STATEMENT

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Risk assessment related to the presence of benzalkonium chloride (BAC), didecyldimethyl ammonium chloride (DDAC) and chlorates in fish and fish products

European Food Safety Authority (EFSA)

Abstract

In compliance with Article 31 of Regulation (EC) No 178/2002, EFSA received a mandate from the European Commission to prepare a statement on the risk assessment related to the presence of benzalkonium chloride (mixture of alkylbenzyldimethylammonium chlorides with alkyl chain lengths of C8, C10, C12, C14, C16 and C18) (BAC), didecyldimethylammonium chloride (mixture of alkyl-quaternary ammonium salts with alkyl chain lengths of C8, C10 and C12) (DDAC) and chlorates in fish and fish products. Within EFSA's annual chemical data collection, EFSA collected monitoring data for the residues of BAC, DDAC and chlorates from EU Member States, Iceland and Norway performed a statistical evaluation, providing estimated residue values for each substance in/on fish and fish products, at the percentile appropriate for the number of the available samples. Based on the information collected, EFSA performed an acute and chronic exposure assessment for EU consumers for BAC, DDAC and chlorates at the lower-bound, medium-bound and upper-bound scenarios resulting from the consumption of fish and fish products. EFSA did not identify potential consumer health risks associated to residues of the substances found in fish and fish products.

Keywords: didecyldimethylammonium chloride (DDAC), benzalkonium chloride (BAC), temporary MRLs, Regulation (EC) No 396/2005, consumer risk assessment, quaternary ammonium compounds (QAC)

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Summary

At the Standing Committee for Plants, Animals, Food and Feed (SCoPAFF) Section Phytopharmaceuticals, Pesticide Residues meeting of June 2021, a Member State expressed concerns on the high frequency and the high levels of findings of residues of benzalkonium chloride (mixture of alkylbenzyldimethylammonium chlorides with alkyl chain lengths of C8, C10, C12, C14, C16 and C18) (BAC), didecyldimethylammonium chloride (mixture of alkyl-quaternary ammonium salts with alkyl chain lengths of C8, C10 and C12) (DDAC) and chlorates in fish and fish products resulting from the outcome of its monitoring programme for pesticide residues in fish and on the impact of those residues from such products on consumer health. These concerns were shared also by other Member States in subsequent SCoPAFF meetings.

In October 2022, EFSA has therefore been mandated by the European Commission to collect monitoring data for the residues of BAC, DDAC and chlorates within EFSA's annual data collection and perform an EU wide exposure assessment based on occurrence data for the three substances in fish and fish products, with a view to possibly proposing guidance levels to the Member States to take action in case of high levels of those residues in such products.

In November 2022, EFSA extracted data collected within EFSA's annual Chemical Monitoring data collection for the residues of BAC, DDAC and chlorates in fish and fish products from EU Member States, Iceland and Norway. For the present assessment data submitted to EFSA in the last 10 years, analysed in the period of 2012–2021 were considered.

Subsequently, EFSA performed a statistical evaluation of the data collected, providing estimated residue values for each substance in the above-mentioned food products at the percentile appropriate for the number of the available samples.

On the basis of those data, EFSA performed an acute and chronic exposure assessment for European consumers for BAC, DDAC and chlorates at the lower-bound (LB), medium-bound (MB) and upper-bound (UB) scenarios resulting from the consumption of fish and fish products using algorithms and methodology based on the internationally agreed international estimated daily intake (IEDI) and international estimated short-term intake (IESTI) equations. Since fish and fish products are not present in the Pesticide Residue Intake Model (PRIMo, revision 3), the occurrence data were matched with the individual consumption data derived from the raw primary commodity (RPC) model of EFSA. The applied approach is also in line with the methodology proposed in the new PRIMo 4 tool.

Based on the data collected and results of the exposure calculations, EFSA did not identify potential consumer long-term intake concerns associated to the exposure to BAC, DDAC and chlorates in fish. The chronic exposure assessment for the SUM BAC and SUM DDAC reported results well below the toxicological reference values (TRVs) even at the UB, with mean and highest reliable percentile (HRP) exposure values lower than 1% of the acceptable daily intake (ADI). Chlorates were the group of substances with the highest chronic exposure results, but still the highest %ADI exposure was lower than 40% at the HRP in the UB scenario. No acute consumer intake concern was identified. The calculated maximum short-term exposure at the UB for SUM BAC and SUM DDAC in the distinct raw primary commodity/raw primary commodity derivative (RPC/RPCD) was lower than 4% of the acute reference dose (ARfD). However, the highest acute exposure results for chlorates reached up to 81.87% of the ARfD, which could indicate a narrow margin for consumer safety for this group of substances in fish meat.

It is highlighted that the risk assessment is affected by some uncertainties which are resulting from the following issues:

- Limited geographical representativeness of the collected data (only six EU countries provided for data);
- Limited availability of detailed information on the fish species and on production method (farmed or wild caught) did not allow to consider fish species and production methods separately for a further subdivision of the data in the assessment;
- Limited availability of samples from processed fish did not allow to implement a separate exposure scenario for them;
- An imputation technique was applied to assign Limits of quantification (LOQs) for entries where this information was not provided which can cause either under or overestimation of the UB and MB scenarios;
- Uncertainties and limitations arising from the use of the EFSA Comprehensive Food Consumption Database (EFSA, 2011);

- Present estimates are using the RPC Consumption Database. The current RPC model cannot be applied to the dietary surveys received by EFSA since 2018, thus they are therefore not yet integrated in the current calculations;
- The possible effect of processing (i.e. cooking the fish) on the residue concentration in the final food product was not taken into consideration in the calculations;
- Appropriateness of the toxicological reference values for BAC and DDAC used in the risk assessment considering they were derived based on local effects.

EFSA concludes that based on the calculations performed according to the internationally agreed methodology, the residues detected in fish and fish products will not result in a consumer intake exceeding the ADI nor the ARfD for each of the substances. However, regarding the short-term (acute) exposure assessment, EFSA noted a narrow safety margin for the exposure to chlorates (81.87% for the ARfD). Hence, if fish contains chlorates residues at the highest residue value reported (17.8 mg/kg in fish meat), an exceedance of the ARfD cannot be excluded as the calculated acute exposure accounts for the (Upper Confidence Limit) UCL P95 as input value.

Risk managers should take this aspect into consideration when deciding whether to establish guidance values for possible use by Member States enforcement Authorities.

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Background

The active substance **didecyldimethylammonium chloride (mixture of alkyl-quaternary ammonium salts with alkyl chain lengths of C8, C10 and C12) (DDAC)** belongs to the class of quaternary ammonium compounds (QACs) and was initially included in Annex I to Council Directive 91/414/EEC[1] on 1 January 2010 by Commission Directive 2009/70/EC[2] and subsequently deemed to be approved under Regulation (EC) No 1107/2009[3], in accordance with Commission Implementing Regulation (EU) No 540/2011[4], as amended by Commission Implementing Regulation (EU) No 541/2011[5]. The initial approval was restricted to indoor use on ornamental crops only.

An EFSA conclusion on the peer review for the pesticide risk assessment is available for this active substance (EFSA, 2009). The EFSA conclusion identified a number of data gaps included by risk managers in Commission Directive 2009/70/EC. Since the notifier failed to provide the required confirmatory information to address the identified data gaps, the approval for DDAC was withdrawn by Commission Implementing Regulation (EU) No 175/2013[6]. According to the period of grace, the use of plant protection products containing DDAC was permitted until 20 March 2014.

Apart from its former use in plant protection products, DDAC is also used in biocidal products. According to the Biocidal Product Regulation (Regulation EU No 528/2012)[7], DDAC is currently approved for several biocidal uses including for Product Type 3 (Veterinary hygiene) and 4 (Food and feed area).

The active substance **benzalkonium chloride (mixture of alkylbenzyldimethylammonium chlorides with alkyl chain lengths of C8, C10, C12, C14, C16 and C18) (BAC)** also belongs to the class of QACs and was never included in Annex I to Council Directive 91/414/EEC in accordance with Commission Regulation (EC) No 2076/2002[8].

An EFSA conclusion on the peer review of the pesticide risk assessment is not available for this substance.

