

Health assessment of didecyldimethylammonium chloride (DDAC) residues in food

BfR opinion No 027/2012, 09 July 2012

On the occasion of quality controls in food business and during official food surveillance, didecyldimethylammonium chloride (DDAC) residues in excess of the currently applicable maximum residue level (MRL) of 0.01 mg/kg were detected in food. The first opinion on DDAC residues, which was issued by the Federal Institute for Risk Assessment (BfR) on 29 June 2012 (BfR opinion No 024/2012, available in German language only) was based on only few residue data. Meanwhile the BfR has been provided with many additional data. Based on these, the BfR has updated its assessment whether the detected residues pose a health risk for consumers.

DDAC is a quaternary ammonium compound belonging to the group of cationic surfactants. The substance is used in disinfectants and detergents. DDAC is both a biocide and a pesticide active substance. In addition, DDAC is contained in products used as plant strengtheners.

The available data indicate “background” levels of DDAC above the currently applicable default maximum residue level for most commodities. Based on the available data the cause can not always be clearly identified. It is noticed, that for citrus fruit and large tropical fruit, for example banana and mango, occasionally especially high residues were reported. It is likely that these fruits received post-harvest treatments with DDAC. Very high residues were also observed for fresh herbs. These residues can be the result of the use of a plant strengthener, which has meanwhile been withdrawn from the market. Disinfection of planting pots or equipment might also have been a source. DDAC residues in milk and ice cream might be due to disinfection of milking equipment, ice cream machines or other equipment.

Based on German and further European consumption data, the BfR estimated the dietary intake of DDAC residues from contaminated food. Neither the acute reference dose (ARfD) nor the acceptable daily intake (ADI) are exceeded. The ARfD is defined as the quantity of a substance that can be ingested during one or several meals in the course of a day without any appreciable health risk. The ADI is the quantity of a substance that can be ingested daily over an entire lifetime without any appreciable health risk. The BfR comes to the conclusion that neither an acute nor a chronic risk for consumers is likely.

The BfR considers it as reasonable to raise the maximum residue levels for DDAC to an adequate extent, if the changes are reviewed as soon as more information becomes available from national product authorizations for biocidal products containing DDAC. Furthermore it is recommended to establish clear guidance on adequate cleaning/washing procedures to be followed after disinfection of equipment that gets in contact with food.

1 Subject of the assessment

On the occasion of quality controls in food business and during official food surveillance, didecyldimethylammonium chloride (DDAC) residues in excess of the currently applicable maximum residue level (MRL) of 0.01 mg/kg were detected in food.

Different toxicological reference values were stated by the Environmental Protection Agency (US-EPA) and the Board for the Authorisation of Plant Protection Products and Biocides (CTGB, Netherlands). The Federal Institute for Risk Assessment (BfR) has assessed which

reference values are supported and whether the detected residues pose a health risk for consumers.

The first opinion on DDAC residues, which was issued by BfR on 29 June 2012 (BfR opinion No 024/2012, available in German language only) was based on only few residue data. Meanwhile the BfR has been provided with many additional data. The updated assessment considers all residue data which have been submitted to BfR by 06 July 2012.

2 Results and conclusions

BfR supports an ADI value of 0.1 mg/kg bw/day and an ARfD of 0.1 mg/kg bw (body weight) for DDAC.

The residues in food reported so far are unlikely to pose an acute or chronic health risk for German or further European consumer groups.

3 Rationale/Risk Assessment

DDAC is a mixture of alkyl-quaternary ammonium salts with typical alkyl chain lengths of C8, C10 and C12, with more than 90 % of C10. DDAC is both a biocide and a pesticide active substance.

DDAC has been evaluated and peer reviewed on EU level in the framework of the fourth stage of the review programme for pesticide active substances. With Commission Directive 2009/70/EC of 25 June 2009 DDAC was included in Annex I of Dir. 91/414/EEC, but with the following restriction: only indoor uses for ornamental plants as bactericide, fungicide, herbicide and algaecide may be authorised. The conclusion was reached on the basis of the evaluation of representative uses comprising soaking or dipping applications for the disinfection of horticultural vessels and equipment, and watering applications for the disinfection of surfaces. In Germany no uses of DDAC-containing plant protection products were authorized since 2002. Some EU Member States still have authorized uses of DDAC in place, but probably uses which are not relevant in terms of residues in food and feed. No further information is available on this issue.

