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Chemicals and Consumer Industries
Chemicals and Plastics Industries

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GROW.D.2/TN

Mr Chris Thornton
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Dear Mr Thornton,

Thank you for your email of 16 November related to EU fertilising products under Regulation (EU) 2019/1009 (hereinafter 'FPR'), and apologies for the time it took us to coordinate the reply between the experts on REACH and FPR respectively.

Several important technical issues related to the compliance of EU fertilising products are discussed in the accompanying position paper you submitted to us. In the Annex to this letter, you will find our replies addressing the specific topics and questions raised.

As you will see in the Annex, there are a number of issues for which we agree with you that clarification in guidance is warranted. We intend to include them in our next edition of the FAQ document for fertilising products, which we intend to present in the next meeting of the Commission expert group on fertilising products provisionally scheduled for March. Many of your concerns have never been raised to us before, and therefore never been discussed in the expert group. Therefore, the opinions in the Annex merely represent the current views of the Commission services (DGs GROW and ENV) responsible for FPR and REACH, and might change once we have had that discussion.

Yours sincerely,

ANNEX

1. RESPONSE TO YOUR CONCERNS

1.1. Technical additives

1.1.1. Additives as a mixture of several "virgin" substances

We understand that according to common industrial practice, several mixtures used in the production of fertilising products may actually be produced by operators other than the manufacturer of a fertilising product. Specifically in the case of what the industry refers to as "additives", several mixtures are supplied ready made by operators not involved in the subsequent production of the fertilising products.

Given that the substances constituting such mixtures are "virgin material substances", the mixtures could be covered by Component Material Category 1 (CMC 1) of Annex II to the FPR if the substances are REACH registered as specified in the relevant provisions of point 2 of CMC 1.

We understand that you are concerned about the difficulties in obtaining information from suppliers on the substances used in such mixtures. In our view, for the purpose of complying with point 2.2(b) in Module A in Part II of Annex IV to FPR, the manufacturer that uses such mixtures in the production of an EU fertilising product should have in his or her possession at least the information which he or she will have by virtue of REACH.

Article 31 of REACH requires suppliers of substances or mixtures to provide the recipients with a safety data sheet, where the substance or the mixture meets the criteria for classification under Regulation 1272/2008 (CLP), the substance is a PBT[1] or vPvB[2], or included in the candidate list established in accordance with Article 59(1) of REACH. The safety data sheet must contain the product identifier as per Article 18 of CLP and, in the case of mixtures, the product identifiers, the concentration or concentration ranges and the classifications for at least all substances meeting the conditions of point 3.2.1 or 3.2.2 of Annex II to REACH.

Furthermore, the supplier should provide a description of the origin and the manufacturing process of the mixture which at least allows the fertilising product manufacturer to guarantee that the criteria of CMC 1 are met (*e.g.* that all substances in the mixture are registered as provided for by point 2 of CMC 1, and that none of them is waste or any of the other types of material listed in (a)-(h) of point 1 of CMC 1). Since it is ultimately the fertilising product manufacturer who is responsible for the product's conformity with FPR, it is advisable for him or her to include a contractual liability for the accuracy of that guarantee, as well as a commitment by the supplier to collaborate with competent national authorities upon reasoned request (mirroring his or her own duty in Article 6(9) of FPR), in the supply contract. In our view, it should be feasible for the fertilising product manufacturer to find a supplier who is prepared to provide him or her with such a guarantee in return for the business opportunity.

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1 Persistent, bioaccumulative and toxic

2 Very persistent and very bioaccumulative

We thank you for having pointed this issue out to us, and we intend to clarify our interpretation of FPR in this respect this in guidance.

1.1.2. Additives as a mixture of "virgin" substances and "by-products"

We share your understanding that, in this case, the substances constituting "virgin substances" could be grouped in a mixture covered by CMC 1, and the by-products would each be separately covered by CMC 11. In our understanding, it is feasible to comply with FPR in this respect.

