



15

# Innovation & safety of EU Fertilising Products: REACH & FPR

16 May 2023, 14:00 – 17:00 CEST

1



GdE

# Welcome



2

## Anti-Trust Reminder

Even though this meeting includes non-industry stakeholders, we would like to emphasise that we remain mindful of competition law and will end any discussions that are not fully compliant with anti-trust provisions.

3

3

## Housekeeping announcements

- We will automatically mute everyone's microphones.
- Because there are so many participants, we ask you to type questions in the chat rather than raising your hands.
- We will try to work as many questions as possible into the discussions, but we cannot guarantee that we will deal with every question.
- In order to encourage a free exchange of ideas and concerns, **we will NOT be recording the event.**
- We are now going to take some screen shots so we have some photos to illustrate reports about this event.
- **We ask everyone to turn off their camera when they are not speaking.**

4

4

## Program overview

GdE

14:00	Welcome
14:10	Commission presentation: "Setting the context for REACH+ requirements in the FPR: highlights from key COM policies" and Q&A
14:40	Case study 1: Tonnage bands and CSR: impact on low-volume and innovative substances
15:00	Case study 2: Substances approved for food and/or feed
15:20	Discussion
15:30	Comfort break
15:45	Impact of REACH+ on EBIC/Fertilizer Europe members - Results of consultations and our recent survey
16:05	Panel discussion: How to ensure the safety of fertilising products proportionately?
16:45	Closing remarks

5



5

## What do we mean when we talk about "REACH-plus/REACH+"?

GdE

REACH+ requirements in the Fertilising Products Regulation versus normal REACH requirements in Reg (EC) 1907/2006

Tonnage Band	Requirement	Annex VI (general info)	Annex VII	Annex VIII	Annex IX	Annex X
0-1t	CSR	Annex VI (general info)	Annex VII	Annex VIII	REACH+ requirements	
1-10t		Annex VI (general info)	Annex VII	Annex VIII		
10- 100t	CSR	Annex VI (general info)	Annex VII	Annex VIII		
100-1000t		Annex VI (general info)	Annex VII	Annex VIII	Annex IX	
>1000t		Annex VI (general info)	Annex VII	Annex VIII	Annex IX	Annex X

REACH+ in FPR does not recognize the registration exemption in Regulation (EC) 1907/2006, Annex V, point 4.

6



6



GdE

# Setting the context for REACH+ requirements in the FPR: highlights from key COM policies

**Theodora Nikolakopoulou**  
**DG-GROW, European Commission**

7

7

GdE  
HC

# Q&A



8



HC



## Tonnage bands and CSR: impact on low-volume and innovative substances

**Sara Tormo**  
**Rovensa Next (EBIC)**

9

9



HC



## Substances approved for food and/or feed

**Riccardo Mulato**  
**Yara (Fertilizers Europe)**

25

25



# Discussion

## Break

Meet back at 15:30  
(we are ahead of schedule)





TS

## Impact of REACH+ on members of EBIC and Fertilizers Europe



Gianluca Bini & Giuseppe D'Ercole  
(EBIC)

28

28

### Background on the survey we conducted

GB

- Members of EBIC and Fertilizers Europe were invited to respond to our anonymous, online survey.
- The time for the survey was relatively short (two weeks) limiting the number of responses. 18 responses were received, of which 10 reported being "large or very large". **Size does not appear to have been a factor in how much this issue affects companies. But the fact that few smaller companies replied** [only 4 reported being micro (2) or medium (2)] may indicate that smaller companies do not even have the resources to engage with the issue.
- No questions were mandatory because we did not want to create artificial obstacles to collecting data to illustrate the issues.
- We chose to focus the issue on technical additives because, unlike the main components of fertilising products which may be produced in-house, technical additives are almost always purchased from suppliers.