In addition, DDAC is contained in plant strengtheners. Two of them are listed in Germany for professional use as preservatives for cut flowers only and thus are not considered to contribute to consumer exposure. Another plant strengthener which has apparently been widely used in organic farming, was recently found to contain considerable residues of DDAC of yet unknown origin. DDAC was not mentioned in the specification. Some of the findings of DDAC in plant commodities in Germany could be traced back to the use of this particular plant strengthener. As a consequence, this plant strengthener has immediately been withdrawn from the market.

Further sources of exposure in agriculture might be related to fertilizers containing DDAC or to plant protection products containing DDAC as co-formulants.

DDAC is currently also being evaluated and peer reviewed on EU level in the framework of the biocide active substances review programme. The decision on its inclusion in Annex I of Dir. 98/8/EC (now Reg. (EC) No 528/2012) is still pending for all product types. For product-type 8 (PT 8, wood preservatives) a decision is expected for September 2012. For PT 1-4 (disinfectants) the peer review of the draft evaluation report by the Member States is cur-

rently ongoing. National product authorizations for DDAC-containing biocidal products will start after Annex I inclusion for the respective PT. Notwithstanding many biocidal products containing DDAC are currently available on the market because they have been used since long before the pre-condition of authorization was introduced for biocidal products. Residues in food and feed which result from biocidal uses are likely to occur but can not yet be quantified due to a lack of application and exposure data. These are expected to be generated to support national authorizations of biocidal products belonging to PT 1-4.

Since DDAC has been evaluated as a pesticide, its residues are under the scope of Regulation (EC) No 396/2005. As long as no specific MRLs have been set for DDAC, the default MRL of 0.01 mg/kg applies for all food commodities of plant and animal origin.

3.1 Toxicological assessment of DDAC

For a detailed toxicological assessment it is referred to:

- the Draft Assessment Report (DAR) submitted by The Netherlands in 2008 in the EU active substances programme for pesticides
- the EFSA Conclusion on Pesticide Peer Review (EFSA Scientific report (2008) 214, 1-54, <http://www.efsa.europa.eu/en/efsajournal/doc/214r.pdf>)
- the draft CA-Reports (Competent Authority Reports) submitted by Italy in the EU active substances programme for biocides PT 1-4 in 2012 and for PT 8 in 2010
- the Reregistration Eligibility Decision for Aliphatic Alkyl Quaternaries (DDAC) published by US-EPA (Docket EPA-HQ-OPP-2006-0338 at: <http://www.regulations.gov>)
- the Evaluation Report submitted by the Netherlands in 2012 concerning the Setting of MRLs for didecyldimethylammonium chloride (DDAC) in citrus (EFSA question EFSA-Q-2012-004840).

Toxicological reference values

In the following table the toxicological reference values relevant for consumer risk assessment as derived for DDAC by different bodies and in different contexts are summarized.

Table 1: Toxicological reference values derived for DDAC by different bodies

| Reference value | Body | Value | Study | Safety factor |
|--------------------------------------|---------------------|-----------------------------------------------------------------------------------------|----------------------------------|---------------|
| ADI | BfR (DE), CTGB (NL) | 0.1 mg/kg bw | 1 year dog | 100 |
| ARfD | BfR (DE) | 0.1 mg/kg bw | 1 year dog | 100 |
| ARfD | CTGB (NL) | 0.61 mg/kg bw | 90 days rat and 2 generation rat | 100 |
| cPAD | EPA (US) | 0.1 mg/kg bw | 1 year dog | 100 |
| aPAD (women in child-bearing age) | EPA (US) | 0.1 mg/kg bw | Developmental tox rat | 100 |
| aPAD (general public) | EPA (US) | Not required | | |
| <i>AEL (biocides, PT 1, 2, 3, 4)</i> | <i>IT</i> | <i>0.15 mg/kg bw (proposal only, not yet harmonized, peer review currently ongoing)</i> | <i>90 days dog</i> | <i>100</i> |

