

Seed treatments

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Agenda

1. Current regulatory framework
2. Seed treatment guidance document
3. Prior informed consent (PIC)
4. Microplastics
5. ESTA- European Seed Treatment Assurance scheme





Current Regulatory Framework



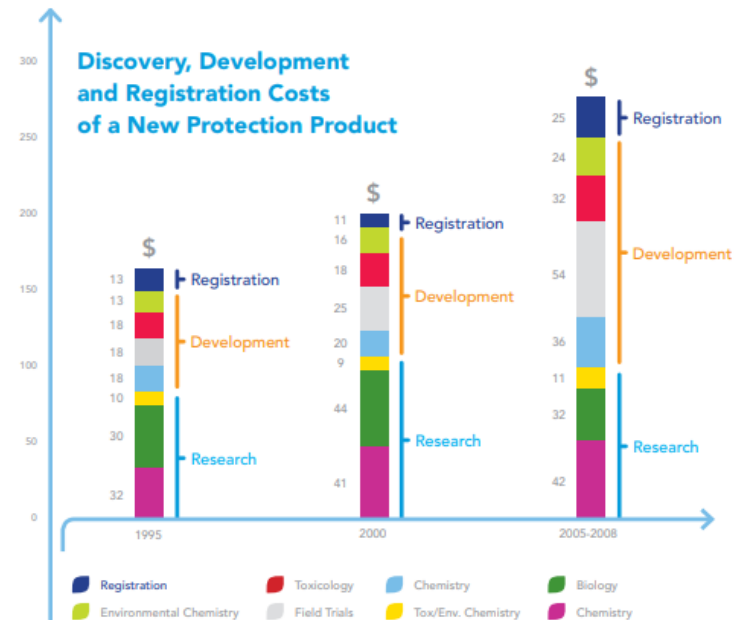
How are seed treatments regulated

Regulation (EC) No 1107/2009

Authorization and use of PPPs for **seed treatments**



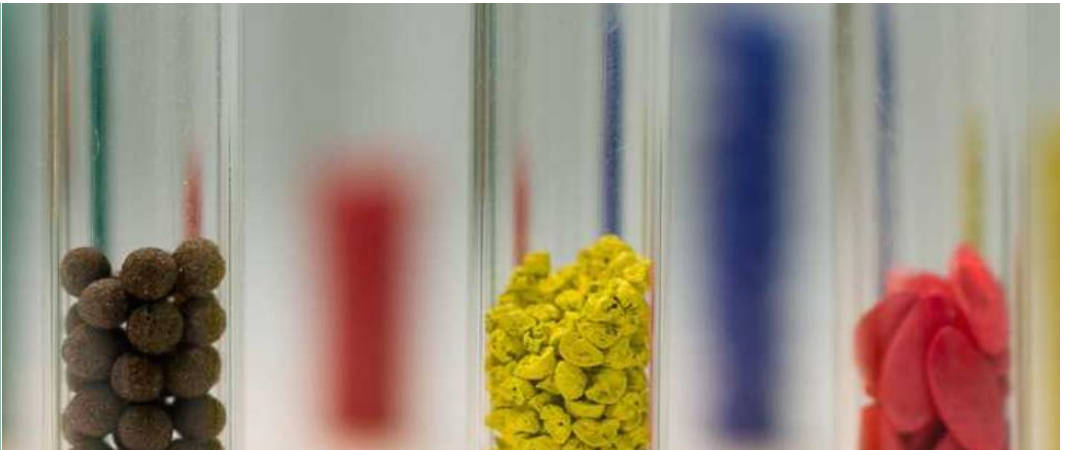
- For a new PPP on the market 10-year time-line
- > 250 € Million investment
- A national authorization is needed to treat seeds



How are treated seeds regulated

Regulation (EC) No 1107/2009 (Article 49)

Placing on the market and
use of **treated seeds**



- Treated seeds are not considered as plant protection products
- Free movement of treated seeds within the EU
- Different rules for emergency uses

