European Crop Protection

POSITION PAPER
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ECPA position on Reg 1107-2009 Annex III impurity limits for PPP

ECPA Position Paper on the proposed Regulation 1107/2009 Annex III impurity limit in PPPs
The 0.01% limit for unintentional impurities contained in the draft Reg 1107/2009 Annex III proposal is a more problematic element of the text than currently seems to be generally recognised, and it needs to be reconsidered. The proposed limit is 10x lower than the comparable limit for impurities established and implemented through REACH and CLP Regulations, no justification for the approach has so far been provided, and it is expected to cause significant and unjustified implementation difficulties together with high compliance costs.

Key comments

- Regulation (EU) 1107/2009 clearly states that a co-formulant (substance or preparation) cannot be **intentionally used** where it is listed in Annex III and is thus the primary regulatory control mechanism, **irrespective of the final concentration**.
- The "unintentional impurity limit" for finished formulations is needed solely as an aid to regulatory compliance, analytical enforcement activities and recognising real-world products **may** contain listed impurities.
- Most of the substances listed in the draft Annex III are not expected to be found as impurities in co-formulants. However, some entries are naturally occurring substances, which could arise in complex or naturally derived co-formulants. A **proportionate** threshold is required for these substances.
- **REACH and CLP already set the default concentration of 0.1%** for identification and hazard communication of substances of very high concern found in **any product** placed on the market in Europe, **including plant protection products**. Because both these regulations also cover co-formulants, the **0.1% threshold** should be respected as a proportionate and fit-for-purpose threshold that is already fully established.
- An impact assessment is requested to evaluate the uncertainties and costs introduced by the proposed 0.01% unintentional impurity limit.

Additional background information

Substances used as co-formulants in plant protection products are general chemicals which are already fully subject to the provisions of the REACH and CLP legislation, and are also used in many other sectors such as cosmetics, household cleaners, industrial products, paints, etc. It is important to recall that co-formulants are used primarily to improve the function of plant protection products. Unlike active substances, they are not deliberately engineered to be biologically active.
Regulation 1107/2009, Article 29(1)c clearly states that a plant protection product **shall only be authorised where** "… its **co-formulants are not included in Annex III**". Furthermore, co-formulants are defined by Article 2(3)h as "substances or preparations which are **used or intended to be used** in a plant protection product…". It therefore follows that a co-formulant (substance or preparation) **cannot be <u>intentionally</u> used at any concentration**, where it is listed in Annex III.

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As a result, the function of the proposed limit for unintentional impurities of 0.01% in finished formulations must not be misinterpreted. Such **a limit is essential to serve as a *de minimis* to provide legal certainty for regulatory compliance**, in particular for comparison with analytical results from enforcement activities. **REACH and CLP already set a default *de minimis* of 0.1%** for the identification and hazard communication of substances of very high concern, which applies to any product placed on the market in Europe, including plant protection products. Both these regulations are already fully applicable to co-formulants and finished plant protection products, are already legally in force, and are already used to identify such impurities down to 0.1% on safety data sheets, including for finished formulations.

The proposed arbitrary limit of 0.01% for Annex III listed substances found as impurities in a finished plant protection product is 10x lower than the current legal limit. There is no scientific or legal basis, or imperative for selecting a value lower than the 0.1% limit currently used as a *de minimis* for classification and labelling. However, such a change will cause significant disruption to the entire co-formulant supply chain, as suppliers to the agrochemical sector will be required to carry out new chemical analysis, with no benefit to safety.

Most of the substances listed in the draft Annex III are not expected to be found as impurities in co-formulants. However, a few entries are naturally occurring substances, or may arise from manufacturing processes, particularly those substances which are complex (containing many component substances). If co-formulants are used at concentrations greater than 10% in a finished formulation, the proposed 0.01% impurity limit effectively represents a lowering of the default 0.1% *de minimis* which is used by all other chemical sectors. No assessment has been made as to whether such a lower limit is technically or economically feasible. Such an approach may lead to the loss of these co-formulants to the agrochemical sector, potentially triggering needless reformulations and additional resource demands for both companies and Member States for no safety benefit.

Impact Assessment required

An impact assessment is requested to assess whether the 0.01% limit on impurities in the draft Regulation is proportionate for both industry and Member State authorities.