Chlorate risk assessment

Joint EFSA-BfR document
(Agreed on 15 June 2015)

This joint document reflects the common understanding of EFSA and BfR on the divergence between the scientific opinion of the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) on the risks to human health related to the presence of chlorate in food and the health assessment of chlorate residues in diverse plant-based foods from BfR.

1. Procedural background

Article 30 of Regulation 178/2002 stipulates that EFSA should identify potential sources of divergence between its scientific opinions and those issued by other bodies carrying out similar tasks and to cooperate with a view of either resolving the divergence or preparing a joint document clarifying the contentious issues and identifying the relevant uncertainties in the data.

Already early in the development of the scientific opinion on the risks to human health related to the presence of chlorate in food, EFSA identified potential scientific divergences with the BfR health assessment of chlorate residues in diverse plant-based foods, published in 2013. Therefore, a BfR representative was invited as hearing expert to the 3rd meeting of the CONTAM WG on chlorate in food, 19-20 January 2015, where views on the risk assessment of chlorate in food were exchanged.

Upon further elaboration of the opinion, on 27 March 2015 EFSA sent a letter to BfR in which the assessment elements diverging from the BfR assessment were presented. In particular, these are: (i) differing acute and chronic health based guidance values and (ii) the non-applicability of variability factors for acute dietary exposure assessments for chlorate.

In their response from 15 April 2015, the BfR welcomed the opportunity to give their views on the EFSA opinion, and agreed with the health based guidance values as proposed by EFSA. However, the BfR retained their position that a variability factor was applicable for acute exposure assessments of chlorate in food in certain instances.

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3 Request of the European Commission to the European Food Safety Authority (EFSA) for a scientific opinion concerning the risks for public health related to the presence of chlorate in food. Available at: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00534
In order exchange views on this remaining potential divergence, BfR was invited to participate to present their views, at the 71st CONTAM Plenary meeting, in April 2015. Upon discussion with BfR and further discussions in a closed session that followed the hearing, the CONTAM Panel agreed to retain its position not to apply a variability factor for acute exposure assessments.

2. Scientific positions on application of a variability factor for acute exposure assessments of chlorate in food

**BfR position:**

The position of BfR, laid down on their letter to EFSA of 15 April 2015 and presented in further detail in a hearing with the CONTAM Panel at their 71st Plenary in April 2015, is that for acute dietary exposure assessments a variability factor of 3 needs to be applied for large food commodities.

Such a variability factor needs to be applied in order to account for variations of residue distribution in field and market samples in acute dietary exposure assessments of chlorate. The entry routes of chlorate yielding residues in food are not yet finally elucidated, and although residues arising from post-harvest treatments are indeed expected to have a higher level of homogeneity than samples from in-field treatments, variability is still observed for such treatments (e.g. from dipping or drenching).

Moreover, there is experimental evidence on unit-to-unit variability with pesticides (diphenylamine, iprodine, carbendazim and imazalil) applied post-harvest to fruits in drenching solutions, which are scenarios comparable to likely chlorate exposure pathways. Based on the results from these investigations it can be concluded that a variability factor of 3 needs to be applied to cover adequately variability occurring within food commodities, if field application is not of relevance, as is likely the case for chlorate.

For very small units (< 25 g) and for commodities usually blended (e.g. cereal grains, oilseeds) or blended and processed before consumption (e.g. fruit juice) residue in the composite sample corresponds to the residue in the ingested portion, and thus a variability factor is not needed.

The BfR notes that based on the lack of toxicity and residue data and the resulting uncertainties in the evaluation, a very conservative assessment of the acute risk was carried out.

**EFSA position:**

The CONTAM Panel appreciates that for acute exposure assessments of pesticides, variability factors are commonly applied for residues in fruit and vegetables with a large unit weight (> 25 g) to account for variation within composite samples. It also acknowledges that in some instances where measurements of contaminants were carried out with composite samples of foods with a large unit size, and depending on the route by which the contaminant enters the food, application of variability factors can indeed be appropriate for such assessments.

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8 EFSA (European Food Safety Authority). 2005. Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from Commission related to the appropriate variability factor(s) to be used for acute dietary exposure assessment of pesticide residues in fruit and vegetables. The EFSA Journal 2005, 177, 1–61.
However, chlorate residues (unlike pesticide residues) usually arise post-harvest through food processing and, thus local contamination resulting in high variation of residues within individual food samples is less likely to occur. The practices leading to the presence of chlorate are most likely the use of chlorinated water for various food processing (e.g. for blanching and hydro-cooling procedures), and the treatment of food processing equipment with chlorate containing/yielding substances. Due to the high solubility of chlorine and chlorate in water an even distribution of chlorate residues in processing water is expected.

In addition, the acute dietary exposure estimations presented in the EFSA opinion are based on a rather large data set of occurrence/monitoring data received upon a call for data. Variability in chlorate levels between samples is already addressed by the use of the highest reliable percentile (in most instances by the 95th but for some of the food groups by the 99th percentile) for the assessment of acute exposure. Non-applicability of variability factors is further corroborated by the fact that food commodities with the highest reported levels of chlorate were mainly frozen vegetables (e.g. broccoli, cucumbers or carrots). These samples refer to small pieces of vegetables obtained from whole vegetables units that were washed, chopped, blanched, cooled and then blended. Therefore, the potential variability in the levels of chlorate during food processing is minimised.

Overall, the EFSA CONTAM Panel concluded that the use of a variability factor for assessment of acute exposure to chlorate in food is not appropriate.

In addition the CONTAM Panel notes that uncertainties are incurred with the acute (and chronic) exposure assessment presented in the opinion based on the lack of representativeness of the occurrence data used for whole Europe, missing occurrence data on particular food commodities and the imputation of occurrence data for drinking water to beer, tea and coffee. With regard to the overall risk assessment of chlorate the CONTAM Panel considers that the uncertainties are large.

3. Conclusions

EFSA and BfR embarked on a continuous, intensive and open scientific dialogue in order to resolve any diverging opinions with regard to the dietary risk assessment of chlorate.

EFSA’s CONTAM Panel acknowledged the reasoning of BfR for applying a variability factor for acute dietary risk assessments of chlorate. However, upon taking into account the arguments of BfR for applying such a factor as laid down in their previous assessment and further specified during the scientific exchange together with the findings and evaluations presented in in their own opinion, EFSA’s CONTAM Panel came to the clear conclusion that application of variability factors for acute dietary assessments would not be appropriate for the case of chlorate.

Thus, the scientific divergence between EFSA and BfR with regard to the application of variability factors for acute exposure assessments for chlorate remains outstanding based on the premises and scientific reasoning outlined in the previous paragraphs.