European Biostimulants Industry Council

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POSITION PAPER

REACH [Regulation (EC)1907/2006] requirements in the FPR

Regulation (EU) 2019/1009 – the Fertilising Products Regulation (FPR) cross-references the REACH Regulation (EC)1907/2006 but imposes stricter requirements for substances produced in amounts less than 10 tonnes per year if they are used in EU Fertilising Products.

This position paper explains EBIC's concerns regarding these "REACH+" requirements, which have emerged as members have studied how to comply with the FPR requirements. We also note that some of the Commission's own answers to FAQs seem to contradict the REACH+ requirements, particularly with regard to points 1-4 of the REACH regulation.

These enhanced REACH+ requirements were imposed without an *a priori* impact assessment, neither how they would improve safety relative to the previous situation under Regulation (EC) 2003/2003 and under national rules (where fertilising products are subject to normal REACH requirements), nor with regard to the burden they would place on enterprises. Furthermore, many of the technical additives in question are already approved for use in food or feed, and the FPR makes no exceptions to the enhanced requirements for those substances, which would be logical to ensure food safety while respecting the Commission's own framework for Better Regulation which seeks to avoid imposing unnecessary administrative burdens.

According to EBIC's calculations, these requirements will be onerous in terms of both time and cost for manufacturers, with disproportionate effects on small companies and innovative substances that do not have a large market to offset the costs of data requirements. Furthermore, they will multiply requirements for animal testing. Yet, there is no evidence there will be any gain for health and safety.

The following points are developed in more detail below, with an explanation of why they are problematic and EBIC's proposed resolution:

1. Substances used in very small quantities (often co-formulants) are subject to excessively costly requirements, even when they are already allowed in food and feed
2. The Fertilising Product Regulation requires a chemical safety report in all cases (except for specifically mentioned exemptions), regardless of production tonnage and regardless of the hazard classification of the substance.
3. The FPR does not allow for substances in EU Fertilising Products to be exempted from REACH registration under point 4 of Annex V of Regulation (EC) 1907/2006, although it is likely that such substances could be found in final products incidental to the functioning of additives. Yet FAQ 8.1 seems to confirm the principle in point 4 of Annex V of Regulation (EC) 1907/2006. Similarly, FAQ 8.15 seems to confirm the principles in points 1-3 of Annex V of Regulation (EC) 1907/2006. It would provide more clarity and legal certainty to recognise these points of the REACH regulation rather then excluding them and them reintroducing the same principles through an FAQ document.
4. The REACH revision launched in early 2022 could be relevant for fertilising products, among others, with the risk that dossiers upgraded to meet the FPR's REACH+ requirements might have to be upgraded again in a short period of time, doubling costs unnecessarily.

Our solutions could be summarised as reinstating the respect of the tonnage bands (at least for substances that have already been approved for use in food or feed) as well as the exemptions in REACH Annex V, points 1-4.

Introduction

According to Annex II of the Fertilising Products Regulation (FPR) [Regulation (EU) 2019/1009], component materials falling into Component Material Categories (CMCs) 1, 6, and 11 and some additives mentioned in CMCs 3, 4, and 5 are subject to the "REACH+"[1] requirements in order to be eligible for inclusion in an EU Fertilising Product placed on the market under the FPR. The text below shows the text as it was recently amended:

> "*All substances incorporated into the EU fertilising product, on their own or in a mixture, except the polymers referred to in point 1(f), shall have been registered pursuant to Regulation (EC) No 1907/2006, with a dossier containing:*
>
> *(a) the information provided for by Annexes VI, VII and VIII to Regulation (EC) No 1907/2006, and*
>
> *(b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product,*
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> *unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by points 6, 7, 8, 9, or 10 (only for magnesia) of Annex V to that Regulation."*

As EBIC members have worked through how to comply with the requirements of the FPR, several concerns have emerged about whether these provisions are feasible or whether they will simply prove to be insurmountable obstacles that will force companies to place plant biostimulants and other fertilising products on the market under national rules where normal REACH requirements still apply.

We are particularly concerned with the disconnect between this text and the current review of REACH that is underway and ask that these requirements be reviewed to better align them with the revised REACH regulation and to acknowledge substances that have already been approved for use in food or feed for which the enhanced "REACH+" requirements are superfluous if the intent is to demonstrate safety for use in the food chain.

