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Zurich, December 2021

Comment to the EFSA public consultation on „Identification and prioritisation for risk assessment of phthalates, structurally similar substances and replacement substances potentially used as plasticisers in materials and articles intended to come into contact with food“

To Whom It May Concern

We would like to thank EFSA for the opportunity to comment on this Scientific Opinion. With our input we hope to help improve the document so that it does justice to best protecting the general public from harmful chemical exposures, in alignment with the [EU Chemicals Strategy for Sustainability](#) (CSS) (EU 2020).

Prioritising chemicals for further assessment

The prioritization approach outlined here has identified chemicals that are likely to be used as plasticizers in different types of food contact materials in Europe. While the approach is clearly described there are several shortcomings and inconsistencies with the CSS.

1. Several chemicals were **excluded** from the prioritization due to them *“not expected to function as a plasticizer based on their chemical nature”* (2.1.1, line 253)

Excluding chemicals from a prioritization must be well documented and clearly argued. This is not the case here: no list of which chemicals were excluded is provided, nor are the detailed criteria for their exclusion described. It is therefore recommended that the **functionality of a plasticiser is described in detail**, and the **related chemical properties are listed in detail**, or a reference is provided where this expert information can be obtained. In addition, the excluded substances shall be listed. Including all of this information will best serve EFSA’s ambition of transparency.

2. Chemicals were **prioritised** based on the date of their risk assessment, **not on their hazard properties**.

The Scientific Opinion states that *“The first prioritization criterion is the date of assessment of the substance”* (2.2.1, line 331). In line with the CSS, **a first prioritization criterion should be based on chemical hazard properties** alone, and not on any other aspect. The chosen approach does not agree with what is laid out in the CSS. Indeed, compiling hazard properties for some hundred chemicals is a feasible task for an expert, and achievable in a reasonable time frame. These hazard data should then be used as starting point for identifying the most hazardous chemicals which can then be prioritized further, for example by selecting those for which a risk assessment was done before 2001. Systematic methodologies for a hazard-based prioritisation approach should be applied and are already published in the scientific literature ([Groh et al. 2021](#)). Importantly, this effort would also highlight for which chemicals no relevant hazard data are available, which would lead to another group of substances requiring further investigation.

3. **Unclear recommendation** for the exclusion group of chemicals with severe hazard properties

According to the CSS, the prioritization of chemicals for further assessment and phasing out should be based on their hazard properties, as is also outlined in the **toxic-free hierarchy for chemicals management** (CSS, p.4). The purpose for this approach is to minimize substances of concern in products (CSS, p.6). The CSS states explicitly that, due to its implementation, “*consumer products do not contain chemicals that cause cancers*” and other detrimental health effects (CSS, p.10). Therefore, for achieving this purpose, a “**generic approach to risk management**” is required, as the regulation on a case-by-case has not delivered.

This failure of chemical risk assessment on a case-by-case basis is especially apparent for the five phthalates addressed in this Scientific Opinion, four of which are being found in humans (including vulnerable population groups) at levels well below regulatory “safe” exposure thresholds ([Maffini et al. 2021](#)), but these **low-level phthalate exposures are robustly linked to adverse health outcomes in humans**, such as cardiovascular disease, neurological disorders, asthma and breast/uterine cancers ([Eales et al. 2021](#); [Trasande et al. 2021](#)). As consequence, the use of these four phthalates should be discontinued in food contact materials (FCMs), and their presence as non-intentionally added substances in FCMs should be further investigated and minimized accordingly.

However, **a clear recommendation to this effect is absent from the Scientific Opinion**. While the phthalates in question have indeed been grouped as “exclusion group”, the logical consequence of a ban is not explicitly mentioned. Instead, the text states that “*The substances included in this group are suggested to be brought forward for risk assessment only if, following the implementation of risk management measures in accordance with the CSS, consumers may be exposed due to the use of the substance(s) in FCMs.*” Indeed, such an approach focused on **exposure, not hazard**, is not aligned with the CSS. Instead, the CSS points towards not using such substances at all, regardless of apparent consumer exposure or not, due to the need of achieving non-toxic material cycles.

Therefore, the Scientific Opinion needs to be aligned with the CSS in this aspect, and **clearly state a recommendation that these substances shall no longer be allowed to be used** in the manufacture of FCMs, and that their presence in FCMs as NIAS requires further investigation and enforcement.

Many thanks to EFSA for providing the opportunity to comment on this important Scientific Opinion.

With best regards,



Dr. Marie Muncke, Managing Director

References

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