It is noted that several different active substances which fall under the general class of BACare distinguished, depending on the composition of the mixture of the alkyl chains (i.e. ADBAC, BKC) (EFSA, 2014). BAC (mixture of alkylbenzyldimethylammonium chlorides with alkyl chain lengths of C8, C10, C12, C14, C16 and C18) is not approved as a biocidal active substance, nevertheless the substance alkyl (C12–16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12–16)) is currently approved according to the Biocidal Product Regulation for several biocidal uses including for Product Type 3 (Veterinary hygiene), 4 (Food and feed area) and 8 (Wood preservatives).

The active substance **chlorates (including Mg, Na, K chlorates)** was not included in Annex I to Council Directive 91/414/EEC in accordance with Commission Decision 2008/865/EC[9]. According to the period of grace the use of plant protection products containing chlorates was permitted until 10 May 2009. An EFSA conclusion on the peer review of the pesticide risk assessment is not available for this substance. Apart from its former use in plant protection products, chlorates are also formed as by-product resulting from the use of chlorine dioxide or hypochlorite for the disinfection of drinking water or water for food production (WHO, 2005).

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
[2] Commission Directive 2009/70/EC of 25 June 2009 amending Council Directive 91/414/EEC to include difenacoum, didecyldimethylammonium chloride and sulphur as active substances OJ L 164, 26.6.2009, p. 59–63.
[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
[4] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
[5] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.
[6] Commission Implementing Regulation (EU) No 175/2013 of 27 February 2013 amending Implementing Regulation (EU) No 540/2011 as regards the withdrawal of the approval of the active substance didecyldimethylammonium chloride. OJ L 56, 28.2.2013, p. 4–5.
[7] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. OJ L 167, 27.06.2012, p. 1–123.
[8] Commission Regulation (EC) No 2076/2002 of 20 November 2002 extending the time period referred to in Article 8(2) of Council Directive 91/414/EEC and concerning the non-inclusion of certain active substances in Annex I to that Directive and the withdrawal of authorisations for plant protection products containing these substances. OJ L 319, 23.11.2002, p. 3–11.
[9] 2008/865/EC: Commission Decision of 10 November 2008 concerning the non-inclusion of chlorate in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (notified under document number C (2008) 6587). OJ L 307, 18.11.2008, p. 7–8.

For the active substances **BAC** and **DDAC**, temporary MRLs were set by Commission Regulation (EU) No 1119/2014[10] for all products, based on the EFSA Reasoned Opinion (EFSA, 2014) on the dietary risk assessment for proposed temporary maximum residue levels (MRLs) of DDAC and benzalkonium chloride (BAC).

MRL values for BAC and DDAC have been recently amended by Commission Regulation (EU) 2023/377[11] (not yet applicable).

No Codex maximum residue limits (CXLs) are established by the Codex Alimentarius Commission and no import tolerances are currently in place for DDAC and BAC.

Temporary MRLs were also recently legally implemented for **chlorates** by Commission Regulation (EU) 2020/749[12] due to use of chlorine disinfectants in food and drinking water processing leading to detectable residues of chlorate in food.

It should be noted that current MRLs are set on products of plants and animal origin as listed in Annex I of Regulation 396/2005, nevertheless, no MRLs are currently set for fish and fish products. For these products, footnote (8) of Annex I to the Regulation indicates that 'no MRLs are applicable until individual products have been identified and listed within this category'.

In June 2021, at the meeting of the *Standing Committee for Plants, Animals, Food and Feed (SCoPAFF) – Section Phytopharmaceuticals, Pesticide Residues*, a Member State expressed concerns on the high frequency and the high levels of findings of residues of BAC, DDAC and chlorate in/on fish and fish products resulting from the outcome of its monitoring programme for pesticide residues in fish and on the impact of those residues from such products on consumer health. These concerns were shared also by other Member States in subsequent *SCoPAFF* meetings.

In October 2022, EFSA has been mandated to collect monitoring data for the residues of BAC, DDAC and chlorates within EFSA's annual chemical data collection and perform an EU wide exposure assessment based on occurrence data for the three substances in fish and fish products, with a view to derive guidance levels that Risk Managers can possibly evaluate and propose to the Member States.

Terms of Reference

In accordance with Article 31 of Regulation (EC) No 178/2002, EFSA was requested to prepare a statement with a risk assessment related to the presence of BAC, DDAC and chlorates in fish and fish products covering the following:

- A collection of monitoring data, as representative as possible, within EFSA's annual chemical data collection, for the residues of BAC, DDAC and chlorates from EU Member States and, where possible, from countries of the European Free Trade Association (EFTA). The data should be presented for the whole group of fish, and, where possible subdivided into data for farmed fish and wild fish and also into data for fresh and frozen fish. If relevant, if specific and sufficient information is available at species level, further subdivision to the level of species (e.g. Pangasius spp.) can be considered.
- Statistical evaluation, providing estimated residue values for each substance in/on fish and fish products, also considering the above subdivisions, at the percentile appropriate for the number of the available samples. With consideration to left censored monitoring data, the output should be presented in lower-, medium- and upper-bound scenarios.
- An acute and chronic exposure assessment for EU consumers for BAC, DDAC and chlorates at the lower-, medium- and upper-bound scenarios resulting from the consumption of fish and fish products. Based on the data available, EFSA is requested to suggest, when possible, an extrapolation between fish species, as consumption data have partly been gained on different species than monitoring data.

[10] Commission Regulation (EU) No 1119/2014 of 16 October 2014 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride and didecyldimethylammonium chloride in or on certain products. OJ L 304, 23.10.2014, p. 43–74.

[11] Commission Regulation (EU) 2023/377 of 15 February 2023 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products (Text with EEA relevance). OJ L 55, 22.2.2023, p. 1–84.

[12] Commission Regulation (EU) 2020/749 of 4 June 2020 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products. OJ L 178, 8.6.2020, p. 7–20.

Assessment

EFSA has based its assessment on the following documents:

- Data collected within EFSA's annual Chemical Monitoring data collection;
- Previous EFSA outputs on BAC, DDAC and chlorates (EFSA, 2009, 2014; EFSA CONTAM Panel, 2015);
- The assessment reports on didecyldimethylammonium chloride (DDAC) (Italy, 2020a);
- The assessment reports on Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16)) (Italy, 2020b).

1. Steps of the assessment

1.1. Collection of monitoring data

EU Member States,[13] Iceland and Norway were invited to submit data within EFSA's annual chemical data collection, for the residues of BAC, DDAC and chlorates in fish and fish products.

Occurrence data were collected and provided to EFSA by six Member states. Reported samples were analysed throughout the period 2013–2021, whereas no data was reported in 2012. Samples from the United Kingdom were analysed during the period 2018 and 2020, when the country was still part of the European Union and were thus included in the analysis. Further details on the collected data are presented in Appendix A (Table A.1 and Figure A.1).

In November 2022, a total of 2,302 analytical results on 527 samples were extracted from EFSA's Scientific Datawarehouse for the substances of interest (BAC, DDAC and chlorates) in fish and fish products. More in details, 1,666 results were extracted on BAC (including summed data on substances in the class of BAC (SUM BAC) and single congeners), 420 on DDAC (including summed data on substances in the class of DDAC (SUM DDAC) and single congeners) and 216 on chlorates. For the two quaternary ammonium compounds, data were reported for the congeners BAC 8, 10, 12, 14, 16 and 18, in addition to SUM BAC (8–18), and DDAC-C08, DDAC-C12 and SUM DDAC (8, 10, 12).

The data collected included information on 29 distinct raw fish commodities, some of which classified at species level (e.g. 'Pike-perch', 'Plaice') and others with a more generic description (e.g. 'Fish (meat)', 'Miscellaneous freshwater fishes'). In addition, data on three processed products were reported ('Fish fingers, breaded', 'Smoked salmon', 'Smoked fish'). Specific information on the processing was not available for all samples and, with the exception of the three mentioned products, it was either unknown (not indicated) or referring to processes not changing the nature of the food (e.g. 'Freezing', 'Raw, no heat treatment'). Information on the production method (farmed or wild fish) was available for only 407 entries out of the 2,302.

