

EBIC REACH+ Workshop 16th May 2023



Substances approved as food additives

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REACH requirements in EU/2019/1009

All substances incorporated into the EU fertilising product, on their own or in a mixture, except polymers, 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;
- (b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product,

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.

REACH Art 2(5)(b) notes that substances approved for and used as food or feedstuffs do not have to register under REACH (but those same substances are subject to normal REACH registration when used for other purposes).



2

REACH requirements in EU/2019/1009

REACH exemptions for substances mainly used in certain sectors, lead to a cut of registered volumes

Total manufactured volume, Substance A



* **8796** substances are registered in the 1 – 10 T-band (source : ECHA)

However, while exempted by REACH registration, these substances are subject to sector specific Regulations.

3

Use of food additive in fertilizers

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Of respondents to the EBIC/Fertilizers Europe survey said that some of the **substances for which their company has concerns about fulfilling the REACH+ requirements in the FPR have already been approved for use in food and/or feed**

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Use of food additive in fertilizers

Brilliant Blue FCF E-133 CAS 3844-45-9



EFSA assessment 2010 : safe intake as a food ingredient up to 6 mg/kg b.w./day

Meaning a safe intake up to **420 mg/day** for an adult of 70Kg weight

Concentration in compound fertilizers products : < 0,5 g/Kg

Technical function : colourant

Fertilizing products application rate : 300 Kg/ha = **< 150 g over 10.000 M²**

22 registrants, altogether $\geq 100-1000 < T/\text{year}$



5

How much would a person have to eat for Brilliant Blue in an EU Fertilising Product to hit the daily limit for dietary intake?



Assumptions:

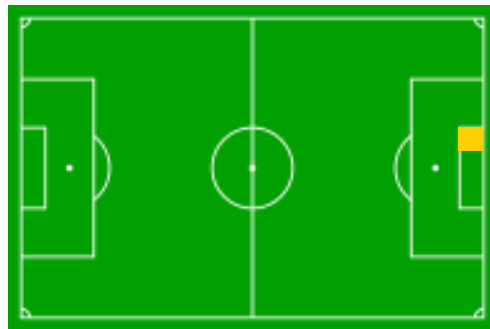
- Concentration and application rate as specified on the previous slide
- 100% of the additive is absorbed by the crop (let's say wheat)
- The consumer eats the entire plant including the straw and the roots.

6

How much would a person have to eat for Brilliant Blue in an EU Fertilising Product to hit the daily limit for dietary intake?



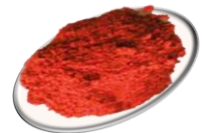
The consumer would have to eat every day all the wheat on a surface equivalent to roughly 1/3 of the goal area in a football field!



About 27 m³

7

Use of food additive in fertilizers



Azorubine (Carmoisine) E-122 CAS 3567-69-9

EFSA assessment 2015 : safe intake as a food ingredient up to 4 mg/kg b.w./day

Meaning a safe intake up to **280 mg/day** for an adult of 70Kg weight

Concentration in micronutrient based fertilizing products : < 20 mg/Kg

Technical function : colourant

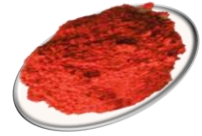
Fertilizing products application rate : 4 Kg/ha = < **80mg over 10.000 M²**

4 registrants, altogether >=10-<100 T/Year



8

How much would a person have to eat for Carmoisine in an EU Fertilising Product to hit the daily limit for dietary intake?

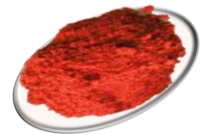


Assumptions:

- Concentration and application rate as specified on the previous slide
- 100% of the additive is absorbed by the crop (let's say wheat)
- The consumer eats the entire plant including the straw and the roots.

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How much would a person have to eat for Carmoisine in an EU Fertilising Product to hit the daily limit for dietary intake?



The consumer would have to eat every day all the wheat on 8.6 football fields!



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Use of food additive in fertilizers

Sunset Yellow (Orange Yellow) E-110 CAS 2783-94-0

EFSA assessment 2014 : safe intake as a food ingredient up to 4 mg/kg b.w./day

Meaning a safe intake up to **280 mg/day** for an adult of 70Kg weight

Concentration in micronutrient based fertilizing products : < 20 mg/Kg

Technical function : colourant

Fertilizing products application rate : 4 Kg/ha = < **80mg over 10.000 M²**

7 registrants, altogether ≥ 10 -<100 T/Year



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How much would a person have to eat for Sunset Yellow in an EU Fertilising Product to hit the daily limit for dietary intake?

Assumptions:

- Concentration and application rate as specified on the previous slide
- 100% of the additive is absorbed by the crop (let's say wheat)
- The consumer eats the entire plant including the straw and the roots.

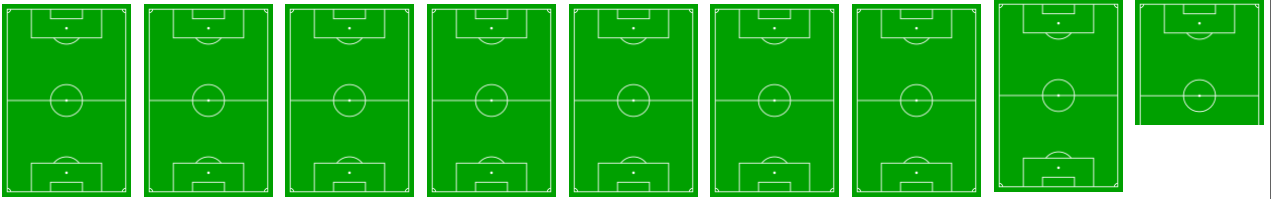


12

How much would a person have to eat for Sunset Yellow in an EU Fertilising Product to hit the daily limit for dietary intake?



