



# Seed Treatment – Regulatory perspective

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# Content

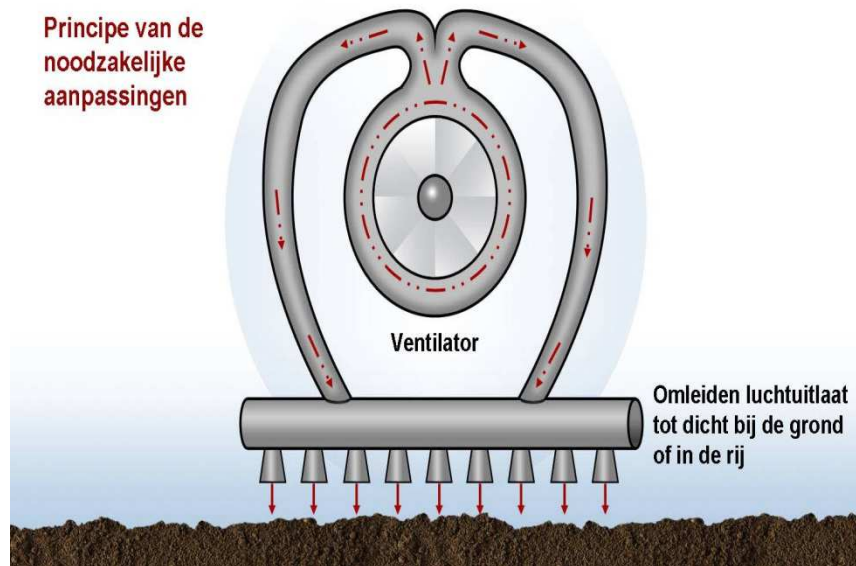
- Introduction
- Ctgb
- Regulatory framework
- Risk assessment environment according to Guidance Document
- Harmonisation

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# Introduction

- ❖ 2008 start discussion dust drift in relation to bee mortality
- ❖ 2010 first measures for seed sowing machines (deflectors) on label

Principe van de noodzakelijke aanpassingen



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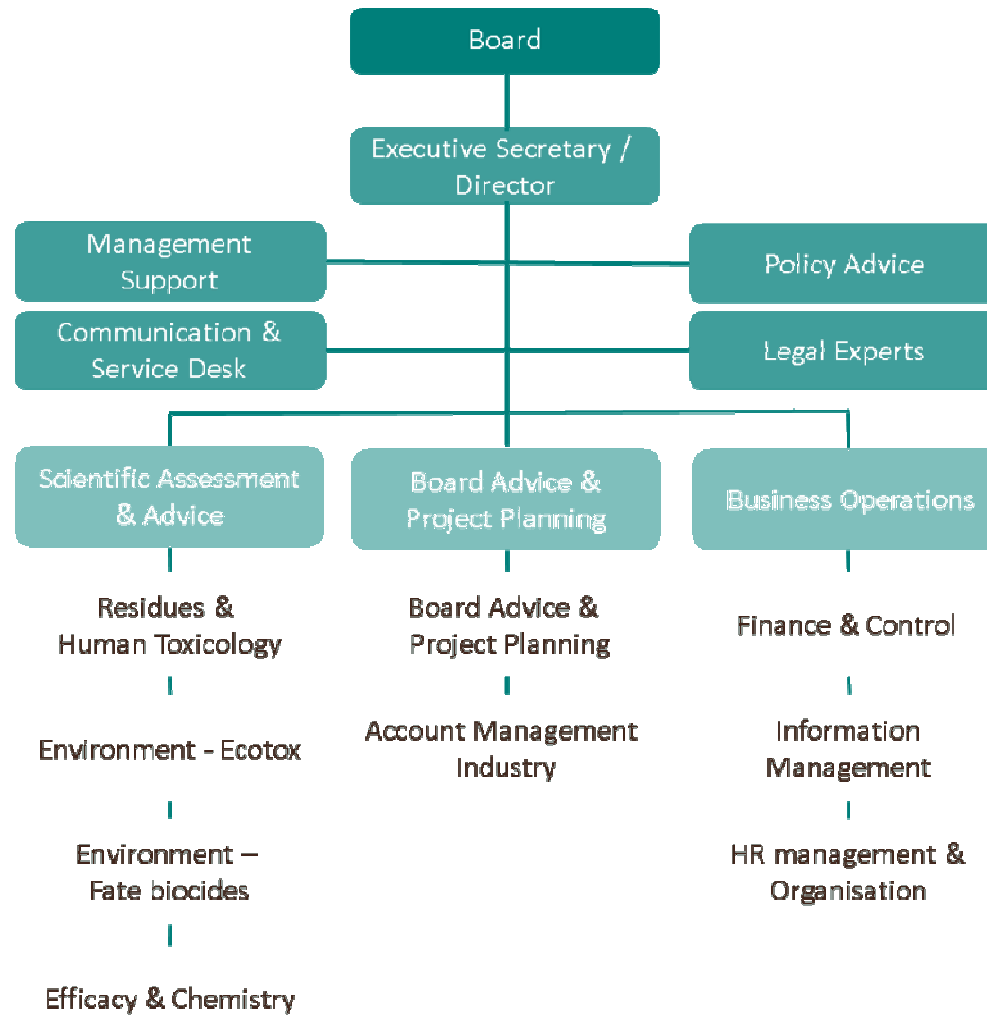
# Ctgb - General data Secretariat