1.2. Data cleaning and statistical evaluation

The data submitted by the reporting countries were cleaned as explained in the steps below:

- Six analysed samples taken from 'suspect sampling' were disregarded from the assessment;
- Nineteen analytical results for 'Processed or preserved fish (including processed offal)' (corresponding to 12 samples), including those labelled with the processing facets 'Breading', 'Marinating' and 'Texturing' were excluded from the analysis since they were insufficient for a separate exposure assessment. All other analytical results were considered as 'Unprocessed' since it was concluded that the processing would not change the residue content of the foods (e.g. 'Slicing', 'Freezing');
- With respect to BAC and DDAC, as the congener specific results (per sample) did not include consistently all relevant substances in the chemical class, they were disregarded and only summed data were considered in the assessment;
- For calculating the mean occurrence value for the chronic exposure the minimum number of analysed samples per substance group and per food category is six. To calculate the acute

[13] Pursuant to Article 5(4) and Section 24 of Annex 2 of the Protocol on Ireland/Northern Ireland, which is an integral part of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, the EU requirements on data sampling are also applicable to Northern Ireland and, for the purpose of this report, references to Member States are read as including the United Kingdom in respect of Northern Ireland.

exposure using the upper confidence limit of the P95 at least ~ 60 observations are required. Therefore, occurrence data was considered only on the generic level of 'fish meat' food category, by aggregating all samples analysed for different fish species as data were insufficient to consider them separately. Detailed information on the number of samples by fish commodity and chemical substance in the final dataset is provided in Appendix B, Table B.2;

- After the removal of the above-mentioned samples, information on the production method (farmed vs wild caught) was only available for a limited number of analytical results (394 out of the total 2,277 results of the final dataset), thus this variable could not be considered in the assessment.

After applying the criteria described above and only considering the three groups of substances for the assessment, the obtained dataset comprised 1,038 analytical results: 422 for SUM BAC, 416 for SUM DDAC and 200 for chlorates. Further details with summary statistics of the resulting cleaned occurrence dataset are presented in Appendix B, Table B.3. Chlorates were the chemical substance with the highest number of quantifications (36.5% of its analytical results), followed by SUM BAC (5.9%) and SUM DDAC (5.8%). A summary of left-censored data in fish meat is presented in Table 1.

Table 1: Number and frequency of left-censored data and quantifications in fish meat (FoodEx2 level 3), by chemical substance

Chemical	Analytical results (n)	Left-censored (n)[(a)]	Quantified (n)	Left-censored (%)	Quantified (%)
Chlorates	200	127	73	63.5	36.5
SUM BAC	422	397	25	94.1	5.9
SUM DDAC	416	392	24	94.2	5.8

(a): The number of left-censored data refers to both the results below the LOQ and those below the LOD. For those analytical results that were reported below the LOD, the LB, MB and UB were assigned as LB = 0, MB = LOD/2 and UB = LOD. For the ones below the LOQ, the same approach was taken, using the value of the LOQ (LB = 0, MB LOQ/2, UB = LOQ).

On the final data set, the following further adjustments were made as part of the cleaning process:

- For 174 analytical results (all referring to the sum of DDAC congeners) it was found that the value of the LOQ was missing. To derive a new LOQ for the missing entries, a substitution method was applied and the median of the LOQs of all other fish meat samples analysed for these groups of chemicals was assigned to them. All the other results kept their original LOQ value, as reported in the initial dataset.
- The left-censored data (results below the limit of detection (LOD) or limit of quantification (LOQ)) were treated by the substitution method as recommended in the 'Principles and Methods for the Risk Assessment of Chemicals in Food' (WHO/IPCS, 2009). The same method is described in the EFSA scientific report 'Management of left-censored data in dietary exposure assessment of chemical substances' (EFSA, 2010) as an option for the treatment of left-censored data. The guidance suggests that the lower-bound (LB) and upper-bound (UB) approach should be used for chemicals likely to be present in the food. At the LB, results below the LOQ or LOD were replaced by zero; at the UB, the results below the LOD were replaced by the numerical values of the LOD and those below the LOQ were replaced by the value reported as LOQ.
- When considering the samples analysed for SUM BAC, SUM DDAC and chlorates, further cleaning was done on the LB, middle-bound (MB) and UB results, following the LOQ substitution:
  - When the value of the measured result/concentration ('resVal') was lower than the (derived) LOQ, the measured result/concentration ('resVal') was used for the LB and the (derived) LOQ was used for the UB. The MB was obtained as MB = (LB + UB)/2, using the new derived LB and UB values.
  - In the case of left-censored data, meaning those cases where the measured result/ concentration ('resVal') was missing (i.e. non-quantified/non-detected values), the new values were assigned as follows: the LB value was set to 0, the MB was set to LOQ/2 (from the newly derived LOQ, when it was applicable), and the UB was set to the (derived) LOQ.

Considering the positive findings from the final dataset, chlorates were the substance group where the highest measured concentration value was reported, in 'Pangas catfishes' (17.8 mg/kg), followed

by SUM DDAC (2 mg/kg) and SUM BAC (1 mg/kg) in 'Fish (meat)'. Data were cleaned and analysed with SAS® Enterprise Guide 8.3.

1.3. Consumer risk assessment

EFSA performed an acute and chronic exposure assessment for EU consumers for BAC, DDAC and chlorates at the lower-, medium- and upper-bound scenarios resulting from the consumption of fish and fish products using algorithms and methodology based on the internationally agreed IEDI and IESTI equations. Since fish and fish products are not present in the Pesticide Residue Intake Model (revision 3), the occurrence data were matched with the individual consumption data derived from the raw primary commodity (RPC) model of EFSA. The applied approach is also in line with the methodology proposed in the new PRIMo 4 tool.

The **food consumption data** used in the exposure calculations are retrieved from the EFSA RPC consumption database, where all the information on food commodities stored in the EFSA Comprehensive European Food Consumption Database[14] (Comprehensive DB) are converted into their RPCs and raw primary commodity derivatives (RPCDs) equivalents. The RPC consumption data are generated based on the principles listed in the technical report of the RPC model (EFSA, 2019), using the consumption data available as of 31 March 2018.

The individual subjects in the Comprehensive DB and in the RPC consumption databases are classified according to the following sub-populations:

- Infants: < 12 months old;
- Toddlers: ≥ 12 months to < 36 months old;
- Other children: ≥ 36 months to < 10 years old;
- Adolescents: ≥ 10 years to < 18 years old;
- Adults: ≥ 18 years to < 65 years old;
- Elderly: ≥ 65 years to < 75 years old;
- Very elderly: ≥ 75 years old.

In the current version of the RPC consumption data, two additional surveys provided information on specific population groups: 'Pregnant women' (≥ 15 years to ≤ 45 years old; Latvia) and 'Lactating women' (≥ 28 years to ≤ 39 years old; Greece).

For the chronic exposure assessments, subjects that were surveyed for 1 day only have been excluded.

In total, dietary information from 18 countries[15] and 33 surveys were considered for the chronic, and from 22[16] countries and 39 surveys for the acute exposure calculations. Further information on the dietary surveys considered in the exposure assessment can be found in the background document to the statement.

With regard to the **toxicological reference values** used for this assessment, as no toxicological values are currently established for DDAC, BAC and chlorates under the pesticides legal framework, EFSA has considered the following reference values:

- For DDAC, the toxicological reference values (TRVs) derived by ECHA in the framework of the BPR review programme: an acceptable daily intake (ADI) of 0.12 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.12 mg/kg bw (Italy, 2020a).
- For BAC, the TRVs derived by ECHA in the framework of the BPR review programme relevant for the similar substance ADBAC/BKC (C12-16): an ADI of 0.12 mg/kg bw per day and an ARfD of 0.12 mg/kg bw (Italy, 2020b).
- For chlorate, the TRVs derived by the EFSA Panel on Contaminants in the Food Chain (CONTAM) under the assessment 'Risks for public health related to the presence of chlorate in food' in 2015: a TDI of 3 μg/kg bw per day and an ARfD of 36 μg chlorate/kg bw (EFSA, 2015).

[14] For more information please visit: https://www.efsa.europa.eu/en/data-report/food-consumption-data
[15] Countries (chronic): Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, the Netherlands, Romania, Spain, Sweden.
[16] Countries (acute): Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, the Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden.

It is noted that, the TRVs for DDAC and BAC, were derived by the Biocidal Product Committee (BPC) based on local effects as there were no primary systemic effects observed (Italy, 2020a,b). Therefore, these TRVs are very conservative.

For the purposes of the requested assessment, the following residue definitions were considered:

- DDAC: mixture of alkyl-quaternary ammonium salts with alkyl chain lengths of C8, C10 and C12.
- BAC: mixture of alkylbenzyldimethylammonium chlorides with alkyl chain lengths of C8–18.
- Chlorates (incl. Mg, Na, K chlorates): chlorate.