| Reference value | Body | Value | Study | Safety factor |
|--------------------------------------------|-----------|--------------------------------------------------------------------------------------------------------|--------------------|---------------|
| <i>AEL (biocides, PT 8)</i> | <i>IT</i> | <i>0.1 mg/kg bw (proposal only, not yet harmonized, procedure currently ongoing)</i> | <i>1 year dog</i> | <i>100</i> |
| <i>ADI and ARfD (biocides, PT 1, 2, 8)</i> | <i>IT</i> | <i>Not required for this PT (proposal only, not yet harmonized, peer review currently ongoing)</i> | | |
| <i>ADI (biocides, PT 3, 4)</i> | <i>IT</i> | <i>0.15 mg/kg bw (proposal only, not yet harmonized, peer review currently ongoing)</i> | <i>90 days dog</i> | <i>100</i> |
| <i>ARfD (biocides, PT 3, 4)</i> | <i>IT</i> | <i>0.45 mg/kg bw (proposal only, not yet harmonized, peer review currently ongoing)</i> | <i>90 days rat</i> | <i>100</i> |

ADI: Acceptable Daily Intake

ARfD: Acute Reference Dose

cPAD: Chronic Population Adjusted Dose

aPAD: Acute Population Adjusted Dose

AEL: Acceptable Exposure Level

BfR agrees with the ADI value of 0.1 mg/kg bw as derived by the Netherlands in 2012.

According to the information in the evaluation report prepared by The Netherlands (EFSA question EFSA-Q-2012-004840), the results of the gavage studies were considered to be less relevant for the setting of an ARfD because “the intestinal surface concentrations of DDAC are not diluted by food” and hence the observed effects would likely be local effects secondary to the corrosive properties. BfR agrees that local effects should not be the basis for setting an ARfD, however BfR would advocate towards an analysis of the observed effects noted in dietary and gavage studies, whether they were induced by local / corrosive properties or whether they were systemic effects.

Lower body weights were observed at the early time points in the 1-yr dog study in animals dosed with 30 mg/kg bw/d. Hence, this should be considered an acute effect. The test compound was administered in an 9:1 water:feed slurry divided in two portions per day. Considering that the test compound was administered with feed, the study is considered relevant for the evaluation of an acute dietary exposure.

Within the biocides procedure, an “acceptable exposure level” (AEL) for acute, medium-term and long-term exposures of 0.1 mg/kg bw/d (based on the 1-yr dog study, SF 100) was established.

In summary, also to obtain harmonisation across sectors, BfR proposes to set an ARfD of 0.1 mg/kg bw based on the findings in the 1-yr dog study and an SF of 100.

3.2 Dietary intake assessment for DDAC

3.2.1 Available information on DDAC residues in food

When quite recently easy-to-use analytical methods became available for quaternary ammonium compounds (see e.g. publication by the European Union Reference Laboratory for Residues of Pesticides¹), an extensive generation of monitoring/surveillance data started. It has to be noted however that *representative* monitoring data covering all kinds of food of plant and animal origin is not available up to now.

It has also to be noted that not all residues reported can be considered as “unavoidable residues” following good practice. This is discussed in more detail below.

Data were made available by quality control institutions in food business and by German Federal States’ (Länder) Authorities which are responsible for official food surveillance/monitoring.

Food of plant origin

Some DDAC-residues could be traced back to an application in agriculture: Residues in parsley following several applications of a plant strengthener amounted to 1-3 mg DDAC/kg and were in the range of 0.5-0.8 mg/kg after only one application of the product. These uses and the residues resulting thereof are considered being of no further relevance since this plant strengthener has been withdrawn from the market meanwhile.

DDAC-containing products are known to be used as a pesticide for pre- and mainly post-harvest uses in a couple of crops outside the EU.

