Position Paper on Chlorate Residues in Xanthan

The positions laid down in this document relate to recent approaches on restrictive measures for Xanthan as a food additive, currently discussed on EU level in context with findings of chlorate residues.

Key Concerns

- **No general EU maximum limit for xanthan:** Xanthan gum is marketed as a food additive and therefore does not automatically fall under the default pesticide maximum residue level (MRL) regime. Under Regulation (EC) No 396/2005, the default value of 0.01 mg/kg applies only to plant and animal commodities listed in Annex I. As Xanthan gum (E 415) is not included in this Annex, this default MRL cannot be directly applied. Any potential limit for xanthan would therefore require a separate risk-based regulatory decision supported by toxicological scientific assessment.

- **Chlorate mainly originates from the manufacturing process:** Available evidence indicates that chlorate found in xanthan gum is not an intrinsic component of the polymer but a secondary, process-derived residue. The most plausible pathway involves the reaction residual chlorine species (e.g. hypochlorite) from chlorinated process water or sanitation agents under certain processing conditions, whereby this pH adjustment is an essential step to inactivate enzymatic activity resulting from the bacterial fermentation process. Chlorate should therefore be considered a **process contaminant**. The occurrence of such residues cannot be taken as evidence that the product was manufactured by a process that would render it **a non-authorised product** or constitute a **different additive** under specification Regulation (EC) 231/2012, as incorrectly concluded in the draft opinion of SCoPAFF. Detailed information on enzyme inactivation and related process steps is typically proprietary and was not fully described in the EFSA evaluations of 2017 and 2023. If this aspect poses a general human health risk, EFSA should be mandated to include certain aspects of manufacturing within the specification regulation.

- **Exposure and toxicological assessment**: Xanthan gum is used at relatively low concentrations in compound food due to its strong technological functionality. As a result, even when chlorate is present in the additive, the resulting dietary exposure from xanthan-containing foods is expected to remain significantly lower than exposure from other dietary sources. Regulatory considerations should therefore rely on a comprehensive exposure assessment comparing realistic use levels with established toxicological reference values (e.g. ARfD), rather than solely on maximum limits in the additive itself.

- **Impact of publishing the Draft SCoPAFF Opinion for the supply chain**: The proposed MRL of 0.1 mg/kg chlorate would disrupt the xanthan supply chain, causing shortages and reformulation in key food sectors (e.g. sauces, plant-based alternatives, gluten-free bakery) where xanthan gum is crucial for ensuring stability, texture, and viscosity, increasing costs and reducing product availability.

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 SCoPAFF draft opinion and point out that the proposed chlorate maximum level of 0.1 mg/kg can be achieved due to recent adjustments applying best available manufacturing techniques, but these would result in residual enzyme activity. With regard to the European Commission's intended establishment of a maximum residue level (MRL) of 0.1 mg/kg chlorate in xanthan, we would like to provide the following background information, including the technical scientific and regulatory assessment for your consideration:

Manufacturing Process of Xanthan Gum (E 415) and Potential Sources of Chlorate

Xanthan gum is produced by fermentation of carbohydrate-containing media using *Xanthomonas campestris*. During fermentation, the pH is typically controlled through the addition of sodium or potassium hydroxide. After fermentation is completed, the broth is treated to inactivate microbiological activity and enzymes. During downstream processing, the pH of the fermentation broth may be reduced to stabilise the polymer and facilitate precipitation. Hydrochloric acid (HCl) can be used for this purpose. Xanthan is then recovered by precipitation with ethanol or isopropanol, followed by filtration, washing and drying. In some processes, a final neutralisation step converts the product into the sodium, potassium or calcium salt. The use of HCl typically occurs at the end of fermentation or during washing steps.[1,2,4]

The most recent re-evaluation of xanthan gum (E 415) by the European Food Safety Authority requires that enzymes used during manufacturing are inactivated but does not prescribe a specific method. Likewise, the EU specifications laid down in Regulation (EU) No 231/2012 do not prohibit the use of hydrochloric acid nor define a specific inactivation technique. Xanthan is generally described as a fermentation product recovered by precipitation with ethanol or isopropanol and meeting defined purity criteria. The use of HCl for pH adjustment and enzyme inactivation is therefore legally permitted and technologically justified, as it ensures compliance with the requirement that the final product must not show residual enzyme activity.

