

Consultation on perchlorate risk assessment
Follow-up on the trilateral meeting on perchlorate risk assessment
held on 12 February 2014, Parma

Joint EFSA-ANSES-BfR report
(Agreed on 28 November 2014)

This report reflects the common understanding of EFSA, ANSES and BfR of the consultation on the EFSA opinion on the risks to public health related to the presence of perchlorate in food, in particular fruits and vegetables ([EFSA-Q-2013-00675](#)). This report is not, and cannot be regarded as, representing the position, the views or the policy of the European Food Safety Authority or of any national or EU Institution, agency or body.

1. Background information

Following the identification of diverging scientific opinions between the draft statement developed by the EFSA CONTAM Panel and published opinions from ANSES and BfR on the assessment of the public health risks relating to the presence of perchlorate in food, a trilateral meeting was organised by EFSA to cooperate with the interested parties either to resolve the divergence or to prepare a joint document clarifying the contentious issues and identifying the relevant uncertainties, as indicated in Article 30 of Regulation (EC) No 178/2002¹.

The conclusions of the trilateral meeting, held on 12 February 2014, were summarised in a meeting report made publicly available on the EFSA website². The outcome of the meeting did not allow for the identified divergences to be conclusively resolved or for the contentious issues to be fully clarified. Therefore, the CONTAM Panel indicated the need to have further consideration on aspects relating to the acute exposure assessment and the hazard characterisation of perchlorate.

The draft statement on perchlorate was further discussed at the 63rd CONTAM Panel plenary meeting (25-27 February 2014), and the CONTAM Panel considered it appropriate to set up an *ad hoc* working group (WG) and to deliver a full scientific opinion. The CONTAM WG on perchlorate amended the draft statement and re-evaluated the scientific evidence in the light of the comments received at the trilateral meeting.

¹ Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 01.02.2002 p. 1-24.

² <http://www.efsa.europa.eu/it/events/event/140212a-m.pdf>

The draft opinion prepared by the WG on perchlorate was presented to the CONTAM Panel at the 66th plenary meeting (16-18 July 2014) for endorsement. The endorsed draft opinion was shared with ANSES and BfR on 26 July 2014 for a four week consultation period.

2. Consultation outcome

Comments received from ANSES

ANSES commented on the draft opinion on perchlorate distributed for consultation as follows:

"In this draft on perchlorate risk assessment, newly endorsed by the CONTAM Panel at the 66th Panel plenary meeting (16-18 July 2014), ANSES has mainly noted that:

- iodine status in Europe has been taken into account in the risk assessment;
- French contamination data on perchlorate in drinking water and bottled water were analysed in the exposure assessment and bibliographic data were selected to characterize perchlorate contamination in infant formulae (powder or liquid);
- a new tolerable daily intake of 0.3 µg/kg b.w. per day has been calculated by a benchmark dose modelling based on the thyroid uptake inhibition data from the Greer et al. (2002) study, using a benchmark response of 5 % and applying an uncertainty factor of 4 to allow for inter-human differences.
- this new analysis leads to conclusions on the risk characterization and recommendations that differ from those drawn from the previous EFSA draft as discussed at the trilateral meeting on perchlorate risk assessment

This conclusion is definitely close from the conclusion drawn by ANSES, and the agency does not have any formal comment related to the new draft opinion".

Comments received from BfR

BfR commented on three specific sections of the draft opinion:

Section	Comment
4.3 Chronic and short-term exposure estimates in humans	The BfR supports that in addition to a chronic exposure scenario a short-term exposure scenario is performed, in order to take into account the possibility of being exposed to relatively high levels of perchlorate for a period of e.g. 2-3 weeks.
5.7 Hazard characterisation 5.7.1 Chronic effects	The BfR supports the TDI of 0.3 µg/kg b.w. per day for chronic risk assessment, based on the BMDL ₅ of 0.0012 mg/kg b.w. per day for inhibition of thyroid iodine uptake in healthy adults and an uncertainty factor of 4.
5.7.3 Short-term effects	The CONTAM Panel concluded that short-term exposure to perchlorate is of concern for breast-fed infants and small children, particularly in the case of low iodine intake. However, the Panel has not established a short-term health-based guidance value (HBGV) for these populations.

In order to complete the hazard and risk characterisation, the BfR suggests that also a short-term HBGV should be established for perchlorate.

3. Comments addressed by the ad hoc WG on perchlorate and the CONTAM Panel

The comments received from ANSES and BfR were considered by the CONTAM WG on perchlorate at the 5th WG meeting (1 September 2014) and by written procedure on 16 September 2014.

ANSES

For the comments received from ANSES, the CONTAM WG concluded that no further action was necessary.

BfR

The CONTAM WG on perchlorate considered it necessary to address the last comment received from BfR. The WG noted that the possibility of establishing a short-term health-based guidance value (HBGV) was discussed in the draft opinion submitted for consultation and it was concluded that the lack of data on the short-term thyroid iodine depletion that could be associated with adverse effects in the relevant subpopulation groups (breast-fed infants and small children) did not allow for conclusions to be drawn.

Following additional e-mail exchange between BfR and EFSA, BfR clarified that there is agreement on the lack of data to allow for the establishment of a short-term HBGV, but it would be helpful for the risk management to get a clear recommendation on the extent and duration of an exposure higher than the chronic tolerable daily intake (TDI) that could be tolerated.

In the absence of a more reliable short-term HBGV, BfR proposed that the level of 0.01 mg/kg b.w. (which was originally used in the BfR acute risk assessment) could be applied as the short term HBGV. BfR stressed that such an approach could help to give clear recommendations for setting maximum residue levels (MRLs) or maximum admissible concentrations for perchlorate in food.

In particular, BfR indicated that it should be considered, based on the estimations of short-term exposure for certain subpopulations, whether the provisional MRLs for perchlorate in food established by the EU Commission are appropriate with regard to risks to human health.

The BfR position of establishing a short term HBGV of 0.01 mg/kg b.w. per day for perchlorate was presented to the CONTAM Panel during the discussion for the adoption of the draft opinion on perchlorate at the 67th CONTAM Panel plenary meeting (30 September-2 October 2014). The CONTAM Panel pointed out that in the absence of reliable information it is not possible to conclude whether short-term exposure to 0.01 mg/kg b.w. per day would pose a risk to the relevant subpopulation groups. Therefore the CONTAM Panel maintained the approach presented in the version of the opinion distributed for the consultation. The opinion on perchlorate was adopted by the CONTAM Panel on 30 September 2014.

Following the adoption of the opinion, BfR was consulted again by e-mail to clarify the position on the scientific divergence. BfR indicated again a general agreement with the scientific content and conclusions of the EFSA opinion. However, BfR noted that, since the chronic TDI is a conservative basis for short-term risk assessment, it is considered essential for the on-going discussion regarding MRL setting for perchlorate that a recommendation for a possible refinement of the short-term risk assessment should be provided, and a recommendation on the extent and duration of an exposure higher than the chronic TDI that could be tolerated should be considered. Alternatively, a provisional short-term health-based guidance value could be proposed.

4. Conclusions

- The scientific divergence between EFSA and ANSES is considered as solved by the interested parties.
- Regarding the scientific divergence between EFSA and BfR, the parties note that there is a general agreement on the scientific content of the EFSA opinion. EFSA notes that the recommendations included in its opinion address the need identified by BfR regarding a refinement of the short term risk assessment. Hence, overall the scientific divergence between EFSA and BfR is considered as solved by the interested parties.