In-depth information on DDAC used as a disinfectant against microbial contaminants for post-harvest dip treatment of citrus fruit is available from an application for import tolerance evaluated by NL (Evaluation report dated 26 March 2012, EFSA’s Reasoned Opinion still pending). According to the NL evaluation, metabolism studies have been carried out on tomato, apple and lemon using [¹⁴C]-DDAC. Only parent DDAC was observed as major radioactive component in surface washes and extracts. In all fruits, DDAC was the only residue identified and accounted for 97-98% of the total radioactive residue (TRR) in tomatoes, 98-99% TRR in apples and 96-99% TRR in citrus. DDAC can be regarded as stable for at least 9 months in orange pulp and peel samples when stored frozen at -18 °C. Decomposition of DDAC is not expected in peel and during pressing of juice. The average ratio pulp/whole fruit is 0.11 which can be considered as an average processing factor for DDAC in peeled citrus. For the processing to juice a processing factor of 0.28 (obtained from 3 studies) has been derived. Residue trials complying with the intended use conditions have been provided for oranges and mandarins. Residues in pulp were: 0.04, 2x0.09, 0.22, 0.27, 0.32, 0.5, 1.0 mg/kg. According to the NL evaluation report, the LOQ was 0.1 mg/kg rendering lower residue values not reliable. Residues in whole fruit were calculated from pulp and peel data: 2x1.2, 1.6, 1.7, 1.8, 1.9, 2.0, 2.3, 4.1 mg/kg. Based on these data an MRL of 6 mg/kg was proposed for citrus but not yet established in Reg. (EC) No 396/2005.

The following table summarizes all DDAC findings in plant commodities which were made available to BfR until 06 July 2012, excluding those where the residues had been traced back to applications of the plant strengthener, which has been withdrawn from the market. All

¹ http://www.eurl-pesticides.eu/library/docs/srm/meth_QAC_ShortMethod_EurlSRM.PDF

samples without clear indication of application of this plant strengthener were included. Figures marked **bold** have been used in the risk assessment described later on.

Table 2: Available monitoring/surveillance data on DDAC residues in food of plant origin

| Code number* | Commodity group | Number of samples Residues (mg/kg) | | |
|--------------|-----------------------|---------------------------------------|------|--------------|
| 0110000 | Citrus fruit | N | >LOQ | 28 |
| | | | <LOQ | 78 |
| | | Mean | | 0.258 |
| | | Median | | 0.185 |
| | | Maximum | | 0.98 |
| | | OECD Calculator result | | 1.5 |
| processed | Juice (Orange) | N | >LOQ | 0 |
| | | | <LOQ | 19 |
| | | OECD Calculator result | | - |
| 0130000 | Pome fruit | N | >LOQ | 5 |
| | | | <LOQ | 75 |
| | | Mean | | 0.061 |
| | | Median | | 0.02 |
| | | Maximum | | 0.13 |
| | | OECD Calculator result | | 0.3 |
| 0140000 | Stone fruit | N | >LOQ | 8 |
| | | | <LOQ | 39 |
| | | Mean | | 0.016 |
| | | Median | | 0.01 |
| | | Maximum | | 0.044 |
| | | OECD Calculator result | | 0.07 |
| 0150000 | Berries & small fruit | N | >LOQ | 7 |
| | | | <LOQ | 147 |
| | | Mean | | 0.163 |
| | | Median | | 0.063 |
| | | Maximum | | 0.83 |
| | | OECD Calculator result | | 1.5 |

| Code number* | Commodity group | Number of samples | | Residues (mg/kg) |
|--------------------|-----------------------------------------------------------------------------------|------------------------|------|------------------|
| | | N | >LOQ | |
| 0161000 | Miscellaneous fruit with edible peel (all reported data referring to sharon/kaki) | N | >LOQ | 6 |
| | | | <LOQ | 3 |
| | | Mean | | 0.016 |
| | | Median | | 0.016 |
| | | Maximum | | 0.022 |
| | | OECD Calculator result | | 0.05 |
| 0162000 | Miscellaneous fruit with inedible peel (small), includes kiwi | N | >LOQ | 3 |
| | | | <LOQ | 10 |
| | | Mean | | 0.047 |
| | | Median | | 0.03 |
| | | Maximum | | 0.08 |
| | | OECD Calculator result | | 0.2 |
| 0163000 | Miscellaneous fruit with inedible peel (large), includes banana, mango, avocado | N | >LOQ | 63 |
| | | | <LOQ | 55 |
| | | Mean | | 0.189 |
| | | Median | | 0.15 |
| | | Maximum | | 0.88 |
| | | OECD Calculator result | | 0.9 |
| 0210000 | Root and tuber vegetables | N | >LOQ | 0 |
| | | | <LOQ | 29 |
| | | OECD Calculator result | | - |
| 0231000 | Solanacea | N | >LOQ | 4 |
| | | | <LOQ | 234 |
| | | Mean | | 0.113 |
| | | Median | | 0.046 |
| | | Maximum | | 0.33 |
| | | OECD Calculator result | | 0.7 |
| 0232000 0233000 | Cucurbits | N | >LOQ | 1 |
| | | | <LOQ | 63 |
| | | Maximum | | 0.22 |
| | | OECD Calculator result | | - |
| 0240000 | Brassica vegetables | N | >LOQ | 1 |
| | | | <LOQ | 37 |
| | | Maximum | | 0.011 |
| | | OECD Calculator result | | - |