Hydrochloric acid produced from hydrogen and chlorine is typically free of chlorate and is therefore not considered the primary source of the chlorate levels occasionally detected in xanthan. Instead, chlorate may form secondarily when HCl reacts with residues containing hypochlorite or other chlorine-based oxidants.

Hypochlorite is widely used in fermentation facilities for cleaning-in-place (CIP) operations. Residues may remain in equipment or pipelines and can react with hydrochloric acid used during processing. In such reactions, chlorine may initially form and subsequently convert in aqueous solution to chloric acid, present as chlorate. Acidic conditions favour this conversion. Because chlorate is chemically stable, it is not effectively removed during subsequent steps such as precipitation, filtration or drying and may therefore remain detectable in the final product. [2,3]

Additional sources of chlorate may include process water or processing chemicals such as sodium hydroxide. Trace levels can occur when these materials are produced or handled using chlorine-based sanitation systems. Even modern membrane or diaphragm processes for sodium hydroxide production may result in low chlorate concentrations. Consequently, chlorate formation during xanthan manufacture may arise from several process-related factors, including sanitation residues, process water and chemical inputs. Once formed, chlorate remains in the aqueous phase of the fermentation broth and may be carried through downstream processing into the dried xanthan gum.[2,3,4]

According to the EFSA re-evaluation (2017), xanthan gum is produced by aerobic submerged fermentation using *Xanthomonas campestris*. The microorganism is cultivated in a nutrient medium containing carbohydrates such as glucose or sucrose together with nitrogen sources, mineral salts and trace elements. Under controlled aeration, agitation and temperature conditions, the bacteria synthesise xanthan as an extracellular polysaccharide that accumulates in the fermentation broth. After fermentation, the bacterial biomass is removed by centrifugation or filtration, and xanthan is recovered by precipitation with ethanol or isopropanol. The precipitated polymer is then dried and milled to obtain a stable powder suitable for commercial use as a thickening and stabilising agent.

The EFSA opinion describes this fermentation-based production process only in general terms and does not fully reflect certain operational steps applied in industrial manufacturing. It does not specify how enzymatic activity in the fermentation broth is inactivated prior to downstream processing, nor does it discuss potential pathways for chlorate formation during processing.

Based on information available to our members, the fermentation broth may undergo an additional inactivation step prior to further processing. This step can be performed either by acidification using hydrochloric acid or by thermal treatment, such as pasteurisation at temperatures typically between 80 and 100 °C. These treatments ensure enzyme inactivation and stabilisation of the fermentation broth before xanthan recovery, although they are not explicitly included in the flow chart (Figure 3) in the EFSA opinion from 2017.

Response regarding use of processing aids during manufacturing of Xanthan

In the safety re-evaluation of xanthan gum (E 415) published in 2017 and 2023, the European Food Safety Authority based its assessment primarily on publicly available literature, previous evaluations, and data submitted by stakeholders in response to EFSA calls for data. The manufacturing process described in the 2017 opinion represents a generalised industrial process and does not reflect proprietary or manufacturer-specific production details. Consequently, individual manufacturers did not submit detailed descriptions of their specific production technologies, as the re-evaluation aimed to assess the safety of xanthan gum as a substance based on representative production methods rather than reassessing each producer's manufacturing process.

Industrial production of xanthan gum follows the conventional fermentation-based process described by EFSA. Xanthan is produced by aerobic submerged fermentation using

Xanthomonas campestris cultivated in a nutrient medium containing carbohydrates such as glucose or sucrose, together with nitrogen sources, mineral salts and trace elements.