Background

The FPR imposes "enhanced" REACH requirements for many Component Material Categories (CMCs) used in products placed on the market under this regulation. The Commission cites the need to ensure the safety of the food chain to justify these additional requirements; however, no exemptions are made for substances already authorised for use in feed and/or food. Since the publication of the FPR legislative proposal in March 2016, EBIC has raised concerns that many of the consequences of these "REACH+" requirements are onerous without enhancing food or feed chain safety, discriminate against small and medium-sized companies, and in some cases are simply unworkable. Our concerns have been confirmed as members have attempted to put in place the necessary measures to comply with the FPR's requirements.

The Commission has not cited any case where the application of "normal" REACH requirements previously applied to fertilisers within the EU (whether placed on the market under Regulation (EC) 2003/2003 or national rules) has led to any deficiency in safety. Indeed, there was no impact assessment of these rules before they were put in place. **Given the disproportionate and**

[1] We use this term to indicate that while the requirements are based on the Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [Regulation (EC) No 1907/2006], the FPR imposes stricter requirements for substances produced in small quantities.

discriminatory effects of the FPR's REACH+ requirements, EBIC has argued that the FPR should respect the standard provisions of REACH unless a scientific case can be made to do otherwise. Now that the FPR has been applied, it is critical to monitor the conformity assessment process to identify situations where the enhanced REACH+ requirements are preventing conformity assessment, even though the products are demonstrated as safe.

In parallel to this monitoring, we urge the European Commission to review the "REACH+" requirements in the FPR in light of what is emerging from the revision of the REACH regulation itself. In some cases, the REACH revision confirms the choices made in the FPR but in others it is rejecting the very options retained in the FPR as unworkable. It is important to keep these two regulations aligned to ensure the smooth functioning of the Single Market and to avoid the creation of two divergent sets of REACH requirements.

The following points summarise the differences between the REACH+ requirements in the FPR and "normal" REACH requirements:

1. The data requirements for REACH registration are normally determined by the tonnage band of production, which implicitly includes a level of exposure and makes REACH provisions more equitable for small and medium-sized enterprises. Substances produced in quantities under 1 tonne are normally exempted from REACH registration. Substances produced in 1-10 tonnes are subject to the data requirements in Annex VII. Substances produced in 10-100 tonnes are also subject to the data requirements in Annex VIII. The data requirements in Annex IX are also added for substances produced in 100 tonnes.

   The current review of the REACH regulation is rethinking the data requirements somewhat, and we expect the new requirements for the 1-10t band to become more stringent.

2. A chemical safety report is normally only required by the REACH regulation for substances subject to registration and produced in quantities of 10 tonnes or more per year per registrant. Furthermore, the REACH regulation specifies cases where no chemical safety report is required even when this production threshold has been crossed, due to the low-risk nature of the substance.

3. The EU Fertilising Products Regulation does not acknowledge the REACH registration exemptions in Points 1-4 of Annex V of the REACH regulation. Point 4, in particular, is extremely relevant for our products.

In the sections below, we describe the specific issues that we have discovered as EBIC members have looked at the details of how to comply with the FPR.

Two cases exist for substances produced in quantities below 1 tonne used in fertilising products:

1. **Substances used in feed and food**. Substances that are used in food and feed are subject to stricter requirements that what is specified in the Component Material Categories of the FPR. Therefore, imposing additional REACH requirements for these substances to be used in Fertilising Products serves only to increase the administrative burden and costs for manufacturers without any demonstrable increase in public safety. This violates one of the main principles of the EU's Better Regulation Initiative. Furthermore, imposing these enhanced REACH requirements on substances already allowed in food and feed needlessly increases animal testing. It should be noted that due to the large amount of data submitted under the REACH regulation, the European Chemical Agency (ECHA) does not have the capacity to check all the data submitted; for the foreseeable future, it is only checking high-volume dossiers and prioritising substances known to be hazardous.

2. **Strategic substances used in small quantities and for which a registration request by the supplier would jeopardise the manufacturer's supply** due to unprofitability or refusal to reveal trade secrets. Even if the supplier refuses to share its test data with the downstream user, a mechanism (C&L Inventory) already exists to flag the dangerousness of substances as needed. As noted above, complementing a supplier's REACH registration with additional tests would require significant investments of time and human resources, while it is unlikely that the submissions would ever be controlled by ECHA. These requirements would significantly raise costs, which would have an impact on the competitiveness of EU Fertilising Products on international markets, since producers in other jurisdictions benefit from the low tonnage exemption for registration. It should be noted that national fertilising products will also continue to benefit from the low-tonnage exemption.