| Code number* | Commodity group | Number of samples | | Residues (mg/kg) |
|-----------------|-------------------------------------|------------------------|------|------------------|
| | | N | >LOQ | |
| 0251000-0255000 | Leaf vegetables without fresh herbs | N | >LOQ | 1 |
| | | | <LOQ | 113 |
| | | Maximum | | 0.041 |
| | | OECD Calculator result | | - |
| 0256000 | Fresh herbs | N | >LOQ | 113 |
| | | | <LOQ | 197 |
| | | Mean | | 0.356 |
| | | Median | | 0.05 |
| | | Maximum | | 3.63 |
| | | OECD Calculator result | | 4 |
| 0260000 | Legume vegetables (fresh) | N | >LOQ | 14 |
| | | | <LOQ | 48 |
| | | Mean | | 0.052 |
| | | Median | | 0.03 |
| | | Maximum | | 0.22 |
| | | OECD Calculator result | | 0.3 |
| 0270000 | Stem vegetables | N | >LOQ | 1 |
| | | | <LOQ | 37 |
| | | Maximum | | 0.029 |
| | | OECD Calculator result | | - |
| 0280000 | Fungi | N | >LOQ | 1 |
| | | | <LOQ | 8 |
| | | Maximum | | 0.03 |
| | | OECD Calculator result | | - |
| 0402000 | Oilfruits (Olive oil) | N | >LOQ | 0 |
| | | | <LOQ | 20 |
| | | OECD Calculator result | | - |
| 0500000 | Cereals | N | >LOQ | 0 |
| | | | <LOQ | 20 |
| | | OECD Calculator result | | - |

* according to Annex I of Reg. (EC) No 396/2005

N: indicates number of analysed samples

Food of animal origin

In a publication by a German Federal States' (Länder) Authority² DDAC residues in ice cream have been reported. The cleaning procedure subsequent to the disinfection of the equipment was found to strongly influence the residue level. Levels of 1 mg/kg and more in ice cream could be reduced to below 0.1 mg/kg by adequate cleaning with hot water after the

² H. Knapp, P. Fecher, K. Werkmeister, Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit, Erlangen, „Desinfektionsmittelrückstände in Lebensmitteln“, Lebensmittelchemie 65, 1-16 (2011). The publication is available in German language only.

disinfection. Though not clearly stated in the publication, the residues might still have exceeded 0.01 mg/kg.

In a poster presentation at the 9th European Pesticide Residue Workshop (Vienna, 25-28 June 2012)³, the following information was given: “322 dairy products were checked for QAC (quaternary ammonium compounds; this includes both Benzalkonium chloride (BAC) and DDAC) and 78 % of them showed positive results (258 samples). Whereas (raw) milk samples presented an average level of QAC of 0.20 mg/kg, yoghurts, Tzatziki samples and Farmers Cheese samples showed levels across a wide concentration range: 0.01 mg/kg up to 17.9 mg/kg. The detected concentration levels also vary significantly within the selected food groups.”

Monitoring/surveillance data has been submitted by German Federal States’ (Länder) Authorities which are responsible for official food surveillance/monitoring. The following table summarizes all findings in milk and milk products which were made available to BfR until 06 July 2012.