Seed treatments & treated seed are regulated differently 

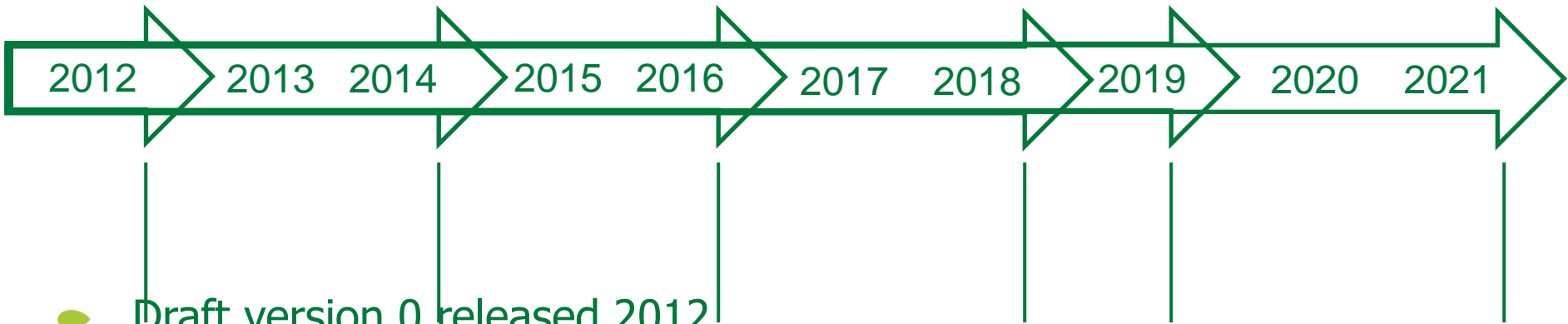


Seed treatment guidance document



Seed treatment guidance document

- Objective of the guidance: Harmonize regulation on seed treatments



- Draft version 0 released 2012
- Draft version ? released 2014
- Draft version 11 released 2016
- Draft version 16 released 2018
- Draft version in 2019 guidance split in two (science and regulatory)
- Draft version 20 “released” 2021: only 23 pages only regulatory
- Commission want to finalize the regulatory part “soon” no news on the science part

In the future a new stricter regulatory environment



What is in the guidance

- ✓ ● Euroseeds proposed realistic & harmonized labeling recommendations
- ✓ ● Reference to ESTA as the gold standard for the treatment of seeds
- ✗ ● Unrealistic sowing rates to conduct environmental risk assessment

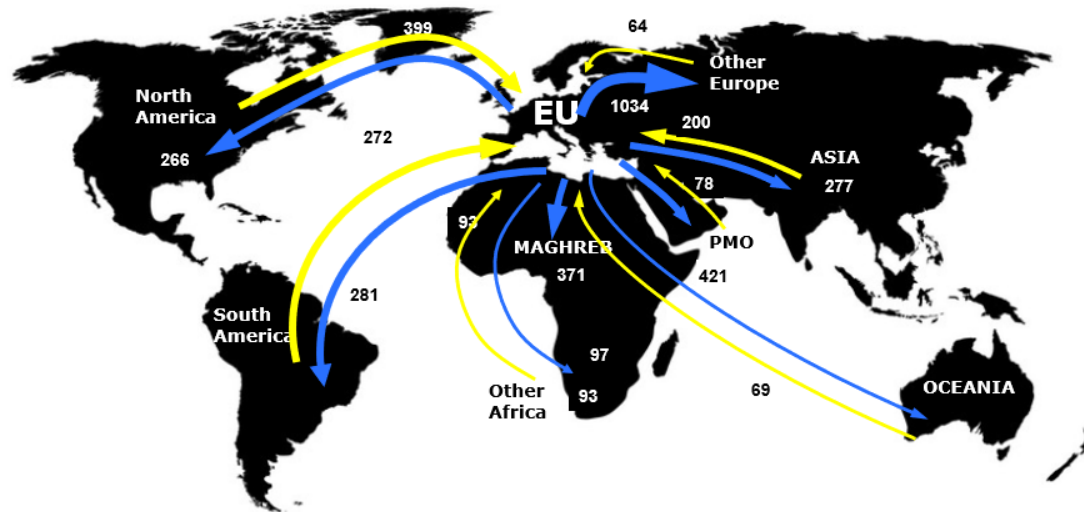


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What is not in the guidance

- An authorization process, as proposed by Euroseeds, that enables innovative seeds to be exported to countries outside of the EU with seed treatment products.



