

Chemicals Regulation Directorate

**Russell Wedgbury**

To: QAC Stakeholders

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Dear Sir/Madam,

**UK enforcement of MRLs for Benzalkonium Chloride (BAC) and Didecyl Dimethyl Ammonium Chloride (DDAC)**

Following on from the meeting of stakeholders held on 17 July, I am writing to confirm the approach that will be taken by UK regulators to monitor and enforce revised MRLs due to apply from 12 August.

Pesticide MRLs exist for all pesticide active substances (primarily but not exclusively plant protection products) currently or formally authorised. EC Regulation 396/2005 explicitly states pesticide MRLs also apply to substances currently or formerly used as biocides or veterinary medicines, and includes residues from any source including environmental contamination and naturally occurring background levels. BAC and DDAC were formerly used as plant protection products. Thus their residues fall clearly within the scope of Regulation 396/2005 – and MRLs apply - regardless of the origin of the residue, and no source can be discounted in checking for compliance.

As you may be aware, non-statutory guideline Maximum Residue Levels (MRLs) of 0.5 mg/kg for residues of DDAC and BAC in all foods have been in place since 2012. These have been applied by all member State Regulatory Authorities.

Commission Regulation 1119/2014 (amending EC Regulation 396/2005), which was published on 23 October 2014, set revised statutory EU MRLs of 0.1 mg/kg. Under the terms of the Regulation these statutory MRLs applied 20 days after publication. However member State Regulatory Authorities agreed to suspend their enforcement of the statutory MRLs and maintain the guideline levels for a further transitional period – until 12 August 2015.

Under the terms of this agreement, Member State enforcing bodies will apply the guideline level of 0.5 mg/kg to all foods up to 12 August 2015. Foods that have been 'produced' before 12 August (i.e. foods that have been distributed or sold and may have acquired residues from the use of DDAC or BAC) will also continue to be subject

to the guideline MRL of 0.5 mg/kg. **However foods produced after 12 August will be subject to the new statutory MRLs of 0.1 mg/kg.**

## **UK approach to monitoring and enforcement action**

HSE has sole statutory responsibility for both pesticide residues monitoring and for the enforcement of EU MRLs in the UK.

It is an offence to sell or supply food with a residue over the relevant MRL. This applies to sale or supply to a food or feed processor or manufacturer – food cannot be rendered legal via processing as food or feed.

BAC and DDAC analysis is already part of HSE's routine programme of monitoring.

- Details of HSE's monitoring programme for 2015 are at [http://www.pesticides.gov.uk/guidance/industries/pesticides/advisory-groups/PriF/PriF\\_Results\\_and\\_Reports/2015\\_Programme](http://www.pesticides.gov.uk/guidance/industries/pesticides/advisory-groups/PriF/PriF_Results_and_Reports/2015_Programme)
- Initial plans for 2016 are set out at [http://www.pesticides.gov.uk/guidance/industries/pesticides/advisory-groups/PriF/PriF\\_Results\\_and\\_Reports/2016\\_Programme](http://www.pesticides.gov.uk/guidance/industries/pesticides/advisory-groups/PriF/PriF_Results_and_Reports/2016_Programme)

The Expert Committee on Pesticide Residues in Food (PRiF) publishes quarterly reports on the results of HSE's monitoring programme. The PRiF are aware of the importance of QACs to food hygiene and will continue to explain the full context of any findings in their reports.

As stated above, the new statutory EU MRL of 0.1 mg/kg applies to all food produced after 12 August 2015.

When considering monitoring results, HSE will initially apply the MRL in place on the date of monitoring. However if residues over 0.1 mg/kg are detected, producers and brand-owners will be given the opportunity to explain that the food was produced before 12 August as well as to make any other observations.

PRiF will also continue to follow their current practice as regards publication of brand-name details. All results of all pesticide residues monitoring including brand name details are published, and samples with residues over an MRL after measurement uncertainty is taken into account are highlighted. An example of the format used is at <http://www.pesticides.gov.uk/Resources/CRD/PriF/Documents/Results%20and%20Reports/2014/Q4%20BNA.pdf>. There are no plans to publish BAC and DDAC results separately to or more often than for other pesticides, or otherwise to draw particular attention to them.

## **Application of BAC and DDAC pesticide MRLs to processed foods**

Pesticide MRLs apply to all foods listed in Annex I of EC Regulation 396/2005, whether in their raw or processed forms. For fresh and frozen foods the MRL set applies without adjustment – for instance, the MRL for shelled peas applies to both fresh and frozen peas.

For some processed foods (other than raw foods that are frozen), Regulation 396/2005 allows, in appropriate circumstances, for processing factors to be applied in determining whether the MRL set for the raw product has been breached (adjusting for the increase or decrease in the amount of residue expected to be found after processing takes place, such as following drying or dilution). However it is important to note that in most cases it will not be appropriate to apply processing factors to residues of DDAC and BAC. This is because these products are used as biocides rather than as agricultural pesticides, and as such residues may be added at any point up to sale to the consumer.

The use of processing factors is appropriate when considering residues arising from the use of agricultural pesticides, because in most cases the pesticide is applied at the crop growth stage or shortly after harvest, with, crucially, no further uses of that pesticide at later food processing stages. So if the food is dried, for instance at a later processing stage, it can be assumed that the resulting increase (concentration) of the residue in the food is a result of the drying process alone– and not because there have been further uses of the product during processing. There is no provision in Regulation 396/2005 that allows the MRL set to be breached because of additional uses of substances at the processing stage.

Therefore, for the reasons stated above, and because DDAC and BAC can be used at any point of production, including during food processing right up to portioning and packaging for supply to consumers, HSE will as a matter of course apply the MRL as set under Regulation 396/2005 to all foods. No adjustment employing processing factors will be routinely applied.

### **Food safety and RASFF alerts**

MRLs are not safety levels, although the evaluation process used in setting them takes account of safety related data and calculations. The primary basis for any substantive MRL set is the level likely to arise from the legal use of the substance concerned, which will usually produce a residue well below any level likely to cause harm to the consumer. Thus residues found over the MRL, although in breach of the statutory requirement, will not automatically result in RASFF notifications being issued.

The Food Standards Agency (FSA) decides whether a RASFF notification should be issued. They will only be issued for pesticide residues in food where the intake would represent a risk to consumers (and also certain other technical requirements of the system are met). Food safety legislation is in place from farm-to-fork to ensure that consumers are provided with food that is safe to eat. All food manufacturers are required to have in place food safety procedures based on the HACCP principles and manufacturers must ensure that the procedures continue to work effectively to help ensure that the food produced is safe.

The Food Standards Agency recognises the importance of BAC and DDAC as disinfectants for food production to ensure the necessary control of food hygiene standards. The FSA would encourage all food manufacturers to review their processes carefully in conjunction with the suppliers of your disinfectants and your Environmental Health Officer to consider whether it is possible to continue using DDAC and BAC whilst ensuring compliance with the new MRL.

HSE carry out consumer risk assessments on all residues detected. Full details including the risk assessments are published in PRiF reports.

**Further information**

Further details of the EU MRLs regime can be found at the website [www.pesticides.gov.uk](http://www.pesticides.gov.uk) .

Yours faithfully,

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MRLs Policy, Chemicals Regulation Directorate