Table 3: Available monitoring/surveillance data on DDAC residues in milk and milk products

| Code number* | Commodity group | Number of samples | | |
|--------------|--------------------------------------------|------------------------|------|-------------|
| | | Residues (mg/kg) | | |
| 1020000 | Milk | N | >LOQ | 1 |
| | | | <LOQ | 37 |
| | | Maximum | | 0.15 |
| | | OECD Calculator result | | - |
| processed | Milk product (cheese incl. farmers cheese) | N | >LOQ | 4 |
| | | | <LOQ | 44 |
| | | Mean | | 0.333 |
| | | Median | | 0.235 |
| | | Maximum | | 0.66 |
| | | OECD Calculator result | | 1.5 |
| processed | Milk product (yoghurt) | N | >LOQ | 0 |
| | | | <LOQ | 10 |
| | | OECD Calculator result | | - |
| processed | Milk product (cream) | N | >LOQ | 6 |
| | | | <LOQ | 29 |
| | | Mean | | 1.383 |
| | | Median | | 0.345 |
| | | Maximum | | 6.72 |
| | | OECD Calculator result | | 15 |

³ A. Friedle, A. Nitsopoulos, G. Lach and S. Bruns, “Determination of Quaternary Ammonium Compounds (QAC) in Food Products”, 9th EPRW, Vienna, 2012

| Code number* | Commodity group | Number of samples | | |
|--------------|--------------------------|------------------------|--------------|-----|
| | | Residues (mg/kg) | | |
| processed | Milk product (ice cream) | N | >LOQ | 18 |
| | | | <LOQ | 104 |
| | | Mean | 2.182 | |
| | | Median | 0.605 | |
| | | Maximum | 19.1 | |
| | | OECD Calculator result | 20 | |

* according to Annex I of Reg. (EC) No 396/2005

N: indicates number of analysed samples

3.2.2 Estimation of the chronic dietary intake

Though knowing that the currently available data were not collected within representative national monitoring programmes, they meanwhile cover most crop groups and were therefore used for chronic risk assessment.

Calculations have been performed with the German NVS II model⁴ (DE, 2011; NVS = National Consumption Survey) and additionally with the EFSA PRIMo⁵ (rev. 2_0, EFSA, 2008, PRIMo = Pesticide Residue Intake Model) which includes a comprehensive set of European and WHO diets for children and adults. The ADI value of 0.1 mg/kg bw/d is used in the calculation.

To provide a worst case calculation, a couple of rules/assumptions were followed:

- It was assumed that all food commodities contain DDAC residues.
- Limits of quantifications (LOQs) were different in the laboratories and were not always specified. Therefore the chronic intake calculation was based on the median residue of all positive samples within a group disregarding the whole number of samples below the LOQ.
- If all values within a commodity group were below the LOQ or if the commodity group was not investigated at all, a DDAC-residue of 0.1 mg/kg was assumed for all commodities in the group.
- If only one value >LOQ was reported for the commodity group and this value was between 0.01 and 0.1 mg/kg, a DDAC-residue of 0.1 mg/kg was assumed for the whole group (higher values were used unchanged in the calculation).
- Concerning milk and milk products, the highest median (0.605 mg/kg) for any of the milk products was used for the whole group. This is a very worst case assumption, since DDAC-residues occur mainly in cream and ice cream machines and not in drinking milk.

The theoretical maximum daily intake (TMDI, PRIMo rev. 2_0) based on the assumptions/rules listed above results in an utilization of 27 % of the ADI (0.1 mg/kg bw) for French toddlers, which were identified as the most critical among European consumer groups. The by far highest contributor was milk and milk products (with the worst case assumption of residues at a level of 0.605 mg/kg). A utilization of 10 % of the ADI value was calculated for

⁴ <http://www.bfr.bund.de/cm/343/bfr-berechnungsmodell-zur-aufnahme-von-pflanzenschutzmittel-rueckstaenden-nvs2.zip>

⁵ http://www.efsa.europa.eu/en/mrls/docs/calculationacutechronic_2.xls

the Swedish general population, which was identified as the most critical among adult European consumer groups.