29

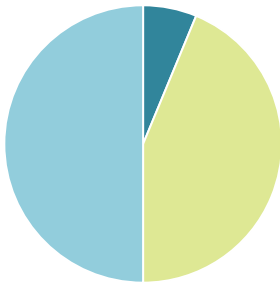


29

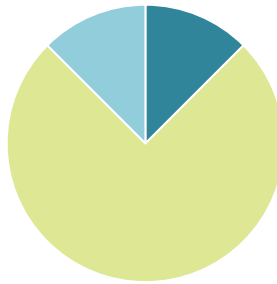
## Understanding the impact – the share of technical additives affected by the FPR's REACH+ provisions

Respondents were asked what share of their additives fall into one of the three categories below

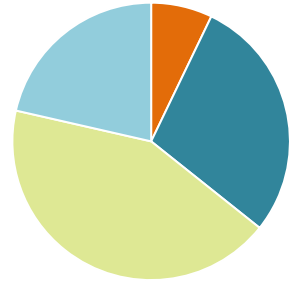
Produced <1t/yr



Produced 1-10t/yr



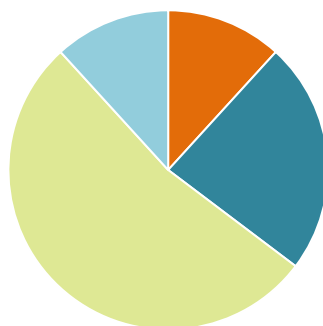
No CSR



■ All ■ Most ■ Some ■ None

## But a single additive can impact many different products in a company's portfolio

Respondents were asked how many technical additives are strategic and used in a wide range of products



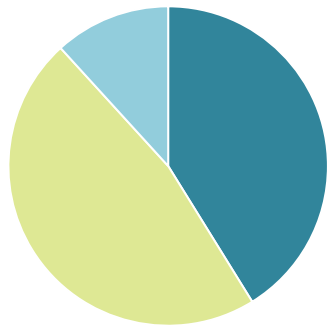
■ All ■ Most ■ Some ■ None



## Additives are often mixtures, which means that we don't know the exact composition, which is a trade secret

GB

Respondents were asked how what share of technical additives are mixtures with unknown formulas



■ All ■ Most ■ Some ■ None

32

**EBIC**  
European Biostimulants Industry Council

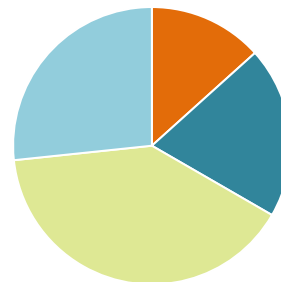
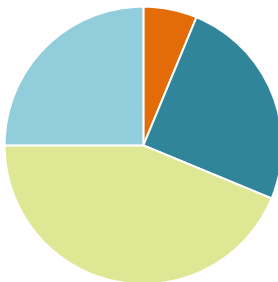
32

## For purchased additives we depend on the willingness of the supplier to provide critical, often confidential, information

GB

Supplier won't upgrade REACH

Supplier won't share formula or REACH data



■ All ■ Most ■ Some ■ None

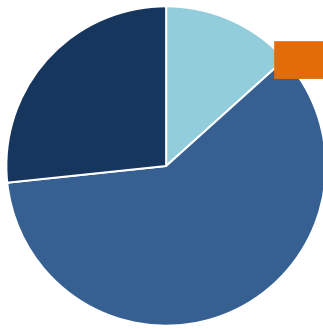
33

**EBIC**  
European Biostimulants Industry Council

33

## What share of your products will be reformulated to meet the FPR REACH+ requirements

Respondents were asked what share of their products would be reformulated to meet the REACH+ requirements



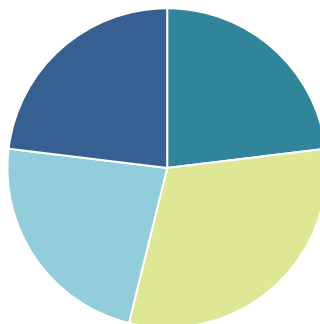
**More than 100 products were reported to be undergoing reformulation**

■ All ■ 76-99% ■ 51-75% ■ 26-50% ■ 25% or less ■ Zero

34

34

## What share of the reformulated products has been affected by one or more undesired impacts on quality or performance?



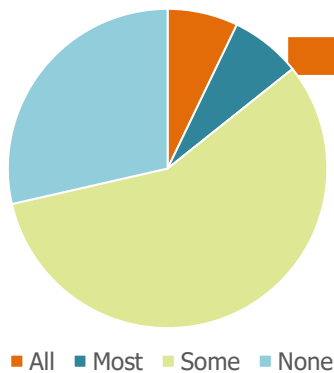
■ All ■ Most ■ Some ■ None ■ Does not apply to my company

35

35

## What share of your products will be registered/marketed under national rules to be able to follow normal REACH rules

We asked respondents to include products already on the market that will not be upgraded to become EU Fertilising Products



More than half of the respondents said that they would keep products under national rules because the REACH+ requirements are too onerous. One company said this is true for most of their products.