1.1.3. Blending using additives:

As the FPR stands, indeed a fertilising product blend is composed only of EU fertilising products, without any other substances, additives included, and the blender can only include components that have themselves undergone the conformity assessment for a fertilising product. Alternatively, the blender could take on the manufacturer's responsibility for the full conformity assessment of all the components of the final fertilising product, and treat the additive as a CMC in that conformity assessment. We do not see any reason why this would not be feasible.

1.2. REACH requirements

The FPR provisions for certain component materials require substances incorporated into an EU fertilising product to be REACH registered with the information provided for by Annexes VI, VII, VIII to REACH and with a Chemical Safety Report covering the use as a fertilising product. We take note of your remark that these technical additives are used *in* fertilising products and that the intended use is not fertilising, but processing or handling.

However, taking into consideration recitals 26 and 27 in FPR, it is clear that the intention of the legislator was to impose REACH registration of chemical substances in fertilising products (*e.g.* technical additives) not only covering the uses processing or handling, but also covering use on arable soil or crops, since that would correspond with the actual exposures to those additives. The main purpose of this requirement of the FPR is to ensure that, when assessing the safety of the said substances or mixtures, the fact that they would end up in direct contact with soil or crops as components of fertilising products is to be assessed. In our view, it should be feasible for the fertilising product manufacturer to find a supplier who is prepared to ensure – under contractual liability – that these REACH registrations have been made, and to commit to collaborating with competent national authorities following a reasoned request, in return for the business opportunity.

It can be discussed whether this objective is best expressed by "in" fertilising products or "as" fertilising products. But since the legislator opted for "as", and since this is in our view not more confusing than "in", we intend to maintain the current text and clarify the intention in guidance.

1.3. Impurities in materials

Having in mind the common industrial practices, it is evident that the materials present in the final composition of a fertilising product cannot be 100% pure. Thus, irrespectively

of the actual industrial process followed, a fertilising product is expected to contain detectable traces of impurities.

Impurities should *not* be considered as substances on their own, but should be dealt with in the context of the relevant substance they are part of and its REACH registration.

As regards the materials that are not chemical substances, and therefore not required to be registered under REACH, and since the FPR does not include any provision on the permitted concentration of impurities, it is under the responsibility of the manufacturer of the EU fertilising product to ensure that the limit values laid down in Annex I and, as the case may be, Annex II are not exceeded.

It should therefore be feasible for manufacturers of fertilising products to comply with the existing requirements of FPR with regard to impurities in substances and other component materials.

We can agree with your request to include this clarification in guidance.

1.4. Additives which to some extent react with the substrate

The omission in FPR of points 1 to 4 of REACH Annex V is intentional:

Points 1-3 of Annex V to REACH are not pertinent for additives falling within the scope of *e.g.* CMC 1. That is because, in such a case, CMC 1 only applies to the *additive as such*, whereas points 1-3 apply to *metabolites* of the additive. Should *the additive* which is subject to CMC 1 subsequently be reacted into a metabolite because of exposure to one of the environmental factors mentioned in point 1, because of storage of the additive or of the fertilising product containing the additive as mentioned in point 2, or in connection with the end use of the fertilising product, *the metabolite* as such would not be covered by the extended REACH registration requirement imposed by point 2 of CMC 1. In our view, it is therefore feasible to comply with FPR in this respect. We can agree with your request to clarify this in guidance.

Point 4 is also not pertinent for additives falling within the scope of e.g. CMC 1 and reacting with a substrate. That is because point 4 only applies to substances which are not themselves placed on the market. FPR, by contrast, only applies to fertilising products that are placed on the market. If an additive reacts with a substrate and forms a new substance in a fertilising product which is subsequently placed on the market pursuant to FPR, that newly formed substance is placed on the market in the fertilising product. As explained in recital 26 of FPR, it is the substance actually formed and contained in the fertilising product that is considered as a component material and must comply with the requirements of CMC 1, including the extended REACH registration requirements of point 2. That is because the REACH registration based safety requirements for chemical substances as component materials in Annex II to the FPR are designed under the assumption that the registration is made for a substance that will be found in the final product, and not for precursors of the substance that will be found in the final product.