The guidance needs to account realistic uses of seeds





Prior Informed Consent (PIC) Regulation 649/2012



Prior informed consent – what is it about

- Prior Informed Consent (PIC Regulation 649/2012) applies to the export of certain hazardous chemicals and places obligations to notify exports on companies that wish to export these chemicals to non-EU countries
- The PIC Regulation applies to banned or severely restricted chemicals listed including recently non-renewed pesticides (e.g. Neonics or Thiram) which makes it now relevant for seeds
- Applies to substances, mixtures and articles
- Feedback from ECHA considered treated seeds mixtures



Principle question: what are treated seeds

- Chemicals exclude living organisms: Seeds are not chemicals
- A seed is not a “substance” because substances are chemical elements
- “Mixture” does not add anything substantively to the definition of a “substance”. Seeds are not mixtures
- Seeds treated with listed pesticides are articles and thus fall under PIC
- Euroseeds recommends to notify as articles as concluded by the legal analysis we commissioned
- We are in contact with the commission on clarifying the incorrect assessment by ECHA which considers treated seeds mixtures





Microplastics



The proposed definition on microplastics

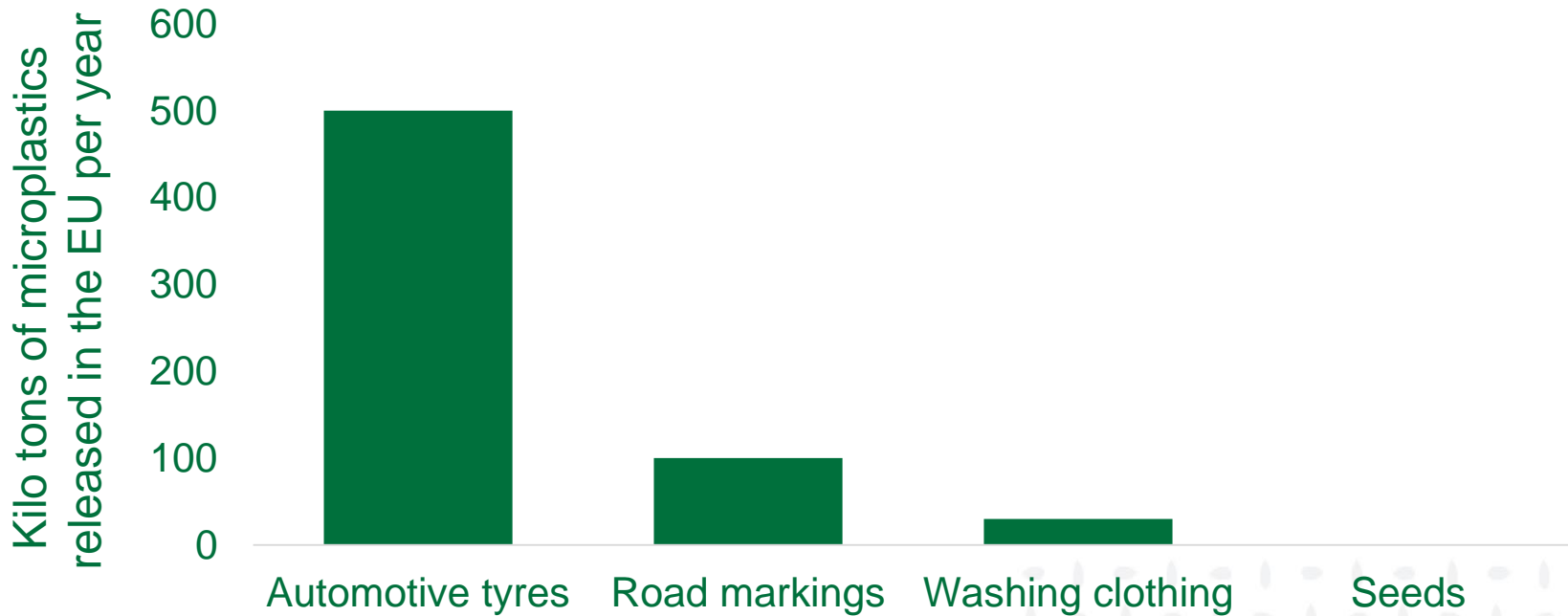
- Restriction proposal which is currently not adopted states “**Microplastic** means a material consisting of solid polymer-containing particles”
- It needs to be released into the environment; seed treatments are not released but the treated seeds are

Parameter	Characteristic	Applies to treated Seeds
Size	>1% of particles are $1\text{nm} \leq x \leq 5\text{mm}$	To most
Degradability of solid polymer	Biodegradability of > 90% 6 M water and 24 M soil	Open, likely for most polymers

Treated seeds will be regulated



How much are we releasing



- Most of the micro plastic release is unintentional
- 450 Ton of microplastic is released through seed coatings
- This is equivalent to an average of 6 gram polymer per hectare per year