The national theoretical maximum daily intake (NTMDI, NVS II model) based on the assumptions/rules listed above results in an utilization of 17 % of the ADI (0.1 mg/kg bw) for German children aged 2-4 years and 10 % for the German general population aged 14-80 years.

Since the calculated chronic intake is below the ADI value for all European consumer groups for which consumption data was available (both children and adults), the long-term dietary intake of DDAC residues is unlikely to present a public health concern.

3.2.3 Estimation of the acute dietary intake (IESTI)

Calculations have been performed with the German NVS II model and additionally with the EFSA PRIMo (Pesticide Residue Intake), both including consumption data for children and adults. Different ARfD values have been derived by BfR (DE) and CTGB (NL): 0.1 and 0.61 mg/kg bw. Since a decision on European level has not yet been taken, both values have been used in parallel in the acute dietary risk assessment.

The following was considered in the acute risk assessment:

- If all values within a commodity group were below the limit of quantification (LOQ) or if the commodity group was not investigated at all, a residue of 0.1 mg/kg was assumed for all commodities in the group.
- If only one value >LOQ was reported for the commodity group and this value was between 0.01 and 0.1 mg/kg, a DDAC-residue of 0.1 mg/kg was assumed for the whole group (higher values were used unchanged in the calculation).
- In all other cases the maximum reported for the commodity group was used for the assessment of all single commodities in this group.
- The maximum residue in citrus (0.98 mg/kg, whole fruit analyzed) was multiplied by 0.11, which is the average processing factor for DDAC in peeled citrus derived by NL.
- Concerning milk and milk products, the maximum values in milk and cheese were considered and the higher one used for the whole group (0.66 mg/kg). The maximum DDAC-residues reported for ice cream and cream were not used in the assessment since these are considered being unrealistic with respect to milk (which makes up the largest part of the large portion).

The international estimate of short term intake (IESTI, PRIMo rev. 2_0)) results in an utilization of less than 100 % of the ARfD for all European consumer groups (children and adults) and all commodities. The highest utilization of the ARfD was calculated for large tropical fruits with inedible peel (pineapple, banana, mango) based on a highest residue (HR) of 0.88 mg/kg and for milk/milk products based on a HR of 0.66 mg/kg:

- Pineapple: 89 % of the ARfD of 0.1 mg/kg bw or 15 % of the ARfD of 0.61 mg/kg bw for UK children (20.5 kg body weight).
- Milk/milk products: 82 % of the ARfD of 0.1 mg/kg bw or 13 % of the ARfD of 0.61 mg/kg bw for UK infants (8.7 kg body weight).
- Banana: 74 % of the ARfD of 0.1 mg/kg bw or 12 % of the ARfD of 0.61 mg/kg bw for UK infants (8.7 kg body weight).

Results for all other commodities and consumer groups (including all adult consumer groups) were less critical.

The national estimated short term intake (NESTI, NVS II model) results in an utilization of less than 100 % of the ARfD for German consumers (children and adults) for all commodities.

The highest utilization of the ARfD was calculated for large tropical fruits with inedible peel (pineapple, banana, mango, avocado) based on a HR of 0.88 mg/kg, for grapes based on a HR of 0.83 mg/kg and for milk/milk products based on a HR of 0.66 mg/kg:

- Banana: 60 % of the ARfD of 0.1 mg/kg bw or 10 % of the ARfD of 0.61 mg/kg bw for DE children (2-4 years).
- Grapes: 59 % of the ARfD of 0.1 mg/kg bw or 10 % of the ARfD of 0.61 mg/kg bw for DE children (2-4 years).
- Milk/milk products: 31 % of the ARfD of 0.1 mg/kg bw or 5 % of the ARfD of 0.61 mg/kg bw for DE children (2-4 years).

Results for all other commodities and for adult consumers were less critical.

Since the calculated intake is below the ARfD value for all commodities and for all European consumer groups for which consumption data was available (both children and adults), the acute dietary intake of DDAC residues is unlikely to present a public health concern.