Requiring Chemical Safety Reports (CSR) and Exposure Scenarios for substances in Fertilising Products that are produced in quantities below 10t per year does not actually help ensure food chain safety

The main goal of tools such as CSR and exposure scenarios (in our case the PC12 for fertiliser) is not to safeguard the food chain but ensuring safe use for workers and the environment. These tools help establish the conditions for operating below the DNEL (worker) and PNEC (environmental) threshold values. These tools therefore will not improve food chain safety as claimed by the Commission, but the extra administrative burden and costs could put companies, especially SMES in difficulty. In addition, food safety is already ensured by compliance with many existing Regulations that the FPR recalls, such as Reg. 852/2004 on the hygiene of foodstuffs; Reg. 882/2004 on official controls performed to ensure the verification of compliance with feed and food law; Reg. No 1881/2006 setting maximum levels for certain contaminants in foodstuffs; Reg. 2017/625 on official controls and other official activities performed to ensure the application of food and feed law; Reg. 396/2005 on maximum residue levels of pesticides, and others.

We therefore suggest that the REACH+ requirements in the FPR be reviewed once the details of the REACH revision are known, especially with regard to the 1-10t band.

Imposing REACH+ at this time is out of step with the current review of REACH

The European Green Deal includes a chemical strategy for sustainability "to better protect people and the environment against hazardous chemicals and encourage innovation to develop safe and sustainable alternatives".

- In this context, the European Commission has launched a review of the rules governing the registration, evaluation, authorisation, and restriction of chemicals (REACH) in the EU.
- In January 2022, the European Commission opened a public consultation on its inception impact assessment for the options for the next revision of the REACH regulation. The European Biostimulant Industry Council (EBIC) submitted a response to the survey questionnaire published by the COM and submitted a supporting document on 11 April 2022. On Monday, 16 May 2022, the European Parliament's Committee on the Environment, Public Health, and Food Safety (ENVI) also held an exchange of views with the Commission and the European Chemicals Agency (ECHA). During this meeting and aligned with the EU Green Deal objectives the Commission announced that a legislative proposal for the REACH revision should be forthcoming in late 2022 or early 2023.

1. Co-formulants used in very small quantities are subject to excessively costly requirements, even when they are allowed in food and feed

The use of co-formulants to ensure technical quality (e.g. anti-caking or anti-foaming agents) are generally used in very small quantities. Under the FPR's : REACH+ requirements, these substances will be subject to onerous data requirements, even when they have already been approved for use in food and feed! This seems to contradict the Commission's argument that the REACH+ requirements are necessary to ensure food chain safety, especial since the Chemical Safety Report would not add any relevant safety information on substances compares to what EFSA already assessed for direct use in food.

In practice, substituting technical additives is very difficult, because performance varies a lot from one additive to another, and they have to be compatible with the product (e.g. specific pH, density, viscosity, etc.). It is even more complicated when products are certified for use in organic production (natural-origin technical additives) because the options are very limited.

Perversely, the REACH+ requirements could make economic considerations the primary criteria for selection and thus reduce the availability of safer co-formulants, more in line with the European society's desire for solutions that are perceived as more "natural". If the cost per unit is so high that manufacturers cannot possibly hope to recuperate their return on investment, they will not pursue that substance, no matter how attractive it may be from a technical or sustainability perspective. See the details below on the link between the proportionality of costs and innovation.

Suggested resolution:

Restore normal REACH requirements for technical additives used in EU Fertilising Products, at least when they are already approved for use in food or feed products.

2. The Fertilising Product Regulation requires a chemical safety report in all cases, regardless of production tonnage

Producing a Chemical Safety Report is costly in terms of time and money and imposes an unnecessary burden on substances of low concern that are produced and used in low quantities. Many of the technical additives used in fertilising products are also approved for food and feed. **The Commission has presented no scientific evidence why a co-formulant present in extremely small amounts would be problematic, especially additives that are already approved for use in the food or feed chains are not exempted from this new requirement, nor has it conducted an impact assessment of the additional costs imposed on industry.**

Suggested resolution:

Revert to normal REACH requirements regarding when a Chemical Safety Report is needed, **at least for substances are already approved for use in food or feed products**.

