

Statement of the Standing Committee on the Food Chain and Animal Health (SCoFCAH)

agreed on 12/13 June 2014

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

Rev 1

Background

The Standing Committee on the Food Chain and Animal Health (SCoFCAH) agreed on “Guidelines as regards measures to be taken as regards the presence of Didecyl Dimethyl Ammonium Chloride (DDAC) in or on food and feed” on 13 July 2012 and “Guidelines as regards measures to be taken as regards the presence of Benzalkonium Chloride (BAC) in or on food and feed” on 25 July 2012, hereinafter ‘the Guidelines’. Both Guidelines were modified on 5 October 2012.

The Guidelines were agreed due to the unexpected presence of DDAC and BAC residues in various food products at levels exceeding the default maximum residue level (MRL) of 0.01 mg/kg laid down in Regulation (EC) No 396/2005. They contained two main elements: (1) agreement on an enforcement level of 0.5 mg/kg for food and feed as listed in Annex I to Regulation (EC) No 396/2005; and (2) recommendation for a monitoring programme.

Monitoring data to investigate the presence of residues of DDAC and BAC in food were generated in 2012 and 2013 by Member States and food business operators. EFSA provided a technical report on the statistical evaluation of the collected data¹. It assessed whether the temporary MRLs proposed by the Commission services sufficiently protect consumers as regards their possible exposure to residues due to the use in biocidal products and gave a reasoned opinion on the proposed MRLs². The Commission presented a proposal to set temporary MRLs in Annex III A to Regulation (EC) No 396/2005 (SANCO/10842/2014) to the SCoFCAH on 12/13 June 2014³. Those temporary MRLs should be reviewed within five years (i.e. by 31 December 2019), to evaluate new data and information that may become available.

¹ European Food Safety Authority; Evaluation of monitoring data on residues of didecyl dimethyl ammonium chloride (DDAC) and benzalkonium chloride (BAC). EFSA supporting publication 2013:EN-483, 30 pp.

² European Food Safety Authority; Reasoned opinion on the dietary risk assessment for proposed temporary maximum residue levels (MRLs) of didecyl dimethyl ammonium chloride (DDAC) and benzalkonium chloride (BAC). EFSA Journal 2014;12(4):3675, 23 pp.

³ Proposal SANCO/10842/2014 received a favourable opinion of the SCoFCAH on 13 June 2014. It was adopted by the Commission on 16 October 2014 and published in the Official Journal of the European Union as Commission Regulation (EU) No 1119/2014 on 23 October 2014. The Commission Regulation entered into force on 12 November 2014.

Guidelines

It was stated in the Guidelines that “The management measures [...] are to be applied on a temporary basis, pending any further decision taken by the SCoFCAH.”

The SCoFCAH considered that it is appropriate to revoke the Guidelines following the entry into force of the above mentioned draft Commission Regulation (SANCO/10842/2014).

However, a reasonable period should be allowed to elapse before the enforcement level agreed in the Guidelines (i.e. 0.5 mg/kg) ceases to apply in order to permit Member States, third countries and food business operators to prepare themselves to meet the new requirements (i.e. 0.1 mg/kg). The SCoFCAH considered that the enforcement level agreed in the Guidelines should cease to apply on 12 August 2015.

Furthermore, in order to allow for the normal marketing, processing and consumption of products, a transitional arrangement should be provided for products which have been produced respecting the enforcement level agreed in the Guidelines before the MRL setting and for which information shows that a high level of consumer protection is maintained. The enforcement level agreed in the Guidelines shall continue to apply to such products which were produced before 12 August 2015.

As is the case for the Guidelines modified on 5 October 2012, the above considerations pertain to food and feed as listed in Annex I to Regulation (EC) No 396/2005 and for which MRLs are set, i.e. for code numbers 0100000 through 1070000. MRLs for foods for infants and young children are set under Commission Directives 2006/125/EC and 2006/141/EC, not subject to the enforcement level agreed in the Guidelines, and hence not affected by draft Commission Regulation (SANCO/10842/2014) or the revocation of the Guidelines.