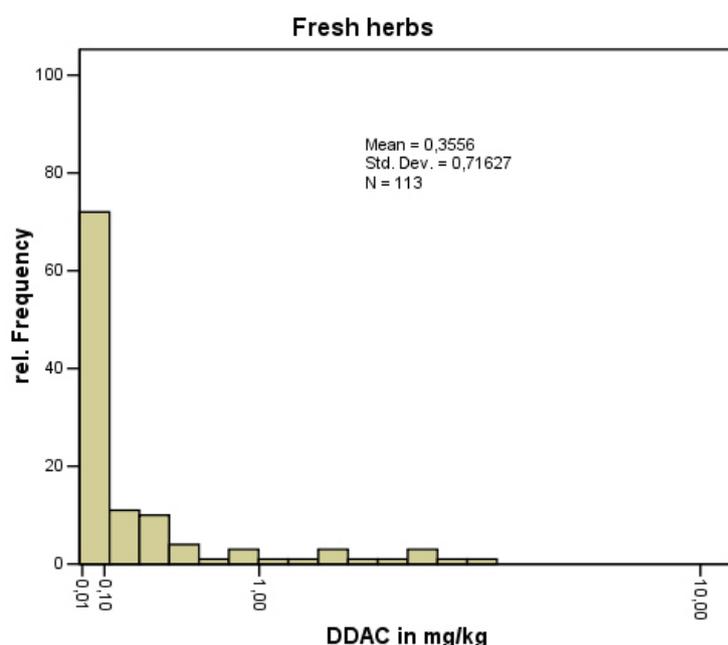
3.2.4 Discussion

The available data indicate “background” levels of DDAC above the currently applicable default MRL (Maximum Residue Level) of 0.01 mg/kg for most commodities.

It is noticed, that for citrus fruit and large tropical fruit with inedible peel (banana, mango) highest residues of 0.98 and 0.88 mg/kg were reported, which is higher than for most other plant commodities. It is likely that these fruits received post-harvest treatments which are common practice in countries outside the EU. An application for import tolerance for DDAC in citrus fruit is currently being processed, while no such application has been submitted for other fruits yet.

A second “hot spot” was seen for fresh herbs, where some very high residues were observed (amounting to 3.63 mg/kg) even when not considering findings that have already been traced back to applications with a plant strengthener, which has meanwhile been withdrawn from the market.

Figure 1: DDAC concentrations in fresh herbs and their relative frequency



Around 70 % of the observed residues were below 0.1 mg/kg. The high residues could be the result of (yet unknown) applications with that particular plant strengthener, which has been withdrawn from the market. Disinfection of planting pots or equipment might also have been a source of DDAC residues. Since exposure pathways are not known, it is not clear, which residue level needs to be considered as “unavoidable” following good practice and which should form the basis for MRL setting. Probably a MRL of 0.1 mg/kg would not be adequate for fresh herbs and should rather be set at a level of 1 mg/kg. No health concerns for consumers would arise for residues in fresh herbs at that level.

Apart from single findings > 0.1 mg/kg, residues in other plant commodities would be covered by raising the Maximum Residue Limits (MRLs) from 0.01 (default) to 0.1 mg/kg. No health concerns for consumers would arise for residues at that level.

No residue data was available for meat and meat products. For milk and milk products several results were reported. In milk, residues were below and in one case at the respective LOQ of 0.15 mg/kg. Obviously an MRL of 0.01 mg/kg (as currently applicable) can not be adequately monitored. DDAC residues might be due to disinfection of milking equipment or other equipment used during milk processing. The “unavoidable” level of residues in milk arising from such biocide uses, which might form the basis for MRL setting, can not be derived from the data. The assessment of findings is even more difficult for processed milk products, especially cream and ice cream. Samples of the latter were mainly taken from ice cream (and cream) machines, which undergo disinfection regularly or have disinfection equipment already integrated. The DDAC residues were highly variable and the level seems to depend on the cleaning/washing procedure followed after the disinfection itself. As far as information on that issue is available, it seems technically feasible to minimize residues in ice cream to levels around 0.1 mg/kg. It is recommended to establish clear guidance on adequate cleaning/washing procedures. It should be discussed if 0.1 mg/kg would be an adequate MRL for milk and milk products to cover residues arising from disinfection treatments. Any decisions on MRLs for DDAC taken now need to be reviewed as soon as more informa-

tion becomes available from national product authorizations for biocidal products containing DDAC.