On the basis of the data set obtained after the cleaning exercise, mean occurrence level and upper confidence limit of the P95 for the LB, MB and UB scenarios were calculated for each chemical group. Upper confidence limit values were considered in the acute exposure scenario and mean occurrence values were considered in the chronic exposure scenario. The input values used in the exposure calculations are summarised in Table 2:

Table 2: Number of analytical results considered, mean and upper confidence limit of P95 (UCL P95) residue levels (mg/kg) of SUM BAC, SUM DDAC and chlorates measured in fish meat

Chemical	N analytical results	Mean LB	Mean MB	Mean UB	UCL LB95	UCL MB95	UCL UB95
Chlorates	200	0.19	0.20	0.21	1.621	1.621	1.621
SUM BAC	422	0.01	0.08	0.15	0.1	0.15	0.2
SUM DDAC	416	0.02	0.02	0.03	0.2	0.2	0.2

LB: lower bound; MB: middle bound; UB: upper bound.

1.3.1. Long-term (chronic) exposure assessments

Chronic exposure was estimated by combining the mean occurrence values (as reported in Table 2) for each of the chemical substances under assessment with consumption data from the EFSA RPC consumption database (section 1.3).

Exposure estimates were performed with algorithms based on the IEDI (FAO, 2016), but calculated on individual basis. The consumed amount of the RPC or RPCD is averaged by the number of surveyed days for each individual, multiplied by the mean occurrence levels and normalised by the body weight of the subject. The exposure results from each food commodity are then summed up by subject. Based on the distributions of individual exposures, the mean and high exposure (highest reliable percentile, HRP) estimates were calculated per survey and age class. HRP is the highest percentile of exposure (limited to percentile 97.5 as highest) that is considered statistically robust for each population class, country and survey. This parameter provides a measure for consumers that, due to their personal dietary habits, may have a higher exposure compared to the 'average' consumer within the same population group. The cut-off values considered to calculate the HRP are reported in the published Draft Technical Report of PRIMo rev. 4 (currently under Public Consultation[17] until 30 June 2023), with more detailed information on the methodology. Tables with summary results are provided in Appendix C, both as absolute exposure (μg/kg bw per day) and as percentage of the ADI, for the three different approaches: lower bound (LB), medium bound (MB) and upper bound (UB). Detailed results are made publicly available as background documents to this output. The highest dietary exposure results for fish and fish products were reported for the 'Toddlers' population group for all the three substances.

Assessment on DDAC

The long-term exposure assessment to SUM DDAC was performed combining the mean occurrence values in fish meat at the LB (0.02 mg/kg), MB (0.02 mg/kg) and UB (0.03 mg/kg) with the food consumption data. Highest mean exposure results ranged from 0.03% (LB) to 0.06% (UB) of the ADI, while HRP exposures varied from 0.08% to 0.14% of the ADI. Summary information is provided in Appendix C, Table C.1.1.

[17] The page for the Public Consultation of the beta version of PRIMo 4 and the related documentation can be found at: https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l09000006qzAA/pc0421

Assessment on BAC

The long-term exposure assessment to SUM BAC was performed combining the mean occurrence values in fish meat at the LB (0.01 mg/kg), MB (0.08 mg/kg) and UB (0.15 mg/kg) with the food consumption data. Highest mean exposure results ranged from 0.02% (LB) to 0.29% (UB) of the ADI, while HRP exposures varied from 0.06% (LB) to 0.70% (UB) of the ADI. Summary information is provided in Appendix C, Table C.1.2.

Assessment on chlorates

The long-term exposure assessment to chlorates was performed, combining the mean occurrence values in fish meat at the LB (0.19 mg/kg), MB (0.20 mg/kg) and UB (0.21 mg/kg) with the food consumption data. Highest mean exposure results ranged from 15.18% (LB) to 16.23% (UB) of the ADI, while HRP exposures varied from 36.88% to 39.43% of the ADI. Summary information is provided in Appendix C, Table C.1.3.

1.3.2. Short-term (acute) exposure assessment

The short-term exposure assessment was performed with the use of algorithms based on the internationally agreed methodology (IESTI) (FAO, 2016). However, in the case of the present assessment, the exposure was calculated on individual basis and considering as input occurrence data the upper confidence limit of the 95th percentile (UCL P95) calculated for each chemical substance in fish meat (Table 2).

Similarly to the chronic exposure, the calculations of the acute exposure scenario make use of IESTI formulae, modified as explained below for the scope of the assessment. Instead of considering the large portion, the acute exposure assessment was performed for the distinct foods consumed by the individual subjects within each consumption day. The total amount of each consumed food within a survey day was combined with the UCL P95 or the mean occurrence (at the LB, MB and UB for each of them) according to the specific IESTI case (1 or 3, for the current assessment) assigned based on the type of fish (product) and normalised by the individual body weight. Exposure results at the highest reliable percentile (HRP) are reported for each raw primary commodity (RPC) and corresponding derivatives (RPCDs). More detailed information on the methodology can be found in the published Draft Technical Report of PRIMo 4 (currently under Public Consultation until 30 June 2023[15]).

A summary of the results of the acute calculations for each chemical substance are reported in Appendix C of the present report, both as absolute exposure and percentage of the ARfD. Detailed results are made publicly available as background documents to this output. The highest results were identified for 'Other children' population class.

Assessment on DDAC

The short-term exposure assessment to SUM DDAC was performed by combining the upper confidence limit of the 95th percentile (UCL P95) of the occurrence data at the LB, MB and UB (0.2 mg/kg) with food consumption data. Results of the calculations for the SUM DDAC reported the highest contribution values at 3.03 %ARfD at both the LB and UB. Summary information is provided in Appendix C, Table C.2.1.

Assessment on BAC

The short-term exposure assessment to SUM BAC was performed combining the UCL P95 of the occurrence data at the LB (0.1 mg/kg), MB (0.15 mg/kg) and UB (0.2 mg/kg) with the food consumption data. The highest estimated short-term dietary intakes for the SUM BAC through the consumption of fish meat were 1.52% and 3.03% of their acute reference dose (ARfD) at the LB and UB, respectively. Summary information is provided in Appendix C, Table C.2.2.

Assessment on chlorates

The short-term exposure assessment to chlorates was performed combining the UCL P95 of the occurrence data at the LB, MB and UB (1.621 mg/kg) with the food consumption data. In the case of chlorates, which were also the substance with the highest number of positive findings (Table 1), the short-term exposure through the consumption of fish commodities reached up to 81.87% of the ARfD in 'Diadromous fish, PROCESS=Unspecified'.

EFSA notes that, although for the calculation of the short-term exposure assessment the UCL P95 has been used as input value (as the most representative for deriving MRLs based on post-marketing (monitoring) data) and although for chlorates no acute consumer intake concerns were identified, the safety margin for acute exposure is narrow. If fish contains residues at the highest residue value reported (17.8 mg/kg), an exceedance of the ARfD cannot be excluded, as the calculated acute exposure accounts for the UCL P95 as input value.

Summary information is provided in Appendix C, Table C.2.3.

Conclusions and recommendations

Based on the data collected and results of the exposure calculations, EFSA did not identify potential consumer long-term intake concerns associated to the exposure to BAC, DDAC and chlorates in fish. The chronic exposure assessment for the SUM BAC and SUM DDAC reported results well below the toxicological reference values (TRVs) even at the upper bound (UB), with mean and HRP exposure values lower than 1% of the ADI. Chlorates were the group of substances with the highest chronic exposure results, but still the highest %ADI exposure was lower than 40% at the HRP in the UB scenario. No acute consumer intake concern was identified. The calculated maximum short-term exposure at the UB for SUM BAC and SUM DDAC in the distinct RPCs/RPCDs was lower than 4% of the ARfD. However, the highest acute exposure results for chlorates reached up to 81.87% of the ARfD, which could indicate a narrow margin for consumer safety for this group of substances in fish meat.

