

## Position Paper on Co-formulants unacceptable for use in PPPs – Regulation 1107/2009, Annex III

### *Background on the Regulation of Co-formulants:*

Substances used as co-formulants in plant protection products are general chemicals which are already 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 ingredients, they are not deliberately engineered to be biologically active. In order to avoid a possible parallel but separate assessment of these same substances under Regulation (EU) 1107/2009, ECPA's preferred approach is that the provisions of REACH and CLP should be utilised as the basis for populating Regulation (EU) 1107/2009 Annex III, and should also serve as a basis for any future additions or changes to the Annex III list.

In practice this means that ECPA is supportive of substances being listed in Annex III if the European Chemicals Agency (ECHA) has already formally concluded that a substance is a Carcinogen, Mutagen, Reprotoxic (CMR) Cat 1A or B, Persistent/Bioaccumulative/Toxic (PBT) or very Persistent/very Bioaccumulative (vPvB), or Endocrine disruptor (ED). REACH and CLP already have the established processes to generate data, share costs, avoid unnecessary animal testing, evaluate registrations, and if necessary restrict or ban particularly hazardous substances in an efficient manner for both industry and plant protection authorities.

**Key comments** on the draft Commission Regulation amending Annex III to Regulation (EC) 1107/2009 listing co-formulants which are not accepted for inclusion in plant protection products:

- ECPA welcomes the fact that the Commission has broadly used the existing chemical legislation frameworks of REACH and CLP to populate Reg 1107/2009 Annex III.
- ECPA welcomes the fact that the Commission has acknowledged the need for a substance-based regulation and the critical use of identifiers such as CAS numbers, EC / List numbers and IUPAC names to correctly identify substances.
- However, ECPA wishes to emphasize the critical importance that the relevant cut-off concentrations for those substances listed in Annex III also be based on the REACH / CLP regulatory cut-off concentrations of 0.1 % w/w in the final mixture (see also additional points made below).
- As a pragmatic approach consistent with the objectives of REACH, co-formulants with CMR category 1A or 1B, PBT, vPvB or ED can be considered undesirable as co-formulant substances.
- **The limit of 0.01% for Annex III listed co-formulants found as impurities in a finished plant protection product is 10x too low**, and should be the same as the cut-off used for classification under CLP: <0.1% w/w. There is no scientific or legal basis for selecting a value lower than that which is used for classification and reporting on safety data sheets. Significant business disruption and cost will be caused in the co-formulant chemical supply chain, with no benefit to safety.

- ECPA would like to highlight that a two year transition period and a grace period of maximum one year is insufficient to find alternative co-formulants, develop a product, generate new data and register it. **This is especially true for substances which do not have a harmonized classification.**
- An impact assessment is requested to assess whether the draft Regulation is proportionate for both industry and Member State authorities, focusing on the following elements:
  - The impact of the arbitrary 0.01% limit on impurities in the final formulation on the co-formulant supply chain.
  - The loss and feasibility of replacing existing commercial products containing substances with no previous harmonized classification (e.g. crystalline silica) within two years.
- Several natural minerals have been listed if they contain crystalline silica (beach sand) as an impurity >0.1% with a particle size <50 µm. These are: kaolin, quartz sand, and diatomaceous earth (kieselguhr). Since crystalline silica has no harmonized classification it should be removed from the Annex III list of unacceptable co-formulants, or at least the unacceptable limits for the three quartz polymorphs need to be changed to ≥1% with <10 µm particle size.
  - The European Commission has recently introduced a binding and strict Occupational Exposure Limit (OEL) of 0.1mg/m<sup>3</sup> making additional regulatory action for the protection of workers unnecessary (Directive (EU) 2017/2398).
  - Crystalline silica does not have a harmonised classification in Europe for any of the criteria given in the draft legislation, and therefore an impurity should in any case not trigger listing in Annex III.
  - The recommended limit used for the non-classification of substances containing respirable crystalline silica impurities is <1% with <10 µm particle size. The recent 14th ATP to Regulation 1272/2008 uses “aerodynamic diameter equal to or below 10 µm” to define a respirable particle size. For consistency across EU legislation, the same definition of respirable particle should be used.
  - The health effects observed for crystalline silica exposure arise through prolonged (chronic) inhalation exposure to high concentrations. These conditions are unlikely to arise through intermittent application of plant protection products, where minimisation of operator inhalation exposure to active ingredients through risk management measures is also an objective, and chronic daily exposure to the same product is unlikely.
  - Because these minerals are of natural origin the crystalline silica is also of natural origin and cannot be removed from them. As a result, we do not believe that co-formulant suppliers can meet these needlessly tightened specifications, and the result would be potentially hundreds of needless reformulations.
- The data quality in the list raises some concerns, as there seem to be quite a number of errors which require correction or clarification. For example, attapulgit is listed although it has no harmonized classification, is incorrectly labelled as Carc. Cat 1B instead of Carc. Cat 2, and is missing the critical fiber specification >5µm present in a Member State list.
- ECPA remains willing to continue to work with the Commission to further develop the relevant REACH and CLP based criteria.