- In house experts for all aspects
- 165 staff (77 fte in 2011 and 150 fte now)
- hourly fee € 132,- (2018)
- budget: ca. € 18.900.000
- 75% income based on fees for applications
- 15% based on a yearly fixed fee per authorised product
- 10% related to requests for advice from ministries

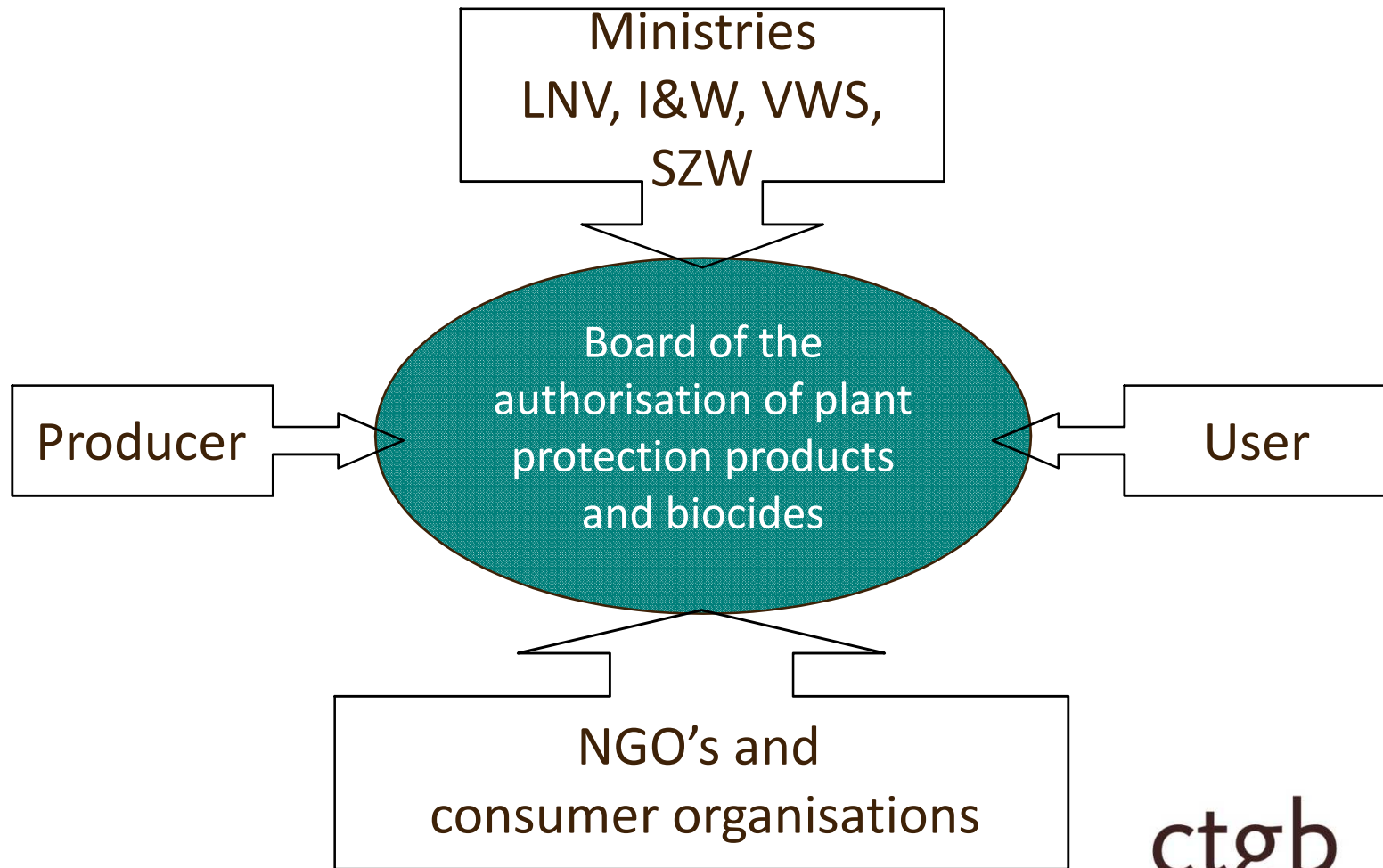


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# Ctgb - Organisational Chart