It is highlighted that the risk assessment is affected by some uncertainties which are resulting from the following issues:

- Limited geographical representativeness of the collected data (only six EU countries provided for data);
- Limited availability of detailed information on the fish species and on production method (farmed or wild caught) did not allow to consider fish species and production methods separately for a further subdivision of the data in the assessment;
- Limited availability of samples from processed fish did not allow to implement a separate exposure scenario for them;
- An imputation technique was applied to assign LOQs for entries where this information was not provided which can cause either under or overestimation of the UB and MB scenarios;
- Uncertainties and limitations arising from the use of the EFSA Comprehensive Food Consumption Database (EFSA, 2011);
- Present estimates are using the RPC Consumption Database. The current RPC model cannot be applied to the dietary surveys received by EFSA since 2018, thus they are therefore not yet integrated in the current calculations;
- The possible effect of processing (i.e. cooking the fish) on the residue concentration in the final food product was not taken into consideration in the calculations;
- Appropriateness of the toxicological reference values for BAC and DDAC used in the risk assessment considering they were derived based on local effects.

EFSA concludes that based on the calculations performed according to the internationally agreed methodology, the residues of the substances found in fish and fish products will not result in a consumer intake exceeding the ADI nor the ARfD for each of the substances. However, regarding the short-term (acute) exposure assessment, EFSA noted a narrow safety margin for the exposure to chlorates (81.87% for the ARfD). Hence, if fish contains chlorates residues at the highest residue value reported (17.8 mg/kg in fish meat), an exceedance of the ARfD cannot be excluded, as the calculated acute exposure accounts for the UCL P95 as input value.

Risk managers should take this aspect into consideration when deciding whether to establish guidance values for possible use by Member States enforcement Authorities.

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Abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
BAC	benzalkonium chloride
bw	body weight
CXL	codex maximum residue limit
DDAC	didecyldimethyl ammonium chloride
FAO	Food and Agriculture Organization of the United Nations
HRP	highest reliable percentile
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
IPCS	International Programme of Chemical Science
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
OECD	Organisation for Economic Co-operation and Development
PRIMo	(EFSA) Pesticide Residues Intake Model
RPC	raw primary commodity
RPCD	raw primary commodity derivative
tMRL	temporary MRL
TRV	toxicological reference values

Appendix A – Summary information on data resulting from the data collection

A.1. Number of samples for chlorates, SUM DDAC and SUM BAC by country

The table provides an overview of the number of samples for chlorates, SUM DDAC and SUM BAC provided by the six European countries (including the United Kingdom) for the years 2013 to 2021. The information reported in the table refers to the number of samples in the original occurrence dataset.

Chemical	Sampling country	N samples
Chlorates	Austria	37
	Germany	163
	Netherlands	16
SUM BAC	Germany	124
	United Kingdom	216
	Italy	7
	Netherlands	11
	United Kingdom (Northern Ireland)	66
SUM DDAC	Germany	124
	United Kingdom	216
	Netherlands	11
	United Kingdom (Northern Ireland)	66

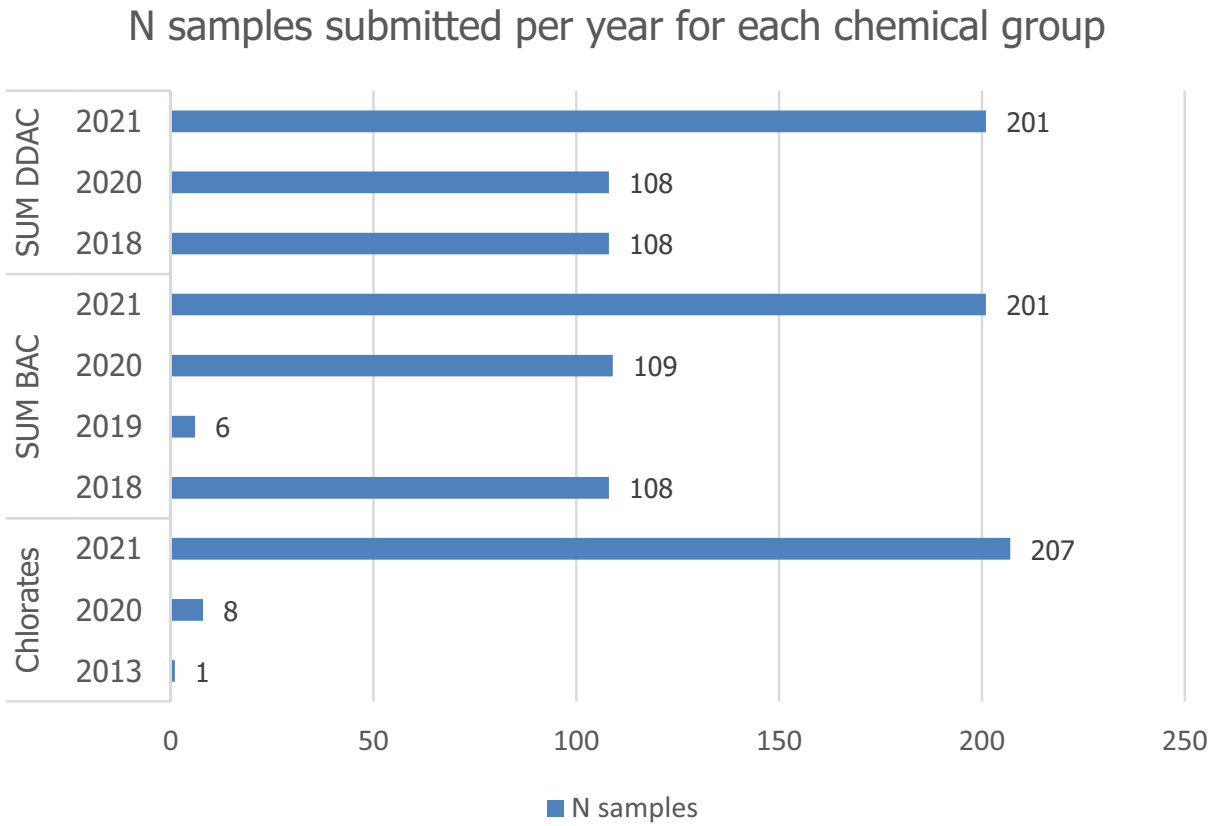

Figure A.1: Number of samples reported in the original dataset for each of the three substances under assessment (SUM BAC, SUM DDAC, chlorates), by year

Appendix B – Summary information on data resulting from data cleaning

B.1. Number of samples for chlorates, SUM DDAC and SUM BAC by country

The table provides an overview of the number of samples for chlorates, SUM DDAC and SUM BAC provided by the six European countries (including the United Kingdom) for the years 2013 to 2021. The information reported in the table refers to the number of samples in the final occurrence dataset.

Chemical	Sampling country	N samples
Chlorates	Austria	36
	Germany	153
	Netherlands	11
SUM BAC	Germany	123
	United Kingdom	216
	Italy	6
	Netherlands	11
	United Kingdom (Northern Ireland)	66
SUM DDAC	Germany	123
	United Kingdom	216
	Netherlands	11
	United Kingdom (Northern Ireland)	66

