COUNCIL DIRECTIVE 2001/102/EC

of 27 November 2001

amending Directive 1999/29/EC on the undesirable substances and products in animal nutrition

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition [1], and in particular Article 10 point (a) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) Directive 1999/29/EC provides that feed materials may only be put into circulation in the Community if they are sound, genuine and of merchantable quality.

(2) The term 'dioxins' covers a group of 75 polychlorinated dibenzo-p-dioxin ('PCDD') and 135 polychlorinated dibenzofuran ('PCDF') congeners, of which 17 are of toxicological concern. The most toxic congener is 2,3,7,8-tetrachlordibenzo-p-dioxin (TCDD) classified by the International Agency for Research on Cancer and other reputable international organisations as a known human carcinogen. The Scientific Committee for Food ('SCF'), in line with the World Health Organisation ('WHO'), concluded that the carcinogenic effect of dioxins does not occur at levels below a certain threshold. Other adverse effects, such as endometriosis, neurobehavioural and immunosuppressive effects occur at much lower levels and are therefore considered relevant for the determination of a tolerable intake.

(3) 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'. The other PCBs do not exhibit dioxin-like toxicity but have a different toxicological profile.

(4) Each congener of dioxins or dioxin-like PCBs presents 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 17 individual dioxin congeners and to the 12 dioxin-like PCB congeners are expressed in terms of a single quantifiable unit: 'TCDD toxic equivalent concentration' ('TEQ').

(5) Dioxins and PCBs are extremely resistant to chemical and biological degradation and therefore persist in the environment and accumulate in the feed and food chain.

(6) The distribution of dioxins, PCBs and dioxin-like PCBs throughout the environment causes background contamination affecting all terrestrial plants directly grazed or used as feed materials for animal feed as well as the aquatic feed chain. The same applies to the soil that might contaminate feed materials or be directly ingested by animals. In addition to background contamination, direct accidental pollution of feed materials may occur due to localised discharge of dioxins from industrial activities, contamination of feed materials during their production, processing and transportation, and illegal practices or management failures during feed production.

(7) More than 90 % of human dioxin exposure derives from foodstuffs. Foodstuffs of animal origin normally contribute to approximately 80 % of overall exposure. The dioxin burden in animals derives mainly from feedingstuffs. Therefore feedingstuffs, and in some cases soil, are of concern as potential sources of dioxins.

(8) The SCF adopted an opinion on the Risk Assessment of Dioxins and Dioxin-like PCBs in Food on 30 May 2001. This is an update based on new scientific information available since the adoption of the SCF opinion on this matter on 22 November 2000. The SCF fixed a tolerable weekly intake ('TWI') for dioxins and dioxin-like PCBs of 14 pg WHO-TEQ/kg body weight. Exposure estimates indicate that a considerable proportion of the Community population has a dietary intake in excess of the tolerable intake.

[1] OJ L 115, 4.5.1999, p. 32.

(9) The reduction of human exposure to dioxins through food consumption is therefore important and necessary to ensure consumer protection. As food contamination is directly related to feed contamination, an integrated approach must be adopted to reduce dioxin incidence throughout the food chain, i.e. from feed materials through food-producing animals to humans. The introduction of measures relating to feed materials and feedingstuffs is therefore a crucial step towards reducing dioxin intake by humans.

(10) The Scientific Committee for Animal Nutrition ('SCAN') has been asked to advise on the sources of contamination of feedingstuffs with dioxins and PCBs, including dioxin-like PCBs, the exposure of food-producing animals to dioxins and PCBs, the carry-over of these compounds to food products of animal origin, and any impact on animal health of dioxins and PCBs present in feedingstuffs. The SCAN adopted an opinion on 6 November 2000. It identified fish meal and fish oil as the most heavily contaminated feed materials, with products of European origin being more heavily contaminated. Animal fat was identified as the next most seriously contaminated material. All other feed materials of animal and plant origin had relatively low levels of dioxin contamination. Roughages presented a wide range of dioxin contamination depending on location, degree of contamination with soil and exposure to sources of aerial pollution.

(11) Measures should be implemented with the aim of reducing the presence and release of dioxin contamination of the environment in order to reduce the impact of environmental pollution on the contamination of feed materials. The SCAN recommended, *inter alia*, that emphasis should be placed on reducing the impact of the most contaminated feed materials on overall diet contamination.

(12) Maximum levels for dioxins and dioxin like PCBs should be an appropriate tool to prevent unacceptably high exposure of animals and to prevent the distribution of feedingstuffs with an unacceptably high level of contamination, e.g. in cases of accidental pollution and exposure. Furthermore, the setting of maximum levels is indispensable for the implementation of a regulatory control system and to ensure uniform application.

(13) Measures based solely on establishing maximum levels for dioxins and dioxin-like PCBs in feedingstuffs would not be sufficiently effective in reducing human exposure to dioxins unless the levels were set so low that a large part of the feed supply would have to be declared unfit for animal consumption. It is generally recognised that, in order to actively reduce the presence of dioxins in feedingstuffs, maximum levels should be accompanied by measures stimulating an active approach, including action levels and target levels for feedingstuffs in combination with measures to limit emissions. Target levels indicate the levels to be achieved in order to ultimately bring human exposure for the majority of the population down to the TWI set by the SCF. Action levels are a tool for competent authorities and operators to identify those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination, not only in the event of non-compliance with this Directive but also where significant levels of dioxins above normal background levels are found. This will result in a gradual reduction of dioxin levels in feedingstuffs, and the target levels will ultimately be achieved. A recommendation from the Commission on this issue is therefore being addressed to the Member States.

(14) Although, from a toxicological point of view, any level should apply to dioxins, furans and dioxin-like PCBs, for the time being the maximum levels are set only for dioxins and furans and not for dioxin-like PCBs, given the very limited data available on the prevalence of the latter. However, monitoring will continue, in particular on the presence of dioxin-like PCBs with a view to including these substances in the maximum levels.

(15) The unacceptability of the dioxin content of feedingstuffs should be assessed in the light of the current background levels of contamination, which differ from feed material to feed material. The maximum level should be fixed, taking account of background contamination, at a strict but feasible level.

(16) In order to ensure that all operators in the food and feed chain continue to make all possible efforts and do all that is necessary to limit the presence of dioxins in feed and food, the maximum levels applicable should be reviewed within a defined period with a view to setting lower maximum levels. An overall reduction of at least 25 % in human exposure to dioxins should be achieved by 2006.

(17) Compound feedingstuffs and feed materials of plant origin do not normally contain high levels of dioxins. Since feed materials of plant origin are by far the largest component in the diet of many species of animals, it is appropriate to set a maximum level also for these feed materials. The more sensitive the method of analysis, the more expensive and time-consuming the analysis to check for dioxin. As it is important that as many samples as possible be analysed, the maximum levels proposed are somewhat higher than normal background levels given that they constitute upper-bound levels.