Under controlled fermentation conditions, the microorganism synthesises xanthan as an extra-cellular polysaccharide that accumulates in the fermentation broth. After fermentation, the bacterial biomass is removed by centrifugation or filtration, and xanthan is recovered by precipitation with ethanol or propan-2-ol, followed by drying and milling to obtain a uniform powder.

Trace levels of chlorate occasionally detected in xanthan gum are not the result of intentional use but can arise from secondary reactions as described during processing. Chlorine-based sources such as chlorinated process water, sanitation systems or residues from cleaning and disinfection agents may introduce trace oxidising chlorine species. Under certain processing conditions, including changes in pH, temperature and contact time these species can undergo oxidation or disproportionation reactions forming chlorate. The temporary use of hydrochloric acid for pH adjustment or enzyme inactivation may facilitate this conversion from pre-existing trace chlorine compounds, which can subsequently remain detectable in the final product.

Regulatory assessment of chlorate findings in Xanthan

Hydrochloric acid used during fermentation qualifies as a processing aid under Regulation (EC) No 1333/2008, as it serves a technological function during processing but is not intended to remain in the final product or exert a technological effect. Any resulting residues or derivatives are therefore considered unintentional and technically unavoidable. Chlorate formed under such conditions is regarded as a process contaminant, i.e. a substance generated during food processing rather than intentionally added. The assessment and management of such contaminants fall under Regulation (EEC) No 315/93, which requires contaminant levels to be kept as low as reasonably achievable (ALARA) in accordance with good manufacturing practice. In addition, Commission Regulation (EU) 2020/749 recognises that chlorate residues may originate from processing sources such as chlorinated water or disinfectants and requires operators to demonstrate any process-related contributions to chlorate levels in the final product.

Conclusion and Recommendation

- Based on presented information, EFSA should conduct a **targeted scientific assessment of xanthan gum (E 415) production** to investigate chlorate formation, evaluate the manufacturing process, and determine whether **risk-based maximum levels (MRLs)** for chlorate should be established.
- **Dietary exposure to chlorate from xanthan** should be reassessed in compound foods, considering **realistic use levels** and its contribution to total exposure, in relation to established toxicological reference values: **ADI 3 µg/kg bw/day, ARfD 36 µg/kg bw**. This reassessment should be aligned with the ongoing EFSA call-for-data on chlorate occurrence (EFSA-Q-2025-00706) to ensure consistency across dietary sources.

•**Production process improvements** by manufacturers have significantly reduced chlorate formation (acc. ALARA principle). Data can be shared with EU-Commission by request. However, **simultaneous compliance with enzyme inactivation requirements** (ensuring no residual amylase or cellulase activity) requires process adjustments that are **interdependent and may take up to 6 months**. Technical details are proprietary.

- **Already imported stocks of xanthan, as well as shipments that are already en route, which exceed the proposed MRL of 0.1 mg/kg**, should undergo a **toxicological risk assessment in accordance with Article 14 of Regulation (EC) No 178/2002**. These products should **not be subject to recalls or border rejections**, as only more recently manufactured batches **comply** with the proposed limit, according to the SCoPAFF Draft Opinion.

- Chlorate residues in xanthan are **likely caused by temporary hydrochloric acid use as a processing aid**, facilitating secondary reactions with trace chlorine species. This mechanism aligns with scientific understanding and EU legal definitions of **process contaminants** and **processing aids** (Regulations (EC) 1333/2008 and (EEC) 315/93).

References

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3. World Health Organization: „Chlorate in Drinking-water: Background document for development of WHO Guidelines for Drinking-water Quality“, 2016.
4. Mohamed, AM.O., O'Kelly, B.C., Soltani, A. Xanthan Gum Production and Structure. In: Sustainability in Ground Improvement: The Case of Xanthan Gum Biopolymer. Green Energy and Technology. Springer, Cham. https://link.springer.com/chapter/10.1007/978-3-031-75313-8_2#citeas, 2024.

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