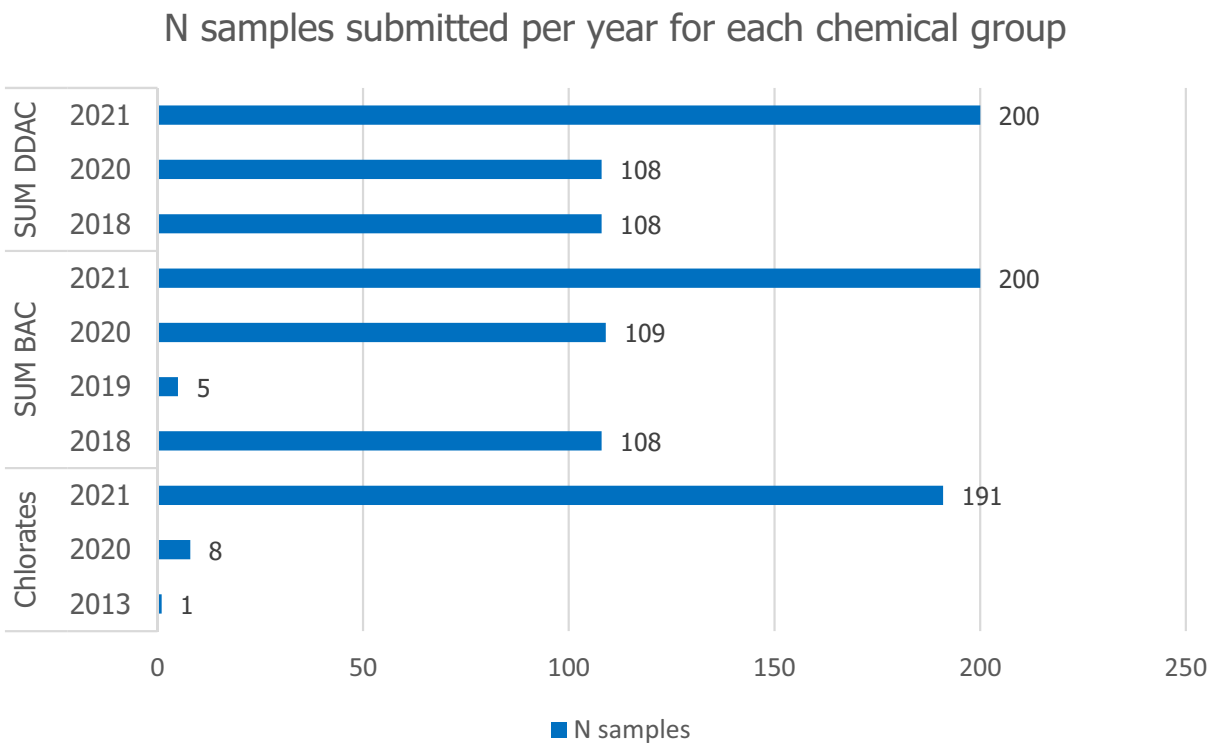

Figure B.1: Number of samples reported in the final dataset for each of the three substances under assessment, by year. The information reported does not include the samples that were removed from the dataset

B.2. Number of analysed samples by food and chemical

Information on the number of samples analysed for each fish commodity (FoodEx2 level 3) and chemical substance is provided. This table refers to the number of samples in the final occurrence dataset.

Food commodity	Chemical	N of samples
Alaska pollock	Chlorates	2
Anglerfish, monkfish and stargazers	SUM BAC	2
	SUM DDAC	1
Carp, common	Chlorates	20
	SUM BAC	20
	SUM DDAC	20
Catfishes (freshwater)	Chlorates	1
Cod	SUM BAC	29
	SUM DDAC	29
Cods, hakes, haddocks	SUM BAC	7
	SUM DDAC	7
Fish (meat)	Chlorates	18
	SUM BAC	108
	SUM DDAC	108
Flounders, halibuts, soles	SUM BAC	1
	SUM DDAC	1
Haddock	SUM BAC	10
	SUM DDAC	10
Halibut, atlantic	SUM BAC	1
	SUM DDAC	1
Mackerel	SUM BAC	19
	SUM DDAC	19
Miscellaneous freshwater fishes	SUM BAC	3
	SUM DDAC	3
Pacific salmon (generic)	Chlorates	1
	SUM BAC	49
	SUM DDAC	49

Food commodity	Chemical	N of samples
Pangas catfishes	Chlorates	76
	SUM BAC	34
	SUM DDAC	34
Pike-perch	Chlorates	23
	SUM BAC	26
	SUM DDAC	26
Plaice	Chlorates	12
	SUM BAC	12
	SUM DDAC	12
Plaice, european	Chlorates	3
	SUM BAC	3
	SUM DDAC	3
Pollack, pollock	SUM BAC	5
	SUM DDAC	5
Rainbow trout	Chlorates	11
	SUM BAC	8
	SUM DDAC	8
Salmons	Chlorates	10
	SUM BAC	9
	SUM DDAC	9
Sardines and sardine-type fishes	SUM BAC	1
Sea bass	SUM BAC	39
	SUM DDAC	39
Sea bream	Chlorates	2
	SUM BAC	6
	SUM DDAC	6
Swordfish	Chlorates	1
	SUM BAC	2
	SUM DDAC	1
Tilapias and similar	Chlorates	6
	SUM BAC	6
	SUM DDAC	5

Food commodity	Chemical	N of samples
Trouts	Chlorates	13
	SUM BAC	20
	SUM DDAC	18
Tuna	Chlorates	1
	SUM BAC	1
	SUM DDAC	1
Whiting	SUM BAC	1
	SUM DDAC	1

B.3. Summary statistics of the final occurrence dataset

The table provides summary statistics information on the number of analytical results for 'fish meat' (FoodEx2 level 3), mean (μg/kg) and 95th percentile (μg/kg) at the lower bound (LB), medium bound (MB) and upper bound (UB). Information is retrieved from the final occurrence dataset and is reported by chemical substance.

Chemical	N of analytical results	Mean LB	Mean MB	Mean UB	LB P95	MB P95	UB P95
Chlorates	200	193.01	199.69	206.36	236	236	236
SUM BAC	422	11.75	78.87	146	60	130	200
SUM DDAC	416	16.41	23.24	30.08	60	60	80

Appendix C – Exposure assessment results

C.1. Chronic exposure results

C.1.1. Chronic exposure to SUM DDAC (ADI: 0.12 mg/kg bw per day)

C.1.1.1. Summary table of the chronic exposure results for SUM DDAC (absolute exposure)

Results are reported by population class, presenting the number of surveys considered (N surveys) for both the mean and the HRP estimates, minimum and maximum absolute values of the exposure (μg/kg bw per day) for both the mean and the HRP at the LB, MB, UB.

Population class	N surveys (mean)	Mean LB (Min)	Mean LB (Max)	Mean MB (Min)	Mean MB (Max)	Mean UB (Min)	Mean UB (Max)	N surveys (HRP)	HRP LB (Min)	HRP LB (Max)	HRP MB (Min)	HRP MB (Max)	HRP UB (Min)	HRP UB (Max)
Infants	5	0.001	0.007	0.001	0.010	0.002	0.013	5	0	0.035	0	0.050	0	0.064
Toddlers	8	0.003	0.039	0.004	0.055	0.005	0.071	8	0	0.094	0	0.133	0	0.172
Other children	17	0.003	0.021	0.004	0.030	0.005	0.038	17	0.026	0.086	0.037	0.122	0.047	0.158
Adolescents	16	0.002	0.012	0.002	0.017	0.003	0.022	16	0.014	0.057	0.020	0.081	0.025	0.105
Adults	16	0.002	0.014	0.003	0.020	0.004	0.026	16	0.013	0.049	0.019	0.070	0.024	0.091
Elderly	13	0.001	0.014	0.002	0.019	0.002	0.025	13	0.015	0.047	0.021	0.067	0.027	0.087
Very elderly	11	0.001	0.013	0.002	0.018	0.002	0.023	11	0	0.031	0	0.044	0	0.057
Pregnant women	1	0.004	0.004	0.006	0.006	0.007	0.007	1	0.028	0.028	0.039	0.039	0.051	0.051
Lactating women	1	0.008	0.008	0.011	0.011	0.015	0.015	1	0.030	0.030	0.042	0.042	0.055	0.055

C.1.1.2. Summary table of the chronic exposure results for SUM DDAC (exposure in % of ADI)

Results are reported by population class, presenting the number of surveys considered (N surveys) for both the mean and the HRP estimates, minimum and maximum values of the exposure as %ADI (0.12 mg/kg bw per day) for both the mean and the HRP at the LB, MB, UB.

