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**CLARIFICATION ON SUBSTANCES NOTIFIED UNDER THE BKC AND
DDAC GENERIC HEADINGS IN ANNEX II OF COMMISSION REGULATION
(EC) NO 2032/2003**

Further to a question raised on the implementation of the 1 September 2006 deadline for the quaternary ammonium compounds BKC (Benzalkonium chloride)¹ and DDAC (Dialkyldimethylammonium chloride)^{2,3}, as these generic names actually address a multitude of structurally-related but different substances, in alkyl chain lengths, alkyl chain distributions and anions, the following approach was agreed between the Member States and the Commission.

In order to ensure a harmonised implementation of Directive 98/8/EC on biocidal products, it was recognised that there is indeed a need for both industry and competent authorities to clarify which substances were captured by the generic names BKC and DDAC. This need for clarification is due to the fact that Regulation (EC) N°2032/2003 only mentions that both are mixtures of EINECS listed substances, with no CAS or EC number given for their more precise identification.

At the 21st CA meeting, it was agreed that any substance, which could be referred to as BKC or DDAC, should be considered as being captured by the notification made for BKC and DDAC. Therefore, these substances should be allowed to remain on the market, for the product-types notified, after 1 September 2006 and until they have been evaluated under the review programme. This would however not apply to product-type 8, as the identity of the substances was already clarified for this product-type.

The Member States asked the Commission to amend Annex III of Regulation 2032/2003 to that effect by deleting the entries of the BKC- / DDAC-related substances from Annex III of Regulation (EC) No 2032/2003. It was also discussed whether it was, in addition, necessary to list the names of all the substances potentially captured by the BKC and DDAC entries in Annex II of Regulation 2032/2003. The CA meeting agreed to the

¹ Included in Annex II of Commission Regulation (EC) No 2032/2003 as quaternary ammonium compounds (benzylalkyldimethyl (alkyl from C8-C22, saturated and unsaturated, tallow alkyl, coco alkyl, and soya alkyl) chlorides, bromides, or hydroxides)

² Included in Annex II of Commission Regulation (EC) No 2032/2003 as quaternary ammonium compounds (dialkyldimethyl (alkyl from C6-C18, saturated and unsaturated, and tallow alkyl, coco alkyl, and soya alkyl) chlorides, bromides, or methylsulphates)

³ Additional information on the molecular structure of these two compounds is provided in the annex to this document.

interpretation that the entries of BKC and DDAC would be considered to cover all such substances, and thus only Annex III of Regulation 2032/2003 would need to be amended.

In addition, the Rapporteur Member State (Italy) was invited to clarify the precise identity of the substances to be eventually covered by the BKC and DDAC Annex I inclusion during the evaluation of the dossiers submitted for these two groups of compounds.

Further to the CA meeting, the Commission has now prepared a modification of Annex III, in which the following entries will be removed:

Name (EINECS and/or others)	EC number	CAS number	BKC/DDAC
Cetalkonium chloride	204-526-3	122-18-9	BKC
Benzyltrimethyl(octadecyl)ammonium chloride	204-527-9	122-19-0	BKC
Benzododecinium chloride	205-351-5	139-07-1	BKC
Miristalkonium chloride	205-352-0	139-08-2	BKC
Didecyltrimethylammonium bromide	219-234-1	2390-68-3	DDAC
Dimethyldioctylammonium chloride	226-901-0	5538-94-3	DDAC
Benzyltridecyltrimethylammonium bromide	230-698-4	7281-04-1	BKC
Decyltrimethyloctylammonium chloride	251-035-5	32426-11-2	DDAC
Benzyltrimethyloleylammonium chloride	253-363-4	37139-99-4	BKC
Quaternary ammonium compounds, coco alkyltrimethyl, chlorides	263-038-9	61789-18-2	TMAC ⁴
Quaternary ammonium compounds, benzylcoco alkyltrimethyl, chlorides	263-080-8	61789-71-7	BKC
Quaternary ammonium compounds, dicocoalkyl trimethyl, chlorides	263-087-6	61789-77-3	DDAC
Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)trimethyl, chlorides	263-090-2	61789-80-8	DDAC
Quaternary ammonium compounds, benzyl-C8-18-alkyltrimethyl, chlorides	264-151-6	63449-41-2	BKC
Quaternary ammonium compounds, di-C6-12-alkyltrimethyl, chlorides	269-925-7	68391-06-0	DDAC
Quaternary ammonium compounds, benzyl-C8-16-alkyltrimethyl, chlorides	270-324-7	68424-84-0	BKC
Quaternary ammonium compounds, benzyl-C10-16-alkyltrimethyl, chlorides	273-544-1	68989-00-4	BKC
Quaternary ammonium compounds, di-C8-18-alkyltrimethyl, chlorides	277-453-8	73398-64-8	DDAC
Quaternary ammonium compounds, benzyl-C8-18-alkyltrimethyl, bromides	293-522-5	91080-29-4	BKC
Alkyl-benzyl-trimethylammonium chloride / Benzalkonium chloride	Mixture	8001-54-5	BKC

From a practical point of view, this means that any product containing active substances referred to as BKC or DDAC could stay on the market beyond 1 September 2006 in the product types notified and until BKC and DDAC have been evaluated under the review programme.

When BKC and DDAC will eventually be included in Annex I or IA of the Directive, the precise identity of the substances covered by these generic names will be clearly spelled out in the inclusion decision. As a consequence, biocidal products containing substances, which will not be listed under the BKC and DDAC inclusion entries, will have to be removed from the market by the date of the inclusion of the substances in Annex I or IA of the Directive.

However, to ensure that companies, which might have expected their particular form of BKC or DDAC to be covered by the two notifications / dossiers submitted for these two groups of compounds, are not taken by surprise and that this does not lead to market

⁴ The Rapporteur Member State has already clarified that this substance is covered by the TMAC entry.

disruption, a period of three months, starting from the date of entry into force of the inclusion Decision, will be given to these companies to inform the Commission of their intention to submit a dossier for the particular form of BKC or DDAC not listed in the inclusion decision, along the lines of Article 8(3) and (4) of Regulation (EC) No 2032/2003.

Companies notifying their interest within the deadline will then be given a period of 18 months to prepare and submit their dossiers. After that 18-month period, only substances for which a dossier would have been submitted will be allowed to remain on the market as active substances in biocidal products.

ANNEX

MOLECULAR STRUCTURE OF THE BKC AND DDAC COMPOUNDS COVERED BY THE ENTRIES IN ANNEX II TO COMMISSION REGULATION (EC) Nr 2032/2003

Based on information received from the European Quats Consortium (EQC), it is understood that:

- BKC would correspond to all substances with a benzalkonium structure (i.e. all alkyl benzyl dimethyl ammonium compounds), where the anionic part is limited to chlorides, bromides, or hydroxides
- DDAC would correspond to all dialkyl dimethyl ammonium compounds), where the anionic part is limited to chlorides, bromides, or methylsulphates.

The molecular structure of BKC and DDAC is illustrated in the table below:



Therefore, a substance like the tetradecyldimethylbenzylammonium fluoride (CAS Nr 61134-95-0), although it is a DDAC like compound, should not be covered by the DDAC entry in Annex II to Regulation 2032/2003 due to its fluoride as anionic part.

Also, the chain length of the alkyl chain part of the structures shall be comprised within the following ranges: C8-C22 for BKC and C6-C18 for DDAC. Therefore, substances, such as the dodecylethyldimethylammonium bromide (CAS Nr 68207-00-1), which have an ethyl as alkyl chain, should not be covered by the BKC/DDAC entries in Annex II to Regulation 2032/2003.