Position Paper on Chlorate Residues in Xanthan

Key Concerns

- **No general EU maximum limit for xanthan:** Xanthan is a food additive and does not fall under the general chlorate maximum residue level (MRL) laid down in the Pesticides Regulation. A fixed value such as the proposed 0.1 mg/kg is therefore neither legally nor scientifically appropriate.
- **Chlorate mainly originates from the manufacturing process:** Chlorate does not originate from xanthan itself but may be formed during cleaning and disinfection processes and remain in the final product.
- **Very low health risk:** Xanthan is used only in very small quantities. Even in cases of high chlorate levels in xanthan, actual dietary exposure remains well below toxicological threshold values (TDI/ARfD).
- **Request/Recommendation:** Instead of setting a fixed maximum level, a risk-based, product-specific assessment should be applied. A renewed scientific evaluation by EFSA is recommended to establish a practical and consumer-protective maximum level.

The VDC (Association of Firms engaged in Wholesale and Foreign Trade in Drugs and Chemicals) represents, among others, the interests of German importers of food additives such as gum arabic (E 414), guar gum (E 412), **xanthan (E 415)** and locust bean gum (E 410). Our member companies are major suppliers to customers in the European food industry.

They express serious concerns regarding the current draft proposal and point out that the proposed maximum levels for residues and contaminants are not feasible in practice, even when applying best available manufacturing techniques. With regard to the planned establishment by the European Commission of a maximum residue level (MRL) of 0.1 mg/kg chlorate in xanthan, we would like to provide the following technical and toxicological assessment for your consideration:

Legal Framework

According to Regulation (EC) No 396/2005, a default MRL of 0.01 mg/kg applies to chlorate, a plant protection active substance that is no longer approved, for plant and animal food commodities listed in Annex I of the Regulation. Xanthan (E 415), as a food additive, is not listed in this Annex and is therefore not subject to a specific maximum residue level under this Regulation.

Furthermore, Commission Regulation (EU) No 231/2012 laying down specifications for food additives does not specify any maximum levels for chlorate in xanthan. In such cases, Article 14 of Regulation (EC) No 178/2002 requires an individual, case-by-case approach. An application of the default MRL to food additives is not foreseen under Article 18 of Regulation (EC) No 396/2005.

In addition, Article 2(2) of Regulation (EEC) No 315/93 establishes the ALARA principle ("as low as reasonably achievable") for contaminants in food. This principle requires that contamination be reduced to the lowest level that is technologically and economically achievable, without necessarily imposing a rigid uniform concentration limit.

Technological Origin of Possible Chlorate Residues

Xanthan is produced by fermentation of sugar-containing media using *Xanthomonas campestris*. During fermentation, pH adjustment is typically carried out using sodium or potassium hydroxide. After completion of fermentation, the broth is heated and/or chemically treated to inactivate microbiological activity and enzymes.

A key step in downstream processing is pH reduction to stabilize the polymer structure and facilitate precipitation; for this purpose, organic acids as well as hydrochloric acid (HCl) may be used. Xanthan is then recovered by addition of a precipitating agent (ethanol or isopropanol), followed by filtration, washing and drying; in some processes, a subsequent neutralisation to the sodium, potassium or calcium salt is carried out. The use of HCl typically occurs at the end of fermentation or during washing.[1,2,4]

The most recent EFSA re-evaluation of xanthan (E 415) requires inactivation of enzymes used in the manufacturing process but explicitly does not prescribe a specific method (e.g. heat treatment only or a ban on HCl). Likewise, the EU specifications in Regulation (EU) No 231/2012 neither prohibit the use of hydrochloric acid nor specify the type of inactivation agent but generally describe xanthan as a fermentation product obtained by precipitation with ethanol or isopropanol and meeting defined purity criteria.

The use of HCl for pH reduction and enzyme inactivation is therefore legally permitted under food law and even desirable, as it ensures compliance with the specification and the absence of relevant residual enzyme activity ("*The final product must not show any residual enzyme activity.*"). This safety requirement is set out in the latest draft amendment to the Food Additives Specifications Regulation for xanthan.

Pure hydrochloric acid produced by the reaction of hydrogen with chlorine generally does not contain chlorate and is therefore not the primary source of the chlorate levels observed. Chlorate is formed secondarily when HCl comes into contact with residues containing hypochlorite.

Hypochlorite is widely used in fermentation facilities for CIP (cleaning-in-place) operations, and residues may remain in pipework. When hypochlorite residues come into contact with hydrochloric acid, chlorine gas is initially formed, which subsequently reacts in water to form chloric acid, present in solution as chlorate. Acidic conditions (low pH) promote chlorate formation. Chlorate is highly stable and is hardly reduced by subsequent processing steps (precipitation, filtration, drying), so it remains in the aqueous phase and can ultimately be detected in the final product.[2,3]

In addition to the reaction between hypochlorite and HCl, other sources of chlorate are relevant. Chlorate may already be present in process water or in alkaline solutions (e.g. sodium hydroxide), particularly if these chemicals were produced or stored using chlorine-based disinfection or cleaning steps.

Even modern membrane and diaphragm processes for NaOH production can result in low chlorate levels. Hypochlorite is also frequently used for disinfecting fermenters and pipelines, leading to unavoidable residues entering the fermentation broth. When combined with subsequent pH reduction using HCl, chlorate can form and, due to its high water solubility, become enriched in the fermentation broth and carried through the downstream process into the dried xanthan.[2,3,4]

Toxicological Assessment and Exposure Calculation (Example: Children)

In 2015, the European Food Safety Authority (EFSA) established a tolerable daily intake (TDI) for chlorate of 0.003 mg/kg body weight per day (3 µg/kg bw) and an acute reference dose (ARfD) of 0.036 mg/kg bw (36 µg/kg bw). Potential health concerns particularly affect children with iodine deficiency, as chlorate can inhibit iodine uptake.[5]

Example: A bread product contains 0.5% xanthan. Assuming a high chlorate concentration of 10 mg/kg in the xanthan, the resulting chlorate content in the final product is 0.05 mg/kg. A child weighing 15 kg consuming 100 g of this bread would ingest 0.005 mg chlorate, corresponding to a dose of approximately 0.333 µg/kg bw. This represents around 11% of the EFSA TDI and is therefore well below the acceptable long-term intake.

Even with daily consumption, neither the chronic nor the acute reference dose would be exceeded. Only a theoretical daily bread consumption of approximately 0.9 kg would fully exhaust the TDI. From a toxicological perspective, chlorate levels in xanthan of up to 90 mg/kg are therefore not of concern at such typical use levels.

Conclusion and Recommendation

Considering the low typical use levels of xanthan (0.1–1%), the case-by-case principle and the ALARA approach, a general maximum limit of 0.1 mg/kg chlorate is not appropriate.

A risk-based, product-specific assessment would be more appropriate. Chlorate levels in xanthan of up to 90 mg/kg do not result in any relevant consumer exposure at normal use levels.

We therefore recommend a renewed scientific evaluation under an EFSA mandate, including an assessment of the transitional arrangements, in order to establish a maximum level that is both practical and ensures a high level of consumer protection.

References

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