The consumer would have to eat every day all the wheat on 8.6 football fields!



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Use of food additive in fertilizers



Tartrazine (Amarillo Tartracina) E-102 CAS 1934-21-0

EFSA assessment 2009 : safe intake as a food ingredient up to 7.5mg/kg b.w./day

Meaning a safe intake up to **525 mg/day** for an adult of 70Kg weight

Concentration in micronutrient based fertilizing products : < 20 mg/Kg

Technical function : colourant

Fertilizing products application rate : 4 Kg/ha = < **80mg over 10.000 M²**

14 registrants, altogether $\geq 100-1000 <$ T/year



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How much would a person have to eat for Amarillo in an EU Fertilising Product to hit the daily limit for dietary intake?



Assumptions:

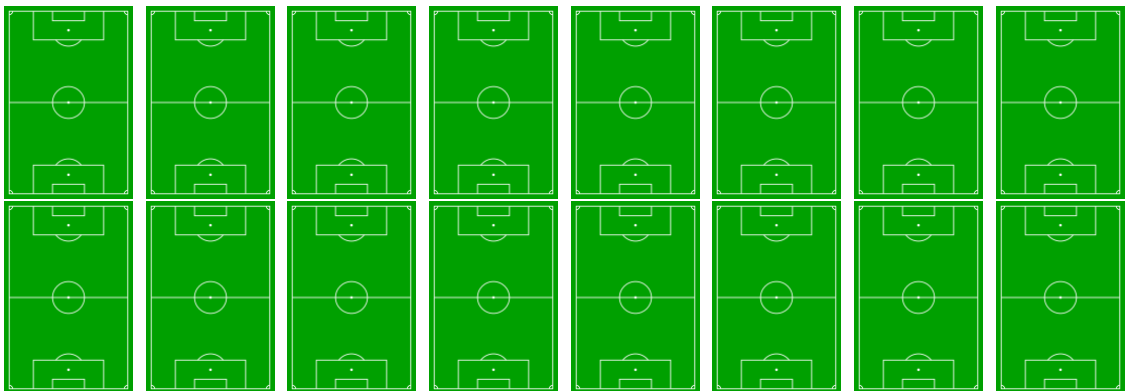
- Concentration and application rate as specified on the previous slide
- 100% of the additive is absorbed by the crop (let's say wheat)
- The consumer eats the entire plant including the straw and the roots.

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How much would a person have to eat for Amarillo in an EU Fertilising Product to hit the daily limit for dietary intake?



The consumer would have to eat every day all the wheat on 16 football fields!



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Use of food additive in fertilizers

Sodium propionate E-281 CAS – 137-40-6



EFSA assessment 2016 : safe intake as a food ingredient up to 5.000 mg/kg b.w./day

Meaning a safe intake up to **350 g/day** for an adult of 70Kg weight

Concentration in micronutrient based fertilizing products : < 1g/Kg

Fertilizing products application rate : 10Kg/ha= < **10g over 10.000 M²**

Technical function : preservative

4 registrants, altogether ≥ 10 - < 100 T/Year



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How much would a person have to eat for Sodium propionate in an EU Fertilising Product to hit the daily limit for dietary intake?



Assumptions:

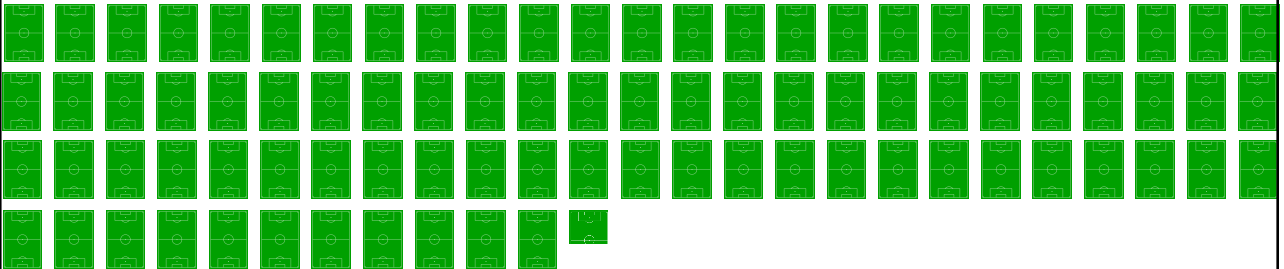
- Concentration and application rate as specified on the previous slide
- 100% of the additive is absorbed by the crop (let's say wheat)
- The consumer eats the entire plant including the straw and the roots.

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How much would a person have to eat for Sodium propionate in an EU Fertilising Product to hit the daily limit for dietary intake?



The consumer would have to eat every day all the wheat on 86.5 football fields!



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Conclusions on the use of food additives in fertilizers

- The assumptions about consumer exposure in our examples are extremely conservative. In reality, the amount of the substance in the final crop would be much lower than in our simulation.
- Enough data exists from the EFSA evaluations for approval of these substances in food to conclude that they can be used safely as additives in EU Fertilising Products without imposing “REACH+” requirements as the Fertilising Products Regulation currently does
- The FPR could be amended to allow food and feed additives in EU Fertilising Products under normal REACH conditions (where approval under as food or feedstuffs means that no further data is required for REACH compliance (Art. 2(5)(b) of Regulation (EC) 1907/2006)

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