany has addressed to EFSA a specific request to assess the risk for infants and young children of the presence of dioxins and dioxin-like PCBs in foods for infants and young children. Therefore, the provisions on foods for infants and young children should be reviewed once the EFSA opinion is available.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

*Article 1*

Regulation (EC) No 1881/2006 is amended as follows:

(1) Article 7 is amended as follows:

(a) The title '**Temporary derogations**' is replaced by '**Derogations**';

(b) paragraph 4 is replaced by the following:

4. By way of derogation from Article 1, Finland, Sweden and Latvia may authorise the placing on their market of wild caught salmon (*Salmo salar*) and products thereof originating in the Baltic region and intended for consumption in their territory with levels of dioxins and/or dioxin-like PCBs

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and/or non-dioxin-like PCBs higher than those set out in point 5.3 of the Annex, provided that a system is in place to ensure that consumers are fully informed of the dietary recommendations with regard to the restrictions on the consumption of wild caught salmon from the Baltic region and products thereof by identified vulnerable sections of the population in order to avoid potential health risks.

Finland, Sweden and Latvia shall continue to apply the necessary measures to ensure that wild caught salmon and products thereof not complying with point 5.3 of the Annex are not marketed in other Member States.

Finland, Sweden and Latvia will report yearly to the Commission the measures they have taken to effectively inform the identified vulnerable sections of the population of the dietary recommendations and to ensure that wild caught salmon and products thereof not compliant with the maximum levels is not marketed in other Member States. They shall furthermore provide evidence of the effectiveness of these measures.;

(c) the following paragraph 5 is added:

5. By way of derogation from Article 1, Finland and Sweden may authorise the placing on their market of wild caught herring larger than 17 cm (*Clupea harengus*), wild caught char (*Salvelinus* spp.), wild caught river lamprey (*Lampetra fluviatilis*) and wild caught trout (*Salmo trutta*) and products thereof originating in the Baltic region and intended for consumption in their territory with levels of dioxins and/or dioxin-like PCBs and/or non dioxin-like PCBs higher than those set out in point 5.3 of the Annex, provided that a system is in place to ensure that consumers are fully informed of the dietary recommendations with regard to the restrictions on the consumption of wild caught herring larger than 17 cm, wild caught char, wild caught river lamprey and wild caught trout from the Baltic region and products thereof by identified vulnerable sections of the population in order to avoid potential health risks.

Finland and Sweden shall continue to apply the necessary measures to ensure that wild caught herring larger than 17 cm, wild caught char, wild caught river lamprey and wild caught trout and products thereof not complying with point 5.3 of the Annex are not marketed in other Member States.

Finland and Sweden will report yearly to the Commission the measures they have taken to effectively inform the identified vulnerable sections of the population of the dietary recommendations and to ensure that fish and products thereof not compliant with the maximum levels is not marketed in other Member States. They shall furthermore provide evidence of the effectiveness of these measures.;

(2) the Annex is amended in accordance with the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2012.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 2 December 2011.

*For the Commission*

*The President*

José Manuel BARROSO