Population class	N surveys (mean)	Mean LB ADI (Min)	Mean LB ADI (Max)	Mean MB ADI (Min)	Mean MB ADI (Max)	Mean UB ADI (Min)	Mean UB ADI (Max)	N surveys (HRP)	HRP LB ADI (Min)	HRP LB ADI (Max)	HRP MB ADI (Min)	HRP MB ADI (Max)	HRP UB ADI (Min)	HRP UB ADI (Max)
Infants	5	0.00	0.01	0.00	0.01	0.00	0.01	5	0	0.03	0	0.04	0	0.05
Toddlers	8	0.00	0.03	0.00	0.05	0.00	0.06	8	0	0.08	0	0.11	0	0.14
Other children	17	0.00	0.02	0.00	0.02	0.00	0.03	17	0.02	0.07	0.03	0.10	0.04	0.13
Adolescents	16	0.00	0.01	0.00	0.01	0.00	0.02	16	0.01	0.05	0.02	0.07	0.02	0.09

Population class	N surveys (mean)	Mean LB ADI (Min)	Mean LB ADI (Max)	Mean MB ADI (Min)	Mean MB ADI (Max)	Mean UB ADI (Min)	Mean UB ADI (Max)	N surveys (HRP)	HRP LB ADI (Min)	HRP LB ADI (Max)	HRP MB ADI (Min)	HRP MB ADI (Max)	HRP UB ADI (Min)	HRP UB ADI (Max)
Adults	16	0.00	0.01	0.00	0.02	0.00	0.02	16	0.01	0.04	0.02	0.06	0.02	0.08
Elderly	13	0.00	0.01	0.00	0.02	0.00	0.02	13	0.01	0.04	0.02	0.06	0.02	0.07
Very elderly	11	0.00	0.01	0.00	0.02	0.00	0.02	11	0	0.03	0	0.04	0	0.05
Pregnant women	1	0.00	0.00	0.00	0.00	0.01	0.01	1	0.02	0.02	0.03	0.03	0.04	0.04
Lactating women	1	0.01	0.01	0.01	0.01	0.01	0.01	1	0.02	0.02	0.04	0.04	0.05	0.05

C.1.2. Chronic exposure to SUM BAC (ADI: 0.12 mg/kg bw per day)

C.1.2.1. Summary table of the chronic exposure results for SUM BAC (absolute exposure)

Results are reported by population class, presenting the number of surveys considered (N surveys) for both the mean and the HRP estimates, minimum and maximum absolute values of the exposure (μg/kg bw per day) for both the mean and the HRP at the LB, MB, UB.

Population class	N surveys (mean)	Mean LB (Min)	Mean LB (Max)	Mean MB (Min)	Mean MB (Max)	Mean UB (Min)	Mean UB (Max)	N surveys (HRP)	HRP LB (Min)	HRP LB (Max)	HRP MB (Min)	HRP MB (Max)	HRP UB (Min)	HRP UB (Max)
Infants	5	0.001	0.005	0.004	0.034	0.008	0.063	5	0	0.025	0	0.169	0	0.312
Toddlers	8	0.002	0.028	0.014	0.186	0.026	0.344	8	0	0.067	0	0.452	0	0.837
Other children	17	0.002	0.015	0.012	0.101	0.022	0.187	17	0.018	0.062	0.124	0.415	0.230	0.768
Adolescents	16	0.001	0.009	0.008	0.057	0.014	0.106	16	0.010	0.041	0.066	0.275	0.123	0.509
Adults	16	0.001	0.010	0.010	0.069	0.018	0.127	16	0.009	0.035	0.064	0.237	0.118	0.439
Elderly	13	0.001	0.010	0.006	0.065	0.010	0.120	13	0.010	0.034	0.070	0.227	0.130	0.420
Very elderly	11	0.001	0.009	0.006	0.061	0.011	0.113	11	0	0.022	0	0.151	0	0.279
Pregnant women	1	0.003	0.003	0.019	0.019	0.036	0.036	1	0.020	0.020	0.134	0.134	0.247	0.247
Lactating women	1	0.006	0.006	0.039	0.039	0.071	0.071	1	0.021	0.021	0.143	0.143	0.265	0.265

C.1.2.2. Summary table of the chronic exposure results for SUM BAC (exposure in % of ADI)

Results are reported by population class, presenting the number of surveys considered (N surveys) for both the mean and the HRP estimates, minimum and maximum values of the exposure as %ADI (0.12 mg/kg bw per day) for both the mean and the HRP at the LB, MB, UB.

Population class	N surveys (mean)	Mean LB ADI (Min)	Mean LB ADI (Max)	Mean MB ADI (Min)	Mean MB ADI (Max)	Mean UB ADI (Min)	Mean UB ADI (Max)	N surveys (HRP)	HRP LB ADI (Min)	HRP LB ADI (Max)	HRP MB ADI (Min)	HRP MB ADI (Max)	HRP UB ADI (Min)	HRP UB ADI (Max)
Infants	5	0.00	0.00	0.00	0.03	0.01	0.05	5	0	0.02	0	0.14	0	0.26
Toddlers	8	0.00	0.02	0.01	0.16	0.02	0.29	8	0	0.06	0	0.38	0	0.70
Other children	17	0.00	0.01	0.01	0.08	0.02	0.16	17	0.02	0.05	0.10	0.35	0.19	0.64
Adolescents	16	0.00	0.01	0.01	0.05	0.01	0.09	16	0.01	0.03	0.06	0.23	0.10	0.42
Adults	16	0.00	0.01	0.01	0.06	0.01	0.11	16	0.01	0.03	0.05	0.20	0.10	0.37
Elderly	13	0.00	0.01	0.00	0.05	0.01	0.10	13	0.01	0.03	0.06	0.19	0.11	0.35
Very elderly	11	0.00	0.01	0.00	0.05	0.01	0.09	11	0	0.02	0	0.13	0	0.23
Pregnant women	1	0.00	0.00	0.02	0.02	0.03	0.03	1	0.02	0.02	0.11	0.11	0.21	0.21
Lactating women	1	0.00	0.00	0.03	0.03	0.06	0.06	1	0.02	0.02	0.12	0.12	0.22	0.22

C.1.3. Chronic exposure to chlorates (ADI: 0.003 mg/kg bw per day)

C.1.3.1. Summary table of the chronic exposure results for chlorates (absolute exposure)

Results are reported by population class, presenting the number of surveys considered (N surveys) for both the mean and the HRP estimates, minimum and maximum absolute values of the exposure (μg/kg bw per day) for both the mean and the HRP at the LB, MB, UB.

Population class	N surveys (mean)	Mean LB (Min)	Mean LB (Max)	Mean MB (Min)	Mean MB (Max)	Mean UB (Min)	Mean UB (Max)	N surveys (HRP)	HRP LB (Min)	HRP LB (Max)	HRP MB (Min)	HRP MB (Max)	HRP UB (Min)	HRP UB (Max)
Infants	5	0.010	0.083	0.010	0.086	0.011	0.089	5	0	0.413	0	0.427	0	0.441
Toddlers	8	0.035	0.455	0.036	0.471	0.037	0.487	8	0	1.106	0	1.145	0	1.183
Other children	17	0.029	0.247	0.030	0.255	0.032	0.264	17	0.304	1.015	0.314	1.050	0.325	1.085
Adolescents	16	0.019	0.141	0.019	0.145	0.020	0.150	16	0.162	0.673	0.168	0.696	0.173	0.720
Adults	16	0.023	0.168	0.024	0.174	0.025	0.179	16	0.155	0.581	0.161	0.601	0.166	0.621
Elderly	13	0.014	0.159	0.014	0.165	0.014	0.170	13	0.172	0.555	0.178	0.575	0.184	0.594
Very elderly	11	0.014	0.150	0.014	0.155	0.015	0.160	11	0	0.369	0	0.382	0	0.394

Population class	N surveys (mean)	Mean LB (Min)	Mean LB (Max)	Mean MB (Min)	Mean MB (Max)	Mean UB (Min)	Mean UB (Max)	N surveys (HRP)	HRP LB (Min)	HRP LB (Max)	HRP MB (Min)	HRP MB (Max)	HRP UB (Min)	HRP UB (Max)
Pregnant women	1	0.047	0.047	0.049	0.049	0.051	0.051	1	0.327	0.327	0.338	0.338	0.350	0.350
Lactating women	1	0.094	0.094	0.098	0.098	0.101	0.101	1	0.351	0.351	0.363	0.363	0.375	0.375

C.1.3.2. Summary table of the chronic exposure results for chlorates (exposure in % of ADI)

Results are reported by population class, presenting the number of surveys considered (N surveys) for both the mean and the HRP estimates, minimum and maximum values of the exposure as %ADI (0.003 mg/kg bw per day) for both the mean and the HRP at the LB, MB, UB.

