

SUMMARY OF KEY CHANGES

Articles

Article 3: Dried, diluted, processed and compound foodstuffs

- The specific concentration or dilution factors shall be provided and justified by the food business operator.

Article 5: Specific rules for products which can be used for feed and food or other purposes

- Groundnuts, derived products thereof and cereals must be clearly labelled indicating their intended use.

Annex: maximum levels for certain foodstuffs

Section 2: Mycotoxins

i) Deoxynivalenol

- Limits now apply to cereal bran marketed for direct human consumption and germ

ii) Zearalenone

- Limits now apply to cereal bran marketed for direct human consumption and germ

Section 3: Heavy Metals

i) Lead

- Milk – extended from just cow's milk to cover all farm animals
- Muscle meat of fish – all species now fall under one limit of 300 µg/kg instead of 200 or 400 according to species.

ii) Cadmium

- Liver and kidney – extended to include horse
- Vegetables and fruit – pine nuts are excluded

Section 5: Dioxins and dioxin-like PCBs

- Meat and meat products – farmed game now excluded
- Liver & derived products, and fat – limit applies only to those animals listed at section 5.1 (i.e. bovines, sheep, poultry, pigs)

BACKGROUND

The consolidation and replacement of Commission Regulation 466/2001 is being driven by the existence of 18 amendments, the need for simplification to remove repetition and the need to move clauses from the Annex to the main Recitals. Where appropriate, updated views on, for example, risk assessments have been included in the Recitals. In addition, clarification of the legal provision and interpretation of the text has been provided.

The draft Regulation was first discussed in January 2006, with further discussions at Working Groups and at the June Standing Committee on the Food Chain and Animal Health. Consequently the document has undergone a number of revisions as a result of these discussions. Interested Parties have been kept informed and invited to comment on the draft document throughout the discussions and copies of the document have been available on request.

A vote on the draft document was originally expected at the June Standing Committee meeting with the view to the Regulation, which will repeal and replace Regulation 466/2001, applying on 4th November 2006. However, the vote is now expected at Standing Committee in September and the application date of the new Regulation is likely to be 1 March 2007.

DETAIL

Articles

Article 3: dried, diluted, processed and compound foodstuffs

The provisions in this Article have been brought in line with the general food law provisions laid down in Regulation (EC) 178/2002.

The Article requires that the specific concentration or dilution factors in respect of these foodstuffs shall be provided and justified by the food business operator. If this information is not available or deemed unsatisfactory by the competent authority the competent authority may apply a concentration or dilution factor, based upon the available information and which is most appropriate for the protection of public health.

The Commission has indicated that in the future they would consider developing a table of general processing factors which can be applied if no other information is available.

Article 5: Specific rules for products which can be used for feed and food or other purposes

For groundnuts, derived products thereof and cereals, in the absence of a clear indication of the intended use, the maximum levels laid down in the Annex apply.

This clear indication of the intended use must appear on the label of each individual packing or on the accompanying document, which must have a clear link with the consignment by means of mentioning the consignment identification code, which occurs on each individual packing of the consignment. In addition the consignee of

the consignment given on the accompanying document must be compatible to the intended use.

Annex

Section 2: Mycotoxins Deoxynivalenol and zearalenone

In our letter of 8 March, we informed you of the proposal to widen the scope of the legislation to include bran and germ intended for direct human consumption. Bran and germ were originally intended to be covered by the Regulations limits for Fusarium toxins in cereals and cereal products to protect consumers of such products from high levels of these toxins. However, these were inadvertently omitted from the published Regulations, which came into force on the 1st July 2006. The Commission stated that bran for direct human consumption should be sourced carefully just like ingredients for baby foods.

Section 3: Heavy metals

i) LEAD

- **Milk**

In our letter of 22 February, we informed you of the proposal to widen the scope of the legislation, which currently only applies to cow's milk. Under the new Regulation the maximum level will apply to all farmed animals as defined in Regulation (EC) No 853/2004¹, as such this will include sheep and goat milk. Milk products including cheese are covered under Article 3. We invited comments and views on the possible implications of this change to the legislation, with a further call for comments on 12 April.

No comments have been made to date

- **Muscle meat of fish**

The maximum level has been revised to bring it into line with the recently agreed CODEX limit of 300 µg/kg. This represents an increase in the general EC limit for fish, currently at 200 µg/kg, and a decrease in the limit for specified fish species, currently at 400 µg/kg. A limited consultation carried out at the end of June did not provide any data.

We would welcome your views on whether-

¹ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 226, 25.6.2004, p. 22)

- i) the reduction of 400 µg/kg to 300 µg/kg is achievable particularly for the older, larger fish and whether this has an impact on the sustainability of the species currently caught by the higher limit; and
- ii) the increase in the general limit from 200 µg/kg to 300 µg/kg is acceptable to consumers

Fish consumed in the UK generally contain lead levels much below this level and the change in limit will have little practical effect on consumer exposure. Lead exposure from fish at the proposed higher level would still be well within recommended maximum intakes.

ii) **CADMIUM**

- **Offal**
The maximum levels for liver (500 µg/kg) and kidney (1000 µg/kg) will also apply to horses.
- **Vegetables and fruit**
Currently a maximum level of 50 µg/kg applies to fruit including edible nuts. However, data from the UK's and other MS' monitoring programmes have shown that the current limit is inappropriate and unachievable as regards pine nuts and these will be excluded from the legislation. The UK considered that this change has no public health significance and it was agreed at the June Standing Committee. The UK has informally notified the appropriate trade associations of this change. A new limit will be established once further data on the presence of cadmium in pine nuts is available.

Section 5: DIOXINS AND DIOXIN-LIKE PCBs

- **Meat and meat products**
Currently Regulation 466/2001 as amended by Council Regulation 2375/2001 sets a maximum level of 2 pg WHO-PCDD/F-TEQ/g fat for dioxins in poultry and farmed game. We believe it was the intention that this latter category referred to farmed game birds but the drafting and the changing legal definition of game has created confusion. The proposal to remove farmed game from the regulation will mean that limits will not apply to categories such as rabbit, venison, pheasant, ratites (ostriches, etc.) some of which might have previously been within the scope of the regulation. It is not proposed to make proposals for limits for these categories unless contaminated products are considered to be a risk to consumers or until further data are available.
- **Liver and derived products thereof and fat**
The current text in sections 5.2 and 5.7 have been clarified – the maximum levels apply to those animals listed in section 5.1. We

have asked the Commission to consider amending the Regulation to make the limit apply to the fresh weight of liver as the current form of the regulation introduces anomalies.

Yours sincerely

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