

Guidelines as regards measures to be taken as regards the presence of DDAC in or on food and feed

agreed by the Standing Committee of the Food Chain and Animal Health (SCoFCAH) on 13 July 2012

Background

The Commission has been informed by food business operators and later by Germany, Denmark, The Netherlands and Belgium that various food products may contain levels of didecyl dimethyl ammonium chloride (DDAC) higher than 0.01 mg/kg (default level as set by Article 18.1.b to Regulation (EC) No 396/2005). Residue levels from analyses provided by food business operators found can be up to 4.3 mg/kg.

DDAC is a quaternary ammonium compound (QAC), which in the EU is both authorised as a plant protection product in ornamental crops and as biocide for disinfection. Because these uses were expected not to result in any residues in food, no specific MRLs were fixed related to these uses and in that case the default MRL of 0.01 mg/kg is applicable.

Food business operators have been investigating the reason(s) of this unexpected presence of DDAC. The residues found could be of several origins and depend on the crops concerned.

The highest levels (between 1 and 4.3 mg/kg) were found on fresh herbs treated in Germany with a plant strengthener that contained DDAC. The authorisations for this plant strengthener have meanwhile been withdrawn by Germany.

94 % of 160 samples contained residues lower than 0.5 mg/kg. For these samples no indications are present of intentional use of DDAC on the crops. Although other causes cannot be excluded and are currently investigated, a likely cause of the presence of these residues is cross contamination due e.g. to contact of the crops with surfaces treated with biocidal products containing DDAC, and/or to the use of DDAC to disinfect washing water in pack houses or to disinfect irrigation water. A study provided by food business operators is available showing that residues up to 0.06 mg/kg can be found on crops after having been in contact with a conveyer belt disinfected with DDAC. However, 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.

On 2 July 2012 BfR, the German federal institute for consumer protection and food safety, issued a statement declaring that based on the findings so far and assuming a (average) residue level of 1 ppm for bananas, citrus and fresh herbs, and for all other an average level of 0.1 mg/kg no long term or short term risk for any consumer group is to be expected. BfR derived an ADI and an ARfD at 0.1 mg/kg bw. It should be noted that also the Netherlands carried out a toxicological assessment of DDAC in the framework of an import tolerance request and they derived an ADI of 0.1 mg/kg bw/d and an ARfD of 0.61 mg/kg bw.

When applying the EFSA PRIMO model for risk assessment and the most conservative toxicological endpoints proposed by BfR, an enforcement level of 0.5 mg/kg on all plant and animal

products would be safe for all consumer groups¹, while all crops not directly treated with DDAC would be marketable.

Guidelines

The SCoFCAH had an exchange of views on the available information and on the results of the risk assessment provided by BfR.

Based on the BfR statement and the results from the EFSA PRIMO model, the SCoFCAH has considered that the current default MRL for DDAC 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 DDAC higher than 0.5 mg/kg and 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 DDAC 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 could consider to carry out targeted sampling in premises where QACs are used as biocidal products.
 - 2.1.5. Member States should analyse for DDAC primarily, but also for other quaternary ammonium compounds and in particular for benzalkonium chloride (BAC).

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

¹ 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.