European Crop Protection

POSITION PAPER
05/10/2020 – POS/20/SR/33078

ECPA comments on future development of Reg 1107 Annex III coformulants approach

ECPA key considerations in relation to development of new regulation/guidance for future additions to Annex III are as follows:

- A transparent and consistent process for the identification of unacceptable co-formulants for future addition to Annex III is required. If hazard-based cut-off criteria are used for identification purposes, it is **essential that only harmonized classifications are used** which have been agreed by the **relevant competent authority** and have been adopted at the European level, i.e. via ECHA and the CLH process. **This appears to be aligned with the principles identified for the European strategy for sustainable chemicals, and one substance-one assessment.**
- An **adequate transition period for reformulation** of any impacted formulations must be provided, acknowledging that using hazard-based cut-off criteria does not equate to a risk with using these co-formulants – therefore there may be no urgency for cessation of use. The transition proposed for the initial population of Annex III is inadequate for reformulation, and therefore **must be longer than 2 years in future**, in particular in responding to the case of any "new" harmonized classifications that may arise.
- For the consistent interpretation of Annex III, ECPA is supportive of setting a **de minimis level for impurities in finished formulations**. These should be consistent with the cut-offs specified in the REACH and CLP legislation. In general for these hazard classes, it is therefore understood that this limit should be set at the CLP generic concentration limit (GCL) of 0.1% w/w (see REACH, Annex II, 3.2), except for cases where a substance has a specific concentration limit (SCL) defined in CLP Annex VI. This approach is aligned with **established declaration limits in European and international supply chains** through GHS.
- SCLs are sometimes set for hazard classes other than the carcinogenicity, mutagenicity, and reprotox classes identified in the preamble to the proposed Annex III, and therefore not all SCLs are relevant.
- It is understood that Regulation (EC) 1107/2009 **Article 27 prevents the intentional use of any substance listed in Annex III** as a co-formulant by a formulator, irrespective of the concentration. This is because an impurity is not a co-formulant. As a result, the 0.1% w/w (or SCL, etc) impurity limit in the finished product serves only as a practical limit, for analytical and enforcement purposes, for any impurities that may be present in those co-formulants (i.e. unintentionally present).
- Substances which may be listed in Annex III and which are specified as an impurity in an approved active substance technical specification are not co-formulants, and should not be considered subject to Article 27 (e.g. residual solvents from chemical synthesis).

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