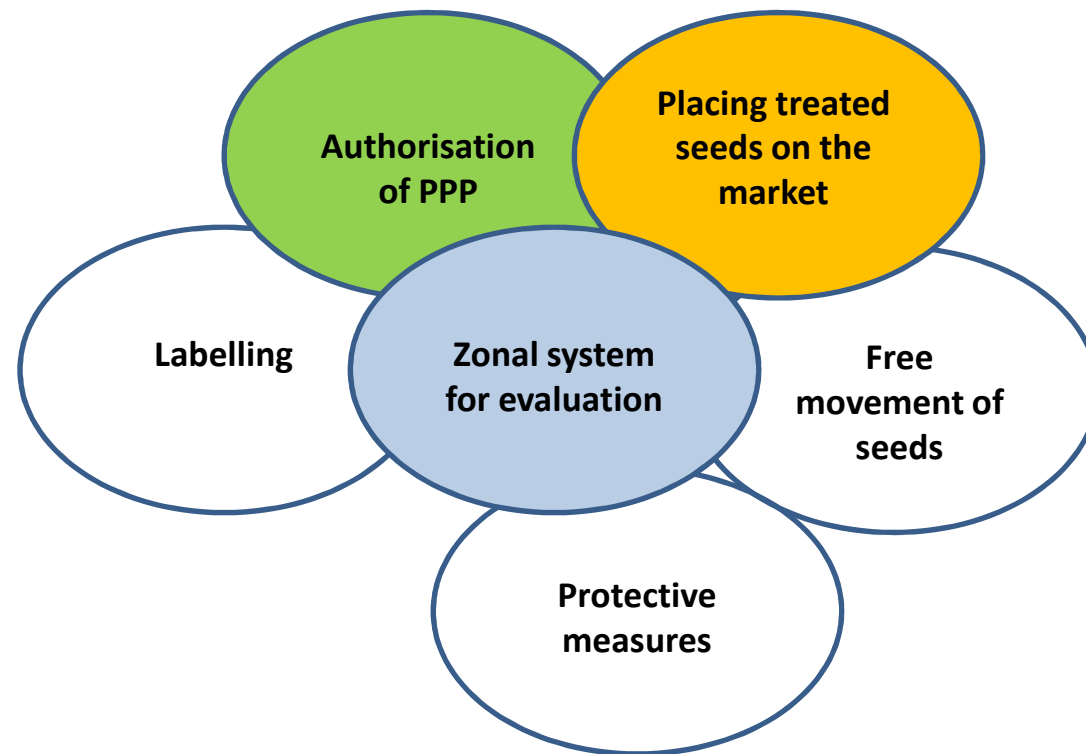
# Environment Ctgb



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# The regulatory framework

## Regulation (EU) No 1107/2009



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# Treatment of seeds

## Art. 28: Authorisation and placing on the market and use

- A national authorisation is required to treat seeds
- Treated seeds are not considered as plant protection products

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# Placing on the market, Art. 49

## Art. 49: Placing on the market and use

- Free movement of treated seeds
- Protective measures
- Labelling of treated seeds

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# Placing on the market, Art. 49 (1)

Free movement of treated seeds:

*'Member States shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use in at least one Member State'*

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## Protective measures, Art. 49 (2)

- Substantial concerns: serious risk to human or animal health or to the environment
- Measures to restrict or prohibit the use and/or sales of such treated seeds (Regulatory procedure)

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# Labelling of treated seeds, Art 49 (4)

Label and documents accompanying treated seeds shall include:

- Name of PPP with which the seeds were treated
- Name of active substance(s) in that product
- Standard phrases for safety precautions
- Risk mitigation measures set out in the authorisation

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# Evaluation of application

## Art. 33.2 (b)

“..for seed treatment, only one Member State shall be proposed, which evaluates the application taking account of all zones.”

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# Differences between MS

- Sowing practice
- Climatic conditions
- Dissipation/degradation in environmental compartments
- Available risk mitigation measures
- Ecology

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# Dust drift deposition

- Exposure based on seed quality
- No information → reference values or worst case assumptions

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# Dossier content

In addition to general data requirements:

- Heubach values including a.s. content in dust
- Residue analytical methods for all concerned MS
- Agricultural practice in all concerned MS
  - Sowing density
  - Machinery
  - Available risk mitigation measures
- Tests with *A. rhopalosiphi* and *T. pyri* (case by case)



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# Risk assessment environment

- Agreed GD to be used when available
- GD particularly considers:
  - risk aquatic organisms due to dust drift
  - risk to bees and non-target arthropods due to dust drift

Fine tuned assessment  
for acute contact dust  
exposure



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# GD Seed Treatment

Scopaff July 2018:

- Seed Treatment Draft GD in consultation.
- Next WG in October to discuss comments.
- Export to third world countries described in § 2.3 (Not allowed under 1107.)

 EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL  
Safety of the food chain  
Chemicals, contaminants, pesticides

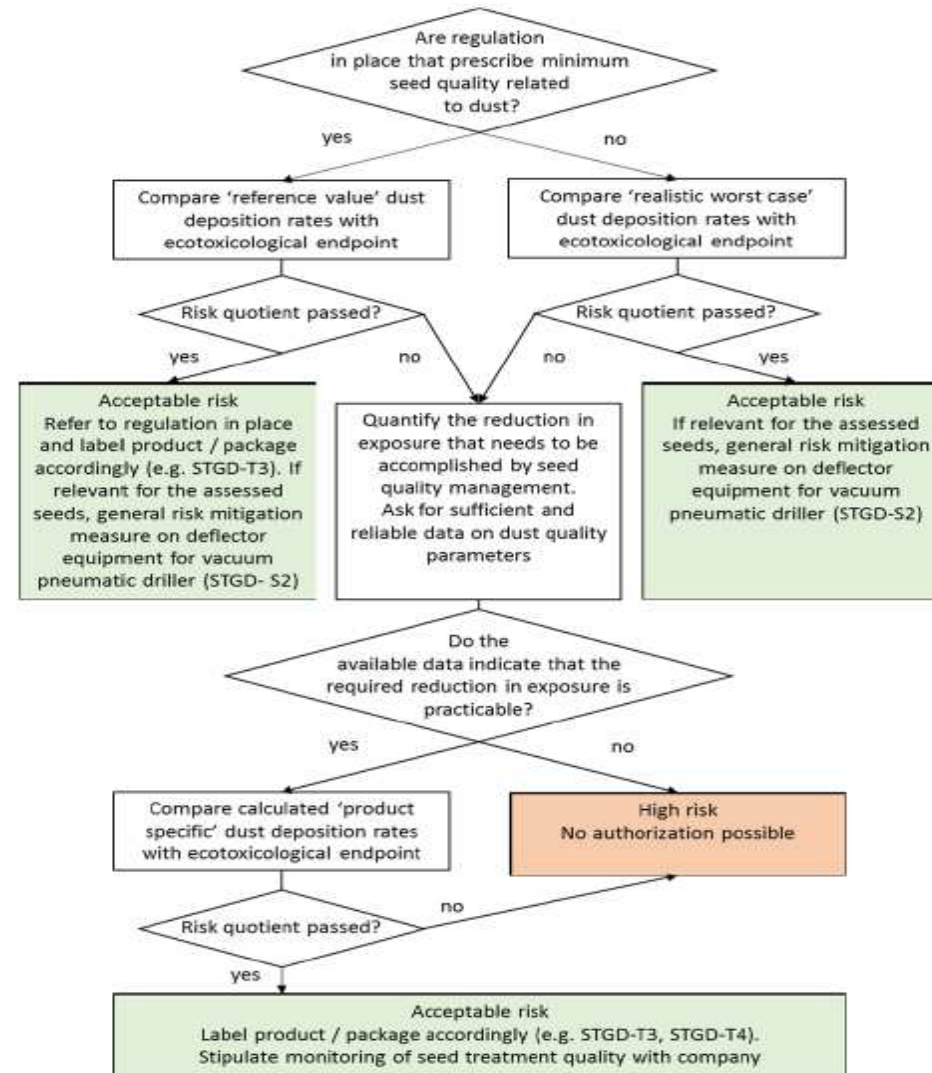
SANCO/10553/2012  
July 2018\_rev 16

Draft  
Guidance document for the Authorisation of Plant  
Protection Products for Seed Treatment

COMMISSION GUIDANCE DOCUMENT - DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE  
COMMISSION SERVICES

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# Risk assessment non targets organisms



1  
2 Figure 11-1: General risk assessment and management scheme for non-target organisms exposed to  
3 active substances in dust drift deposited in off-crop areas after sowing of treated seeds

# Ctgb and Harmonisation

- Ctgb organises workshops → Guidance  
e.g.: New EPPO standard “principles of efficacy evaluation for low-risk plant protection products”
- Evaluation Manual available
- Ctgb in discussions with EFSA on assessment micro-organisms
- Green: Ctgb keeps obstacles as low as possible (low efficacy)



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# Positive take-aways

- GD seed treatment finalised soon
- Updated risk assessment for bees
- Information on seed quality is key
- Better harmonisation of the risk assessment for seed treatments is foreseen



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# Further Considerations

Authorisation will not become easier

Applicant is responsible for application - Ctgb can only assess the information provided

Higher tier assessments left open to MS level

- especially ecological refinements and risk mitigation

→→ MS level



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Thank you for your attention !



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