With this in mind, whenever an additive reacts with a substance, the additive has to be considered, together with the said substance, as a precursors; in any event, by virtue of the REACH Regulation itself, it needs to be registered under REACH unless exempted or considered a constituent part of the *reacted* substance. The compliance with the requirements of CMC 1 is to be assessed for the final substances and it is for them to be registered in REACH, unless exempted under that Regulation and under point 2 of

CMC 1. We cannot see why it would not be feasible for manufacturers of fertilising products to comply with the existing provisions of FPR in this respect.

We would suggest *not* to include any wording on Point 4 of Annex V to REACH in any guidance on FPR, since it will simply never be pertinent, as substances contained in EU fertilising products will by definition always be placed on the market.

1.5. Polymers, other than those for nutrient and release-control

The issue related to polymers and their exclusion from the component material categories 1 and 11 of Annex II to the FPR has been discussed in the Commission Expert group on fertilising products. Taking into consideration the views of Member States and stakeholders and the ongoing work on a REACH restriction for microplastics (ECHA restriction on microplastics), we are currently working on a proposal to amend the FPR in order to allow the inclusion of several polymers under CMCs 1 and 11 depending on their nature.

2. YOUR SUGGESTIONS

2.1. Clarification for substances present at trace levels

You have suggested that the Commission should use its delegated powers to amend Annex II to FPR for certain substances. As far as we understand, what you suggest is to entirely exclude from all requirements of Annex II substances within the meaning of REACH (and FPR), which

- would qualify as "technical additives", "processing agents", "unreacted ingredients" or polymers;
- are present below a certain concentration (to be defined) in the mixture constituting a CMC under FPR;
- are either registered under REACH or exempted from REACH registration; and
- do not result in classification for any chronic risk under CLP of the mixture constituting a CMC under FPR.

We currently do not see the rationale for such an amendment of FPR. As explained above under section 1, we believe that it is feasible to comply with Annex II of FPR as it currently reads with regard to technical additives, with the foreseen amendment that will include certain polymers in the scope of CMCs 1 and 11.

We also consider that your 4 suggested conditions raise a number of questions and concerns:

- Condition 1 does not seem to contribute to protection of health or the environment at all, since the categorisation you suggest has nothing to do with hazardousness or risk.
- Condition 2 would add a contribution to protection of health or the environment in limiting exposure. The level of protection would depend on the percentage defined. It should be kept in mind, though, that hazardous substances can make

mixtures hazardous at very low concentrations. Furthermore, due to your suggested condition 4, condition 2 appears redundant for substances that are classified for chronic hazards, and therefore meaningful only for other substances.

- The exemption in condition 3 is in direct contrast to the objective expressed in recital 26 of FPR, since the fact that a substance is exempted from REACH registration – albeit sometimes a proxy for chemicals safety – is by no means a guarantee that the substance can be safely used in contact with the food chain, which is precisely why FPR introduces an extended REACH registration requirement in CMCs 1 and others.

- Condition 4 would add a meaningful contribution to protection of health or the environment. However, it is unclear why this would only apply to substances with chronic effects.

2.2. Clarification on documentation required for conformity assessment

As mentioned under point 1.1.1 above, we consider that a manufacturer that uses chemical substances or mixtures in the production of an EU fertilising product should have in his or her possession at least the information which he or she will have by virtue of the REACH Regulation (i.e. essentially the information in the safety data sheet if the substance or mixture used is hazardous).

Furthermore, he or she should have a description of the origin and the manufacturing process of the mixture which at least allows him or her to guarantee that the criteria of CMC 1 are met (*e.g.* that all substances in the mixture are registered as provided for by point 2 of CMC 1, and that none of them is waste or any of the other types of material listed in (a)-(h) of point 1 of CMC 1). Since it is ultimately the manufacturer of the fertilising product who is responsible for the product's conformity with FPR, it is advisable for him or her to include a contractual liability for the accuracy of that guarantee, as well as a commitment to collaborate with market surveillance authorities upon reasoned request, in the supply contract.

We thank you for your suggestion to clarify this in guidance, and as mentioned above we intend to do so.

Joint letter to

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

16th November 2020

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)

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