## Registering substances that have not been intentionally added

**The answer to question 8.4 in the Commission's FAQs related to Regulation (EU) 2019/1009 states that:**

"...The Fertilising Products Regulation requires in point 2 of CMC 1 that all substances are registered under REACH unless exempted by virtue of the last paragraph of point 2 of CMC 1. Even though, in accordance with the REACH Regulation, a substance has to be registered only when it is manufactured or imported above one tonne, that requirement of FPR applies for substances to be used in EU fertilising products even below one tonne. This is regardless to their concentration in the component material or the fertilising product. **This only applies to substances intentionally added**, as such or in a mixture, by the manufacturer of the fertilising product...."

## FAQ 8.4 seems to contradict the fact that the REACH+ requirements in the FPR do NOT recognize Annex V, point 4 of the REACH regulation

ANNEX V. EXEMPTIONS FROM THE OBLIGATION TO REGISTER...

4. **Substances which are not themselves manufactured, imported or placed on the market and which result** from a chemical reaction that occurs **when:**

- (a) a [technical additive]\* or quality control reagent functions as intended; or
- (b) a substance solely intended to provide a specific physicochemical characteristic **functions as intended.**

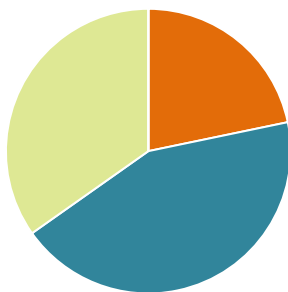


These substances are not intentionally added to the product

38 \* The original text specifies a long list of technical additives



38



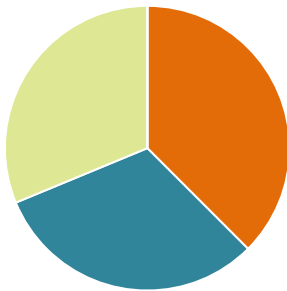
■ Strongly Agree   
 ■ Agree   
 ■ Neutral/DK  
■ Disagree   
 ■ Strongly disagree

The non-recognition of the Annex V, point 4 exemption seems to be contradicted by FAQ 8.4, which states that the REACH+ registration requirement in the FPR “only applies to substances intentionally added.” However, the FAQ has no legal value, whereas a recognition of Annex V, point 4 of Reg (EC) 1907/2006 would have legal value.



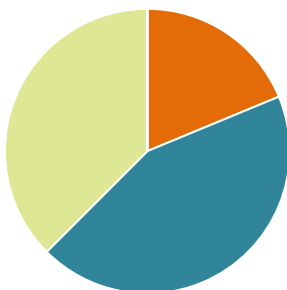
39

39



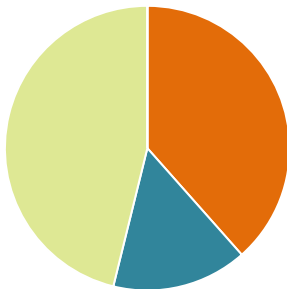
■ Strongly Agree    ■ Agree    ■ Neutral/DK  
■ Disagree    ■ Strongly disagree

Because we do not know the exact (confidential) composition of the technical additives we purchase, which are often mixtures of several substances, we cannot predict the unintended substances that might be produced when we formulate our products.



■ Strongly Agree    ■ Agree    ■ Neutral/DK  
■ Disagree    ■ Strongly disagree

There are no analytical methods to detect all of the unintended substances that might be produced as the result of using a complex technical additive.



■ Strongly Agree    ■ Agree    ■ Neutral/DK  
■ Disagree    ■ Strongly disagree

Since the Annex V, point 4 exemption was removed from the FPR without any lower threshold that would trigger registration, we would have to REACH register any presence of these unintended substances above the Limit of Detection, even if it is present in infinitesimal amounts.

