

Joint letter to

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Head of Unit: Chemicals and Plastics Industries (DDG1 - D.2) - European Commission DG GROW

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Object: EU Fertilising Products Regulation (2019/1009):

Need for clear and workable solutions, coherent with REACH, for additives, processing agents, unreacted ingredients and polymers

Our organisations (signatories below) welcome and thank the European Commission for the work already engaged by DG GROW to complete, adapt and prepare implementation the new EU Fertilising Products Regulation: STRUBIAS, Labelling Guidance, FAQ, first JRC report on By-Products, divers amendment proposals, etc.

We wish to **jointly underline the following points which concern all of our industries**, in addition to the specific questions raised elsewhere by each of our organisations for our sectors:

- **Technical additives:** we underline the significant problems posed by the current texts of Annex II (CMCs) as regards additives used in fertilising products for purposes other than nutrient content/control or effects on soil or plants.

Such additives are widely used in many fertilising products and are essential for preparation, storage and stabilisation, safe handling, placing on the market and efficient use of fertilising products. A non-exhaustive list of such additives can be found in REACH Annex V points 4(a) and 4(b).

- Additives which are a mixture of a number of “virgin” substances:

In many cases, additives are supplied by companies as a formulation for a given purpose (e.g. “granulation aid”) and this company will not disclose the substances used (because the recipe is their know-how and added-value). If all of these substances are “Virgin material substances” then this formulation can itself be CMC1, subject to all of the substances in this formulation being REACH Registered as specified in CMC1 §2. In this case, we are not clear how is implemented Conformity Assessment Module A §2.2(b) which requires the fertiliser manufacturer to provide “a list of component materials used ... and information about their origin or manufacturing process”.

- Additives which are a mixture of “virgin” substances and “by-products”

In this case, the above formulation would (as we understand CMC11) have to be considered as several different CMCs mixed together: one being a mixture of “virgin” substances, and one additional CMC for each by-product.

- Blending:

The introduction of additives during blending is not anticipated in PFC7, so any additives used in blending (e.g. to facilitate mixing, handling, storage) would have to be themselves validated as an EU fertilising product (PFC, CMC, labelling and conformity criteria).

- **REACH requirements:** it was already underlined in the Joint Letter signed by fourteen industry and stakeholder organisations on 20th November 2017 that the ‘additional’ REACH requirements in Annex II pose difficulties: data requirements for 10-100 tonnes band (annexes VI, VII, VIII) and a Chemical Safety Report “*covering the use as a fertilising product*”. These difficulties are particularly problematic for technical additives (**the intended use is not fertilising** but processing or handling ...). To address this, we propose to **modify the REACH registration requirement** from “*as a fertilising product*” to “*in a fertilising product*”
- **Impurities:** a fertilising product may contain detectable traces of unreacted ingredients or processing agents (e.g. solvents used to extract a substance), not intended to be present in the final product but inevitably present at very low levels in industrial production. REACH specifies in art. 3(1) “*substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used ...*”. The REACH ECHA “Guidance for identification and naming of substances under REACH and CLP” specifies how to deal with such unintended constituents. This needs to be similarly clarified for the FPR, for CMCs subject to the FPR REACH registration requirement, and for CMCs which are not subject to this requirement. This should be coherent with the definition of “impurities” in the FPR Labelling Guidance.
- **Additives which to some extent react with the substrate.** Points 1 to 4 of REACH Annex V exempt from REACH regulation the following:

1 – Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors ... ;

2 – Substances which result from a chemical reaction that occurs incidental to storage of another substance ...

4 - Substances which ... result from a chemical reaction that occurs when ... a substance ... functions as intended.”

However, REACH Annex V points 1 to 4 are NOT included in the exemptions from the FPR REACH registration requirements (CMC1 point 2 and elsewhere). It needs to be clarified that additives which react with the principal CMC substrate to perform their function are treated under the FPR in a comparable way to under REACH.

- **Polymers, other than those for nutrient and release-control:** polymers used for other purposes are currently excluded from CMC1 and CMC11 (by-products). Plant-derived polymers are excluded from CMC2, unless extracted from plant material by mechanical processing only. This excludes the use of polymers as additives, or their presence at trace levels, even for water-soluble polymers.

We understand that this issue is likely to be partially addressed in the near future through an amendment that will allow the use of polymers as long as they respect the criteria of the proposed REACH microplastics restriction currently under development by ECHA.

To address the general problem of additives, we suggest to

- 1) **clarify* that substances present at trace levels do not need to be identified** if they respect specific safety conditions**, which could be specified as follows:

- technical additives, processing agents, unreacted ingredients, polymers only
- present below a certain specified % concentration in the CMC (% to be defined)
- must be REACH registered (normal requirements) or exempted from such registration
- must not result in the CMC being classified with hazard phrases relevant for chronic environmental or health risks***.

The assurance of these criteria could be provided by the upstream supplier and/or the fertiliser producer, without the full list of such trace additives. Such a measure would be commensurate with the treatment of co-formulants under the plant protection regulation, where such coformulants are subject to normal REACH registration.

- 2) **clarify, in Annex IV (Conformity Assessment)** that conformity to CMC criteria and to REACH registration requirements can be provided by documentation from the upstream supplier, without the full list of chemical substances.

This should enable flexibility, that is modification of the formulation of an additive by the upstream supplier, or changing to a different supplier for a similar additive, should not result in the need for a new conformity assessment.

If not addressed, these problems will be a significant obstacle to CE-labelling of many fertilising products because a wide range of specialist additives are necessary for production, processing, storage and application.

List of and contacts for signatory organisations below:

* We would suggest that the European Commission use the delegated powers of art. 42 to add to this clarification to the introductory paragraphs of Annex II (after "...applicable requirements of that Annex").

** Additives and trace substances respecting these criteria would not need to meet CMC requirements and would not affect the Conformity Module applicable.

*** This could be based on the list of Hazard Phrases relevant for chronic environmental or health risks in some EU Ecolabel criteria <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009D0300> - H340 (mutagen 1B), H350 - H351 (carcinogen 1A or 2), H400 – 413 (acute or chronic aquatic toxicity), H 360 – 361 (reprotoxicity 1 or 2)

Signatories:

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