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ETAD's Position on the proposed restriction of formaldehyde, dioxins, furans, PCBs and PAHs in single-use baby diapers

ETAD, the Ecological and toxicological association of dyes and organic pigments manufactures is a global association with a specific focus on the safety of colorants and its constant improvement.

In their recently published restriction proposal the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) expressed strong concerns about the presence of the hazardous substances formaldehyde, dioxins, furans, PCBs and PAHs in single-use baby diapers and the potential related health risks to consumers. As a result of a corresponding evaluation, ANSES suggested restriction as the appropriate action to address the problem.

Against this background, ETAD would like to state and explains its concerns over the proposed restrictions.

Parts of the outside of diapers are typically colored with organic pigments: they not only serve the purpose of a colorful design but also ensure certain technical functions (e.g., proper fitting and tape placement) as well as the identification of a lot number for quality control measures.

Organic pigments may contain some of the substances addressed by the proposal as unwanted contaminants (non-intentionally added substances or NIAS). Over the years, to ensure the safety of products used in this application, **ETAD members companies have carried out regular testing of their pigments placed on the market**, in compliance with EU and global regulations as well as the corresponding REACH requirements. Therefore, organic pigments are considered safe for this purpose.

As regards the specific safety assessment carried out by the proposal submitters, we share the comments provided by the association EDANA and by the Swedish competent authorities: the risk identification in the dossier was highly overestimated, which led to unrealistically low concentration limits for the substances in the scope of this restriction proposal. Therefore, to reduce the limits to such a low value is **overly ambitious and is lacking scientifically sound background**. According to available data, no indication of any adverse effects can be attributed to baby diapers and the suggested limits are not considered necessary from a safety point of view.

In fact, the proposed limits are at natural or anthropogenic background levels. Even with the best available manufacturing technology and selected raw materials such low limits would be impossible to achieve. Additionally, at the moment, there is **no validated analytical method** available to check these low limit values, which are far below nowadays possible limit of quantification (LOQ). It has also to be noticed that, even if such methods existed, their implementation to check possible compliance with the proposed limits would only cause additional costs for the supply chain with no additional benefits.

For all above-mentioned reasons, it will be **impossible for the industry to comply with these restrictions**; this would have a huge impact on the market and cause severe business disruption, without actually enhancing the safety of the final products.