Time-line

Date	Description
Call for evidence	1 March - 1 May 2018
Stakeholder workshop	30 - 31 May 2018
RAC opinion & SEAC opinion	June 2020
Public consultation on draft SEAC opinion	Summer 2020
Combined final opinion submitted to the Commission	Q4 2020
Discussions with Member State authorities and vote	2021
Scrutiny by Council and European Parliament	Before adoption
Potential Restriction proposal adoption (if agreed)	Unclear maybe 2022
Potential Labeling required	Unclear maybe 2022 - 2023
Potential Entry into force for seeds	Unclear maybe 2027 - 2030

Euroseeds meeting

Realistic release rate

Participation of Euroseeds

Letter for realistic entry into force

- Earliest from 2022 onwards the supply chain will be able to draw conclusions on the microplastic status of seeds



Euroseeds fighting for a realistic entry into force

- Entry into force for treated seeds needs to be realistic to do reformulation work, and testing and registration

- Seed treatment



- Euroseed requested 11 years EiF after publication of restriction

Realistic entry into force needed





European Seed Treatment Assurance Industry Scheme





Development of



Background

2008

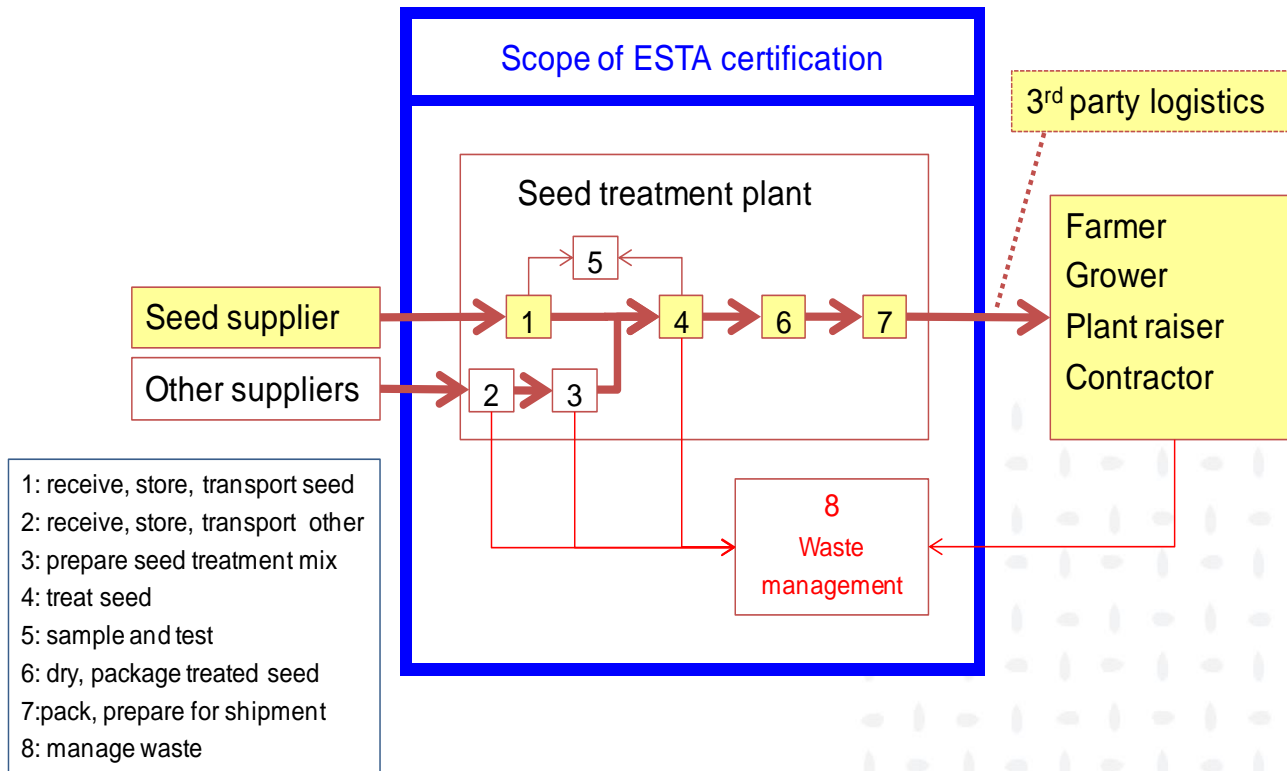
- Bee deaths in Germany → restrictions on the use of CNIs in Germany and Italy