Population class	N surveys (mean)	Mean LB ADI (Min)	Mean LB ADI (Max)	Mean MB ADI (Min)	Mean MB ADI (Max)	Mean UB ADI (Min)	Mean UB ADI (Max)	N surveys (HRP)	HRP LB ADI (Min)	HRP LB ADI (Max)	HRP MB ADI (Min)	HRP MB ADI (Max)	HRP UB ADI (Min)	HRP UB ADI (Max)
Infants	5	0.33	2.76	0.35	2.86	0.36	2.95	5	0	13.76	0	14.23	0	14.71
Toddlers	8	1.16	15.18	1.20	15.70	1.24	16.23	8	0	36.88	0	38.16	0	39.43
Other children	17	0.98	8.23	1.02	8.51	1.05	8.79	17	10.13	33.83	10.48	35.00	10.83	36.18
Adolescents	16	0.62	4.68	0.64	4.85	0.66	5.01	16	5.40	22.43	5.59	23.21	5.77	23.98
Adults	16	0.78	5.60	0.81	5.79	0.83	5.98	16	5.18	19.37	5.36	20.04	5.54	20.70
Elderly	13	0.45	5.31	0.47	5.49	0.48	5.67	13	5.74	18.51	5.94	19.15	6.14	19.79
Very elderly	11	0.47	5.00	0.48	5.17	0.50	5.35	11	0	12.29	0	12.72	0	13.14
Pregnant women	1	1.58	1.58	1.63	1.63	1.68	1.68	1	10.90	10.90	11.28	11.28	11.66	11.66
Lactating women	1	3.15	3.15	3.26	3.26	3.37	3.37	1	11.69	11.69	12.10	12.10	12.50	12.50

C.2. Acute exposure assessment

C.2.1. Acute exposure to SUM DDAC (ARfD: 0.12 mg/kg bw)

The highest exposure results by raw primary commodity derivative (RPCD) are reported in the table. Information on the population class, survey, and country where these were estimated is provided. When 'All countries' and 'All surveys' are reported for country and survey, this means that the exposure value was calculated on population class level (i.e. grouping all countries and surveys under the same population class). HRP estimates are provided at the LB, MB and UB as absolute value (μg/kg bw) and %ARfD. Indication of the percentile that was calculated (HRP comment), the number of consumption days and total number of days on survey/population class level are also presented.

RPC FoodEx2 name	RPCD FoodEx2 name	HRP LB	HRP MB	HRP UB	HRP comment	HRP LB (% ARFD)	HRP MB (% ARFD)	HRP UB (% ARFD)	Total N days	N consumption days	Country	Survey	Population class
PRODUCTS OF ANIMAL ORIGIN – FISH, FISH PRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS	Diadromous fish, PROCESS = Cooking and similar thermal preparation processes	0.742	0.742	0.742	P95	0.62	0.62	0.62	29,533	110	All countries	All surveys	Other children
	Diadromous fish, PROCESS = Unspecified	3.636	3.636	3.636	P97_5	3.03	3.03	3.03	5,875	146	Sweden	NFA	Other children
	Freshwater fish, PROCESS = Unspecified	1.705	1.705	1.705	P95	1.42	1.42	1.42	29,533	63	All countries	All surveys	Other children
	Marine fish, PROCESS = Canning/ jarring	0.01	0.014	0.018	P75	0.01	0.01	0.02	5,680	17	Sweden	RIKSMATEN 2010	Adults
	Marine fish, PROCESS = Cooking and similar thermal preparation processes	1.685	1.685	1.685	P97_5	1.40	1.40	1.40	5,875	285	Sweden	NFA	Other children
	Marine fish, PROCESS = Frying	1.431	1.431	1.431	P95	1.19	1.19	1.19	1,875	59	Belgium	REGIONAL FLANDERS	Other children
	Marine fish, PROCESS = Roasting	0.106	0.106	0.106	P50	0.09	0.09	0.09	106,292	10	All countries	All surveys	Adults
	Marine fish, PROCESS = Unspecified	2.588	2.588	2.588	P75	2.16	2.16	2.16	108	26	Italy	INRAN SCAI 2005–06	Toddlers

C.2.2. Acute exposure to SUM BAC (ARfD: 0.12 mg/kg bw)

The highest exposure results by raw primary commodity derivative (RPCD) are reported in the table. Information on the population class, survey, and country where these values were estimated is provided. When 'All countries' and 'All surveys' are reported for country and survey, this means that the exposure value was calculated on population class level (i.e. grouping all countries and surveys under the same population class). HRP estimates are provided at the LB, MB and UB as absolute value (μg/kg bw) and %ARfD. Indication of the percentile that was calculated (HRP comment), the number of consumption days and total number of days on survey/population class level are also presented.

RPC FoodEx2 name	RPCD FoodEx2 name	HRP LB	HRP MB	HRP UB	HRP comment	HRP LB (% ARFD)	HRP MB (% ARFD)	HRP UB (% ARFD)	Total N days	N consumption days	Country	Survey	Population class
PRODUCTS OF ANIMAL ORIGIN – FISH, FISH PRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS	Diadromous fish, PROCESS = Cooking and similar thermal preparation processes	0.371	0.556	0.742	P95	0.31	0.46	0.62	29,533	110	All countries	All surveys	Other children
	Diadromous fish, PROCESS = Unspecified	1.818	2.727	3.636	P97_5	1.52	2.27	3.03	5,875	146	Sweden	NFA	Other children
	Freshwater fish, PROCESS = Unspecified	0.852	1.278	1.705	P95	0.71	1.07	1.42	29,533	63	All countries	All surveys	Other children
	Marine fish, PROCESS = Canning/ jarring	0.007	0.048	0.089	P75	0.01	0.04	0.07	5,680	17	Sweden	RIKSMATEN 2010	Adults
	Marine fish, PROCESS = Cooking and similar thermal preparation processes	0.842	1.264	1.685	P97_5	0.70	1.05	1.40	5,875	285	Sweden	NFA	Other children
	Marine fish, PROCESS = Frying	0.716	1.073	1.431	P95	0.60	0.89	1.19	1,875	59	Belgium	REGIONAL FLANDERS	Other children
	Marine fish, PROCESS = Roasting	0.053	0.08	0.106	P50	0.04	0.07	0.09	10,6292	10	All countries	All surveys	Adults
	Marine fish, PROCESS = Unspecified	1.294	1.941	2.588	P75	1.08	1.62	2.16	108	26	Italy	INRAN SCAI 2005–06	Toddlers

C.2.3. Acute exposure to chlorates (ARfD: 0.036 mg/kg bw)

The highest exposure results by raw primary commodity derivative (RPCD) are reported in the table. Information on the population class, survey, and country where these were estimated is provided. When 'All countries' and 'All surveys' are reported for country and survey, this means that the exposure value was calculated on population class level (i.e. grouping all countries and surveys under the same population class). HRP estimates are provided at the LB, MB and UB as absolute value (μg/kg bw) and %ARfD. Indication of the percentile that was calculated (HRP comment), the number of consumption days and total number of days on survey/population class level are also presented.

RPC FoodEx2 name	RPCD foodex2 name	HRP LB	HRP MB	HRP UB	HRP comment	HRP LB (% ARFD)	HRP MB (%ARFD)	HRP UB (% ARFD)	Total N days	N consumption days	Country	Survey	Population class
PRODUCTS OF ANIMAL ORIGIN – FISH, FISH PRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS	Diadromous fish, PROCESS = Cooking and similar thermal preparation processes	6.01	6.01	6.01	P95	16.70	16.70	16.70	29,533	110	All countries	All surveys	Other children
	Diadromous fish, PROCESS = Unspecified	29.473	29.473	29.473	P97_5	81.87	81.87	81.87	5,875	146	Sweden	NFA	Other children
	Freshwater fish, PROCESS = Unspecified	13.815	13.815	13.815	P95	38.38	38.38	38.38	29,533	63	All countries	All surveys	Other children
	Marine fish, PROCESS = Canning/ jarring	0.118	0.122	0.126	P75	0.33	0.34	0.35	5,680	17	Sweden	RIKSMATEN 2010	Adults
	Marine fish, PROCESS = Cooking and similar thermal preparation processes	13.655	13.655	13.655	P97_5	37.93	37.93	37.93	5,875	285	Sweden	NFA	Other children
	Marine fish, PROCESS = Frying	11.598	11.598	11.598	P95	32.22	32.22	32.22	1,875	59	Belgium	REGIONAL FLANDERS	Other children
	Marine fish, PROCESS = Roasting	0.863	0.863	0.863	P50	2.40	2.40	2.40	10,6292	10	All countries	All surveys	Adults
	Marine fish, PROCESS = Unspecified	20.972	20.972	20.972	P75	58.26	58.26	58.26	108	26	Italy	INRAN SCAI 2005–06	Toddlers

Annexes

The following annex can be found in the online version of this output ('Supporting information' section):

- **Annex A**: Occurrence data, food consumption surveys and exposure assessment results for BAC, DDAC and chlorates in fish and fish products.