## Conclusions from the EBIC/Fertilizers survey

- The REACH+ requirements in the Fertilising Products Regulation have **implications for many fertilising products** and many manufacturers.
- Even with goodwill, it is **unfeasible** for manufacturers **to upgrade REACH dossiers** for technical additives where suppliers protect trade secrets such as formulation or the original REACH data.
- These requirements could have the unintended consequences of **diverting innovative products to the most interesting national markets** (potentially leaving farmers in smaller markets without access)
- The REACH+ requirements could also have the unintended consequence of **reducing the quality of EU Fertilising Products** by encouraging the use of older technical additives (that have already met the critical mass of 10t production / year)
- The FAQ has acknowledged that the REACH+ obligations should only apply to substances that have been intentionally added to an EU Fertilising Product.  
**Recognizing Annex V, point 4 of the REACH regulation in the FPR would reinstate legal certainty on this issue.**



# Panel discussion How to ensure the safety of fertilizing products proportionately

**Theodora Nikolakopoulou – DG GROW**  
**Jaroslav Houček – Czechia**  
**Giel Tettelaar – EFCI**  
**Nicolas Willaume – ICL/EBIC**

**Moderator: Kristen Sukalac- Prospero/EBIC**



15

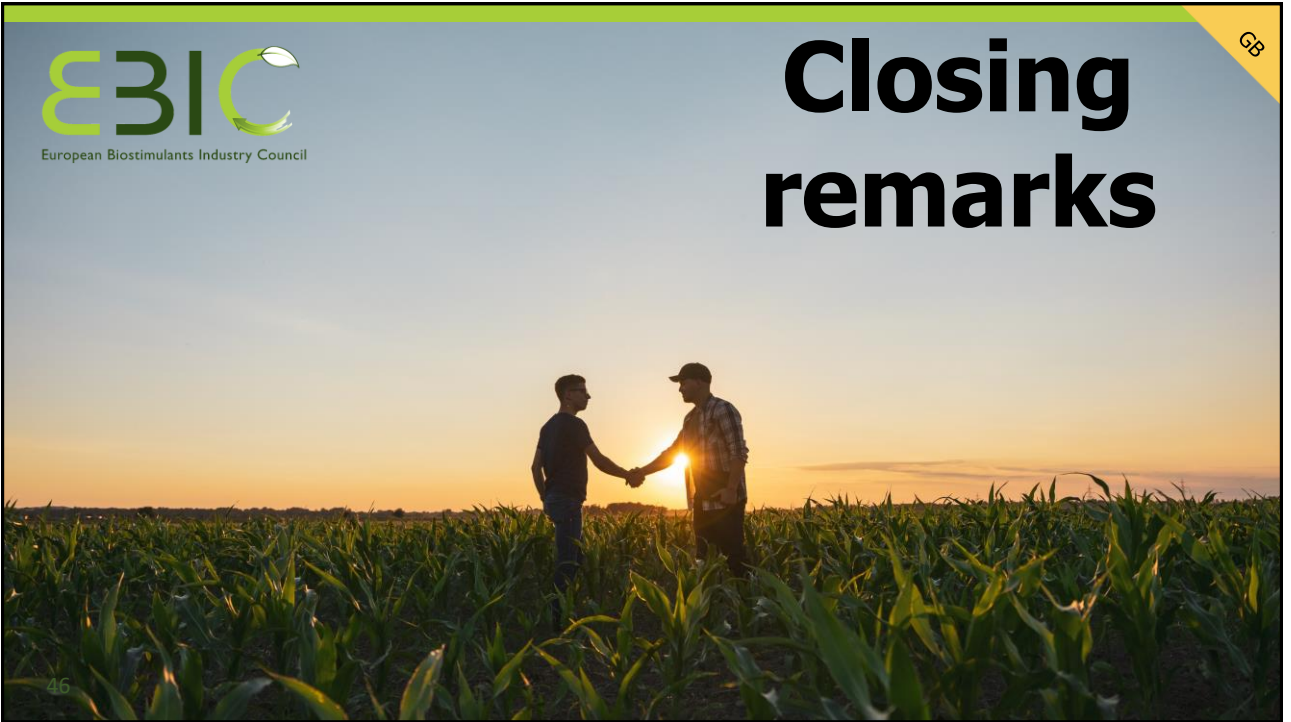
# Discussion





# Closing remarks

GB



46