



ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΓΕΩΤΕΧΝΙΚΟ ΕΠΙΜΕΛΗΤΗΡΙΟ ΕΛΛΑΔΑΣ
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ΘΕΜΑ: «Ενέργειες στο πλαίσιο των Οδηγιών που εξέδωσε η Μόνιμη Επιτροπή για την Τροφική Αλυσίδα και την Υγεία των Ζώων στις 13 & 25/07/2012»

ΕΞΑΙΡΕΤΙΚΑ ΕΠΕΙΓΟΝ

Αθήνα, 1 Αυγούστου 2012

Αρ. Πρωτ.: 624

ΠΡΟΣ:

Ενιαίο Φορέα Ελέγχου
Τροφίμων – Ε.Φ.Ε.Τ.
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ΚΟΙΝΟΠΟΙΗΣΗ:

- 1) Κ.Υ. ΓΕΩΤ.Ε.Ε.
- 2) Περιφ. Παρ/τα ΓΕΩΤ.Ε.Ε.
Έδρες τους

Με βάση τις οδηγίες που εξέδωσε η Μόνιμη Επιτροπή για την Τροφική Αλυσίδα και την Υγεία των Ζώων (SCoFCAH) της Γενικής Διεύθυνσης Υγείας και Προστασίας των Καταναλωτών (DG SANCO) της ΕΕ στις 13 και 25/7/2012 παρακαλούμε να μας ενημερώσετε για εξής θέματα:

1) Η υπηρεσία σας διαθέτει πληροφορίες, για το ποια ήταν τα τρόφιμα (εμπορική ονομασία, παρασκευάστρια εταιρεία, παρτίδα), στα οποία ανιχνεύθηκαν σε χώρες της ΕΕ (Γερμανία, Δανία, Ολλανδία και Βέλγιο) οι ουσίες didecyl dimethyl ammonium chloride (DDAC) και benzalconium chloride (BAC) σε επίπεδα πολλαπλασία του προσωρινού ορίου 0,5 mg/kg, κατόπιν δειγματοληπτικού ελέγχου;

2) Γνωρίζετε εάν τέτοια τρόφιμα εισήχθησαν στην Ελλάδα και αν ναι ποια τα μέτρα για τον εντοπισμό και την απόσυρσή τους;

3) Πώς προτίθεται να προστατεύσει η υπηρεσία σας τον καταναλωτή, από την ενδεχόμενη παρουσία στα τρόφιμα, ενώσεων της ομάδας του τεταρτοταγούς αμμωνίου (QACs) και κυρίως από προϊόντα προέλευσης Δανίας, η οποία αρνήθηκε να υιοθετήσει τις οδηγίες για το DDAC;

Συνημμένα:

1. 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 (σελ. 2).

2. 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 (σελ. 2).

Ο Πρόεδρος
της Δ.Ε.

Σταύρος Ζαννόπουλος

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/kg¹. 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 an 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 groups². 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.

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.