3. The REACH+ requirements in the FPR do not respect the tonnage bands defined in REACH to ensure costs proportionate to the likely exposure and to the size of the entreprise

The data requirements imposed by the FPR are so high that no manufacturer or importer of substances that are produced in quantities of less than 1 tonne per year would be able to cover the costs of REACH registration under these conditions, especially since low tonnages are exempted from such requirements in competing markets like the USA, so they will not have produced the data for other jurisdictions. Therefore, **such producers/importers will probably simply refuse to supply any**

company requiring proof of REACH registration to these levels, distorting the market and discriminating against SMEs. In addition to costs, the availability of alternate suppliers is also an issue. EBIC has recently submitted a list of substances to ECHA for which our members are currently having difficulties sourcing supplies, with a request to facilitate the REACH-registration of alternate suppliers from outside the EU to reduce supply chain scarcity.

This issue of disproportionate testing requirements is more likely to affect technical additives, which are contained in small quantities (as little as 10kg per 50t of final product) in final products (see the point above) than the primary functional components. However, even some primary (from a functional perspective) components are produced and used in small amounts because the application rates for plant biostimulants are generally extremely low compared to other crop inputs (e.g. 500g to <5kg per hectare).

Because the composition of technical additives is often a trade secret, it is unrealistic to think that manufacturers will be willing to disclose this data to their customers who would need it to upgrade the REACH registration themselves. Nor will such information necessarily be on the Safety Data Sheet according to Article 31 of Regulation (EC) 1907/2006, if the additive is a mixture and contains substances that are not hazardous. Indeed, in such a case, it would be impossible for the purchasing company to know at what level the undisclosed substances were REACH-registered, if at all.

Examples to illustrate the economic impacts of the REACH+ requirements

The following calculations were done in 2021 and do not take into general inflation and prices spikes of specific substances that have been witnessed in 2022.

- **Substance 1** (exempted from REACH registration according to the supplier because produced below 1t/year) is used by a company at about 150 Kg/year and incorporated below 0.5% in the end product. Substance 1 helps mineralisation for better plant growth. REACH registration for the 1-10t band plus a Chemical Safety Report would cost around 50K€ including ECHA's fee. If the additional cost is spread over 5 years, the raw material cost would increase by two and a half (2.5) times. Substance 1 already represents about 16% in the end product's final cost even though it is only around 0.5% of the volume/weight of the final product. If the cost of Substance 1 were to rise by 2.5 times, it would be 40% of the cost of the end product (again spread over five years), with important knock-on effects since the **customer price would have to be increased by 26%** to be offset only after five years. REACH registration in the 10-100t band would be even more expensive.

- **Substance 2** is a colorant that costs about 33 €/kg and is present in the final product at 0.01–0.05 % w/w. Substitution is difficult and may even be impossible because performance varies a lot from one additive to another. You need to find a technical additive compatible with the finished product formula at a specific pH, density, viscosity. Whatever works under the specific combination of pH, viscosity and density may not work if even one parameter is changed. Assuming REACH registration costs of 240K€ and production of 9999 kg/yr, REACH registration in the 10-100t band would **raise the price of the component by 48€/kg** if offset over five years, an increase of 146%.

- **Substance 3** is a synthetic amino acid used as an active component and present in the product at 0.04–3.5% w/w. Substitution would not be possible since any other amino acid produced in under 10 t/y would face the same situation. It is currently purchased for 2.63€/kg and REACH registered for the 1-10 t/y band. Upgrading the registration for requirements equivalent to the 10–100 t/y is estimated to cost 155K€. **Spread over 5 years, this would raise the cost per kg by 3€ or 117%,** assuming 9999 kg are produced.

- **Substance 4** is a UVCB substance present in the final product (at 0.2-5% w/w) as an additive. The substance is not currently REACH registered because <1 t/y is produced and used. Substitution is difficult and may even be impossible because performance varies a lot from one additive to another. You need to find a technical additive compatible with the finished product formula at a specific pH, density, viscosity. Whatever works under the specific combination of pH, viscosity and density may not work if even one parameter is changed. Registering the substance for requirements equivalent to the 10 – 100 t/y is estimated to cost 270K€. Spread over 5 years, this would raise the cost about 54€/kg (assuming a production of 9999.99 kg). The **current cost of the substance is 10€/kg, which would increase 540% under these conditions**.
- **Substance 5** is a UVCB substance present in the final product (at 0.2-5% w/w) as an additive. The substance is currently REACH registered for the 1-10 t/y band. Substitution is difficult and may even be impossible because performance varies a lot from one additive to another. You need to find a technical additive compatible with the finished product formula at a specific pH, density, viscosity. Whatever works under the specific combination of pH, viscosity and density may not work if even one parameter is changed. Upgrading the registration for requirements equivalent to the 10 – 100 t/y is estimated to cost 200K€. Spread over 5 years, this would raise the cost between 4€/kg and 40€/kg (depending on how close production is to one or ten tonnes). **The current cost of the substance is 10€/kg, which would increase by 40-400%** under these conditions.
- The practice of allowing companies to omit non-hazardous substances from the SDS of mixtures is common in the EU and other markets like Canada, USA, Australia, and Turkey and allows for the protection of competitive know-how where patenting is not an option.

