Commission Regulation (EU) No 277/2012 of 28 March 2012 amending Annexes I and II to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels and action thresholds for dioxins and polychlorinated biphenyls (Text with EEA relevance)

COMMISSION REGULATION (EU) No 277/2012

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[(1)], and in particular Article 8(1) thereof,

Whereas:

(1) Directive 2002/32/EC provides that the use of products intended for animal feed which contain levels of undesirable substances exceeding the maximum levels laid down in Annex I to that Directive is prohibited. Its Annex II sets action thresholds triggering investigations in cases of increased levels of such substances.

(2) Dioxins as referred to in this Regulation cover a group of 75 polychlorinated dibenzo-para-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 termed dioxin-like PCBs (DL-PCBs). The other PCBs do not exhibit dioxin-like toxicity but have a different toxicological profile.

(3) Of the congeners of dioxins or dioxin-like PCBs which are of toxicological concern, each 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) has been introduced to facilitate risk assessment and regulatory control. This means that 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) As regards dioxins and dioxin-like PCBs, the World Health Organisation (WHO) has suggested in 2005 new toxic equivalency factors values in comparison with the values set by WHO in 1998. At a request from the Commission the European Food Safety Authority (EFSA) delivered a scientific report ‘Results of the monitoring of dioxin

levels in food and feed'[2] where those new values, as suggested by WHO, and recent information collected by the Commission are taken into account. In view of that report, it is appropriate to modify the maximum levels and the threshold values for dioxins and dioxin-like PCBs.

(5) As regards non-dioxin-like PCBs, upon a request from the Commission EFSA adopted an opinion related to the presence of non-dioxin-like PCBs in feed and food[3].

(6) Polychlorinated biphenyls (PCBs) cover a group of 209 different PCB congeners. The sum of the six indicator PCB congeners (PCB 28, 52, 101, 138, 153 and 180) comprises about half of the amount of total non-dioxin-like PCBs (NDL-PCBs) present in feed and food. EFSA considered the sum of the six indicator PCBs an appropriate indicator for occurrence and human exposure to NDL-PCBs. Furthermore, it is unpractical and very expensive without any benefit for enforcement purposes to analyse for official control each time all 209 PCB congeners. Therefore it is appropriate to set maximum levels as sum of these 6 PCBs.

(7) The maximum levels for non-dioxin-like PCBs have been established taking into account recent occurrence data. These recent occurrence data are compiled in the EFSA scientific report 'Results of the monitoring of non-dioxin-like PCBs in food and feed'[4]. Although it is possible to achieve a lower limit of quantification (LOQ), it can be observed that a considerable number of official control laboratories apply a LOQ of 0,5 ng/kg product or even 1 ng/kg product. Expressing the analytical result as an upper-bound level would already result in some cases in a level close to the maximum level even if no PCBs have been quantified. It was also acknowledged that for certain feed categories the data were not very extensive. Therefore it would be appropriate to review the maximum levels in three years' time based upon a more extensive database obtained with a method of analysis with sufficient sensitivity to quantify low levels.

(8) Carry-over studies indicate that the presence of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in feed at the maximum levels set in Annex I to Directive 2002/32/EC may in some cases result in food of animal origin exceeding the applicable maximum levels set by Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in food[5]. However, it is not possible to set lower maximum levels taking into account the sensitivity of currently available methods of analysis and the fact that the maximum levels are established as upper-bound levels. Moreover in most cases it is unlikely that an animal is exposed for a long time to a feed that is compliant but contains a level of dioxins and/or PCBs close to or at the maximum level.

(9) 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

Annexes I and II to Directive 2002/32/EC are amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from the date of entry into force.

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

Done at Brussels, 28 March 2012.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 277/2012. (See end of Document for details)*

ANNEX

(1) In Annex I to Directive 2002/32/EC, Section V: Dioxins and PCBs is replaced by the following:

SECTION V:

DIOXINS AND PCBS

Undesirable substance	**Products intended for animal feed**	**Maximum content in ng WHO-PCDD/F-TEQ/kg (ppt)[a] relative to a feed with a moisture content of 12 %**
1. Dioxins (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors), 2005[b])	Feed materials of plant origin with the exception of:	0,75
	— vegetable oils and their by-products	0,75
	Feed materials of mineral origin	0,75
	Feed materials of animal origin:	
	— Animal fat, including milk fat and egg fat	1,5
	— Other land animal products including milk and milk products and eggs and egg products	0,75
	— Fish oil	5,0
	— Fish, other aquatic animals, and products derived thereof with the exception of fish oil and fish protein, hydrolysed, containing more than 20 % fat[c]	1,25
	— Fish protein, hydrolysed, containing more than 20 % fat	1,75

	The feed additives kaolinitic clay, vermiculite, natrolite-phonolite, synthetic calcium aluminates and clinoptilolite of sedimentary origin belonging to the functional groups of binders and anti-caking agents	0,75
	Feed additives belonging to the functional group of compounds of trace elements	1,0
	Premixtures	1,0
	Compound feed with the exception of:	0,75
	— compound feed for pet animals and fish	1,75
	— compound feed for fur animals	—
Undesirable substance	**Products intended for animal feed**	**Maximum content in ng WHO-PCDD/F-PCB-TEQ/kg (ppt)[a] relative to a feed with a moisture content of 12 %**
2. Sum of dioxins and dioxin-like PCBs (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors), 2005[b])	Feed materials of plant origin with the exception of:	1,25
	— vegetable oils and their by-products	1,5
	Feed materials of mineral origin	1,0
	Feed materials of animal origin:	
	— Animal fat, including milk fat and egg fat	2,0
	— Other land animal products including	1,25