Guidelines as regards measures to be taken as regards the presence of Benzalkonium Chloride (BAC) in or on food and feed

agreed by the Standing Committee of the Food Chain and Animal Health (SCoFCAH) on 25 July 2012

Background

On 13 July 2012 the Standing Committee on the Food Chain and Animal Health (SCoFCAH) endorsed, with the exception of Denmark, *Guidelines as regards measures to be taken as regards the presence of DDAC in or on food and feed*.
At the same meeting, the SCoFCAH was also informed that the German risk assessment body BfR was about to finalise a toxicological assessment of another compound, Benzalkonium Chloride (BAC), belonging to the group of Quaternary Ammonium Compounds (QACs) and which had been found in several fruit and vegetables, as well as in dairy products, at levels higher than 0,01 mg/kg[1]. The highest residue levels seem to occur in dairy products (up to 19 mg/kg in soft ice cream).
Based on this information and on the fact that BAC and Didecyl Dimethyl Ammonium Chloride (DDAC) are used in a comparable way and have been recently found in several conventional and organic products of plant and animal origin, the SCoFCAH agreed to possibly endorse, following written consultation, guidelines for BAC similar to those endorsed on DDAC on 13 July 2012.

On 16 July 2012 Germany submitted to the Commission the BfR toxicological assessment on BAC. Based on the available toxicological information, BfR derived and ADI of 0.1 mg/kg bw/day and an ARfD of 0.1 mg/kg bw.

It should be noted that BAC is not a single compound, but rather a mixture of C12-16–alkyl (C12-16) dimethylbenzyl ammonium chlorides (also known as ADBAC), which might be present in different percentages.

Unlike DDAC, BAC is not approved under Regulation (EC) No 1107/2009, but it is covered by the review programme of Directive 98/8/EC within the product type "food and feed area disinfectants". According to the information available to the Commission, the same sources of contamination for DDAC can be assumed also for BAC (for further details see *Guidelines as regards measures to be taken as regards the presence of DDAC in or on food and feed* agreed by the SCoFCAH on 13 July 2012). Furthermore, according to the information given by BfR, other possible sources of exposure in agriculture might be related to fertilisers containing DDAC/BAC or to plant protection products containing DDAC/BAC as co-formulants.

It is clear that further monitoring and investigation by food business operators and official control authorities are needed to better understand the causes of the contamination and to allow, if necessary and possible, to set temporary MRLs under Reg. (EC) No 396/2005.
In the meantime urgent measures are needed to allow the placing on the market of the many types of plant and animal products affected by the problem, provided that these products are safe.
Based on the toxicological endpoints derived by BfR, it is proposed to enforce a safety level of 0.5 mg/kg on all plant and animal products, which, according to the results of the EFSA PRIMO model for risk assessment is safe for all consumer groups[2]. This would ensure a high level of consumer

[1] As BAC was included in the review programme of Directive 91/414/EEC, but eventually not approved as no dossier was submitted, a general default MRL of 0.01 mg/kg applies according to Regulation (EC) No 396/2005.
[2] According to the EFSA PRIMO model, with an MRL of 0.5 mg/kg for all commodities covered by Annex I of Reg. (EC) No 396/2005 and by applying an ADI and an ARfD of 0.1, no concerns, neither chronic nor acute were identified. The worst case results of the risk assessment were as follows: chronic risk: 38% of ADI (FR toddler); acute risk: 77% ARfD for the consumption of potatoes based on the UK infant consumption data.

protection, while allowing all crops not directly and intentionally treated with BAC to be marketed, pending any further measures to be taken by the SCoFCAH.

Guidelines

The SCoFCAH was informed about the available information on BAC contamination and toxicological assessment.
Based on the BfR statement and the results from the EFSA PRIMO model, the SCoFCAH has considered that the current default MRL for BAC is not a health standard and that it is appropriate to take the following proportionate risk management measures on a temporary basis, ensuring a high level of consumer protection in the European Union:

1. Food and feed of plant and animal origin with a level of BAC higher than 0.5 mg/kg should not be placed on the market and be withdrawn from the market and safely disposed of.

2. Member States are recommended to carry out investigations on the causes of the contamination and to put in place a monitoring programme with a view to have a clear understanding of the levels of BAC in all food and feed of plant and animal origin. Member States should without any delay communicate to the Commission and to EFSA the results of the monitoring programmes and investigations by the end of February 2013, with a view of taking any necessary measure under Reg. (EC) No 396/2005.

   2.1. Member states should consider the following guidelines for their national monitoring programmes:

      2.1.1. Samples should be taken both for domestic and for imported products.

      2.1.2. Member States should establish and justify the proportion between samples of different commodities as listed in Annex I to Reg. (EC) No 396/2005. The following commodity groups should be covered by each national programme: citrus fruit, pome fruit, miscellaneous fruit (in particular bananas), root and tuber vegetables (in particular potatoes), fruiting vegetables, leafy vegetables, and dairy products. Member States are also encouraged to collect and analyse samples of other commodity groups, such as stone fruit, berries, stem vegetables, cereals, oilseeds, tea and herbal infusions and processed products such as orange juice, flour, olive oil.

      2.1.3. For each commodity group, the Member States should analyse both conventional and organic products, in a proportion to be decided by each Member State.

      2.1.4. Member States could consider to carry out targeted sampling in premises where QACs are used as biocidal products.

The management measures referred to in point 1 are to be applied as from 26 July 2012 and on a temporary basis, pending any further decision taken by the SCoFCAH.