Suggested resolution:

Reinstate the original REACH tonnage bands for substances that are either of low concern or not hazardous, while maintaining them for substances that are carcinogenic, mutagenic or toxic for reproduction (CMR) (which is already planned under the REACH revision). At a minimum, substances already considered safe enough and approved for use in food or feed chains should not be concerned by the REACH+ requirements in the FPR.

4. The FPR does not allow for substances in EU Fertilising Products to be exempted from REACH registration under point 4 of Annex V of Regulation (EC) 1907/2006.

The FPR does not allow for substances in EU Fertilising Products to be exempted from REACH registration under point 4 of Annex V of Regulation (EC) 1907/2006.

Point 4 of Annex V of Regulation (EC) 1907/2006 states that:

> "Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:
>
> (a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or
>
> (b) a substance solely intended to provide a specific physicochemical characteristic function as intended."

The Commission explained in a recent FAQ document that the FPR does not recognise Annex V, Point 4 because such substances are never placed on the market. However, there appear to be conflicting responses within the Commission FAQ on this point:

- Response 8.14A states that "an EU fertilising product cannot be 100% pure. Thus, irrespectively of the actual industrial process followed, component materials belonging to CMC 1 in a fertilising product are expected to contain detectable traces of impurities." The FAQ then goes on to quote the Guidance for identification and naming of substances under REACH and CLP (p.15), which defines an impurity as 'an unintended constituent present in a substance as manufactured. It may originate from the starting materials or be the result of secondary or incomplete reactions during the manufacture process. While it is present in the final substance it was not intentionally added'. We welcome this response. However, it seems contradictory to the fact that the FPR does not recognise the Annex V, point 4 REACH registration exemptions which deals with exactly the examples described in response 8.14A. Rather than providing this interpretation in an FAQ document with limited legal weight, wouldn't it be simpler to simple reinstate the respect of Reg (EC) 1907/2006, Annex V, point 4?

Reasons for concern:

The ECHA *Guidance for Annex V Exemptions from the obligation to register (version 1.1, 2012, p.3)* give further details on the application of this exemption:

"*In some cases the mode of action of a substance performing a specific function involves a chemical reaction. The aim is not to manufacture the substance which is thus formed, but for example to prevent an unwanted reaction [...] or to promote processes [...]. Therefore, provided that this reaction is not a deliberate manufacturing process of the substance(s) […],* ***they do not need to be registered*** *as the* ***risks of the substances generated will be assessed through the assessment of the precursors of the reaction****. […] The exemption* ***only applies to the substances generated when the substances listed in Annex V(4)(a) and (b) function as intended***"

For the formulation of both liquid and solid fertilising products, such substances, performing as additives, are often used and currently substances generated during their technical function are covered by the registration exemption laid down in REACH Annex V, point 4. The presence of the substance generated is never claimed in the commercial product as the reaction is not intentional, simply the unavoidable outcome of the technical function. A common example is the neturalisation of the pH of liquid products; the neutralisation may create new substances, but this is not considered an intended ingredient in the final substance. All the examples given in FAQ 8.10 are for solid products; there are significant differences in the manufacturing processes for liquid and solid products. Nonetheless, an example from the realm of solids is when ions link with other counter ions than was intended by the manufacturer. REACH considers this to be a mixture of ions rather than a new substance.

The omission of REACH Annex V, point 4 in FPR would lead to the creation of an analytical dataset for substances generated from the substance acting as additive and could require the development of analytical methods that do not currently exist. From a technical point of view, it will be difficult to isolate the newly formed substance(s). From an economical point of view, this will lead to an unmanageable amount of REACH registrations for formulators of fertilising products.