2010

- Directive 2010/21/EC → requires seed treatment with CNIs and fipronil only in professional seed treatment facilities



Scope of ESTA certification



SPECIFIC REQUIREMENTS

Seed quality

Seed treatment application recipes and rates

Material safety data sheets and labels

Monitoring applications

Dust level testing

Seed labelling

Record keeping



ESTA DUST REFERENCE VALUES

- **Corn: 0.75g of dust/ 100 000 seeds**
- **Oilseed rape: 0.50g of dust/ 700 000 seeds**
- **Sugar beet: 0.25g of dust/ 100 000 seed pellets**
- **Sunflower: 0.40g of dust/ 75 000 seeds**
- **Cereals: 4 g of dust/100 kg**
- **Carrots, endives: 0.1 g of dust/100 000 seeds**
- **Onions: 0.2 g of dust/100 000 seeds**
- **Sweet corn: 0.75 g of dust/100 000 seeds**
- **Green and seeded beans: 0.4 g of dust/ 100 000 seeds**
- **Vegetable peas: 0.2 g of dust/100 000 seeds**
- **Cotton: 6 g of dust/100 kg. The value will be advisory for the time being. It will become normative on July 1, 2023.**

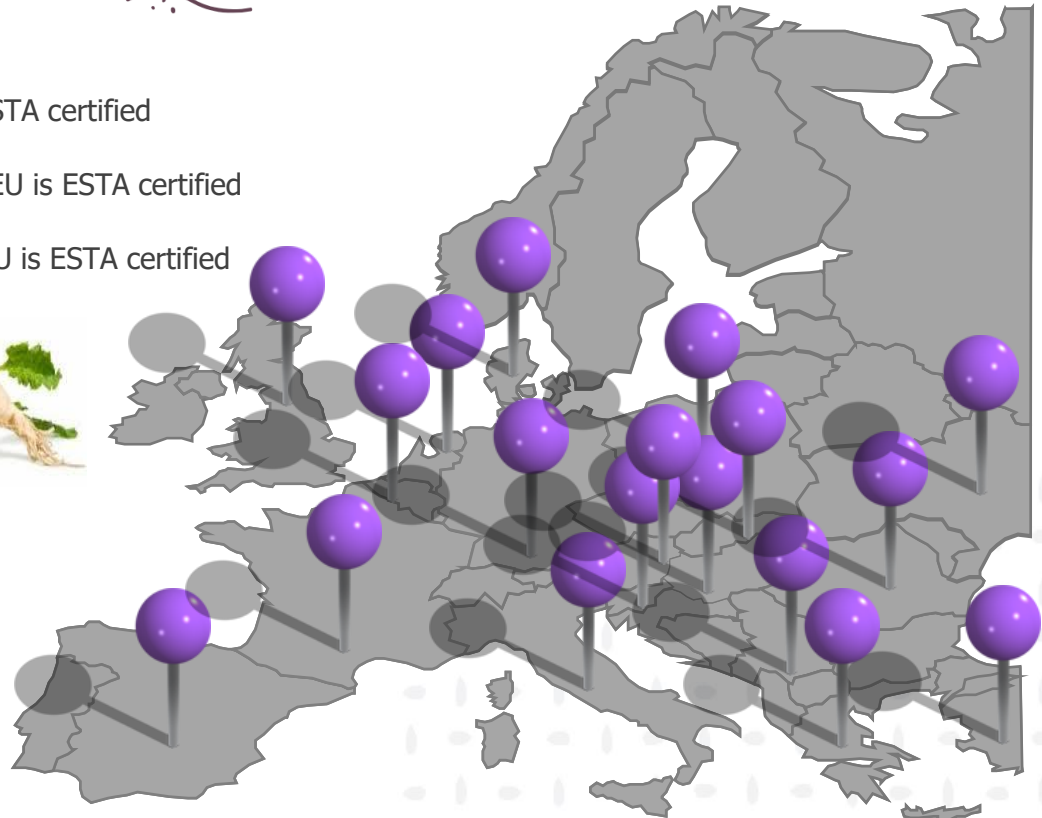


Implementation of



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- Almost 90% of maize that is treated in the EU is ESTA certified
- Almost 90% of oil seed rape that is treated in the EU is ESTA certified
- Almost 100% of sugar beet that is treated in the EU is ESTA certified





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