The Commission's justification for leaving this exemption out of the FPR cross-refence appears to be based on an erroneous interpretation. The substances covered by the REACH regulation are not finished products placed on the market, but substances produced during the manufacturing process, and therefore not placed on the market as such. These substances are derived from a mixture of precursor materials which are subject to REACH registration, just as the finished product is subject to

safety assessment in accordance with the CLP Regulation (1272/2008). The recommendations of the ECHA guidance specify that substances arising during the manufacturing process do not need to be registered but are assessed via the registration of the precursor elements to the reaction when the reaction works as intended.

A consistent interpretation of the provisions of point 4 of Annex V of the REACH regulation and the FPR would therefore exempt these secondary substances from registration. In order to guarantee their chemical safety, a DU CSR (Downstream User Chemical Safety Report) related to the use of the EU Fertilising Product could be considered, if not already existing.

Suggested resolution:

Reinstating point 4 of REACH Annex V is pertinent and **highly important for additives** within the scope of all CMCs that cross-reference REACH registration of FPR in order to cover substances generated when the additive functions as intended. It provides much more clarity to reinstate recognition of this point than to acknowledge exactly the same principle in the FAQ.

Similarly, there seems to be a contradiction between the fact that the FPR does not recognise the exemptions for Reg (EC) 1907/2006, Annex V, points 1-3 and the response given in FAQ 8.15, which notes that certain substances will evolve over time when exposed to air, soil, etc. and mentions this is often desirable. The rationale for this answer is that the "REACH Regulation exempts from the registration substances which result from a chemical reaction that occurs incidentally to exposure of another substance to environmental factors." But the part of the REACH regulation that says that is Annex V, point 1, which the FPR explicitly repudiates! If the Commission is going to recognise the content of Annex V, point 1 in the FAQ, could it not simply reinstate the exemption foreseen in the REACH regulation for the sake of clarity and legal certainty?

6. A revision to the REACH framework was launched in early2022 and is likely to be relevant for fertilising products

Because of the ongoing revision of Regulation (EC) 1907/2006, 2022 seems like a particularly ill-timed moment to impose requirements that are based on REACH but deviate from its requirements. If companies do the FPR tests now at elevated levels and then the revision changes the requirements, Companies may have to repeat tests twice within a short period.

There are also points that have been imposed in the FPR on the basis of what "might" be coming down the pipeline in the REACH revision, rather than simply cross-referencing REACH in such a way that such new requirements would automatically be applicable to Fertilising Products.

Suggested resolution:

Reinstate the original REACH requirements for substances that are either of low concern or nonhazardous, while maintaining REACH+ requirements for substances that are carcinogenic, mutagenic or toxic for reproduction (CMR), as already planned under the REACH revision. The existing REACH regime works well for fertilising products placed on the market under Regulation (EC) 2003/2003 and national regulations. It also ensures safety for items such as toys and paints, which may also lead to ingestion, especially by young children who may chew or suck on them (as demonstrated by concerns over these items containing lead).

At a minimum, substances already considered safe enough for use and approval in the food or feed chains should not be concerned by the REACH+ requirements. A total reversion to normal REACH requirements would be preferred, especially in the absence of an impact assessment demonstrating

that this change is scientifically justified and proportionate according to the principles of Better Regulation.

Conclusion

The EU Fertilising Product regulation is intended to modernise the placing of fertilising products on the market and to foster innovation within a Circular Economy mindset.

However, as demonstrated above, the REACH+ requirements in the Fertilising Products Regulation impose onerous and costly burdens on the industry particularly for substances being used in innovation ways (which is used test-marketed in small quantities before a full rollout. Furthermore, there does seem to have been an impact assessment demonstrating that any gains in public safety would result from imposing higher testing requirements on substances that are not classified as hazardous. Indeed, in the case of substances already approved for use in the food in feed chain, the REACH+ requirements would require additional costs to demonstrate a lower level of safety than has been demonstrated for use in the food and feed chains. The REACH+ requirements are therefore counter to the Commission's own principles of Better Regulation.

For more information about this topic, please contact Hélène Collignon at helene@prospero.ag

European Biostimulants Industry Council

The European Biostimulants Industry Council (EBIC) promotes the contribution of plant biostimulants to make agriculture more sustainable and resilient and in doing so promotes the growth and development of the European Biostimulant Industry. Our mission is to ensure biostimulant technologies are valued as integral to sustainable agriculture, while securing an enabling regulatory framework for all of them.