

# DATA TRANSPORTABILITY OF CFT IN THE EU FOR IMPORT APPROVAL

Adinda De Schrijver, Ph.D.

“the speaker has no financial relationships to declare”

ILSI ERA Workshop Japan – November 2018

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## SUMMARY

In the EU, the persistence and invasiveness potential of the GM plant are assessed through a combination of existing knowledge of the biology of the crop and agronomic and phenotypic data from CFT carried out outside of the EU.

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## OVERVIEW

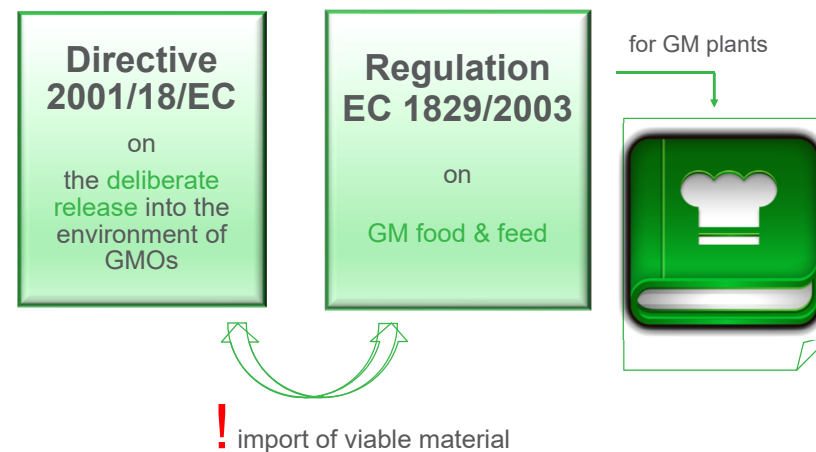
REGULATORY SYSTEM IN THE EU

IMPORT - FOOD/FEED ASSESSMENT & CFT

IMPORT - ERA & CFT

CONCLUSIONS ON USE OF CFT

## The regulatory system in the EU



## The regulatory system in the EU



GMO PANEL



## The regulatory system in the EU

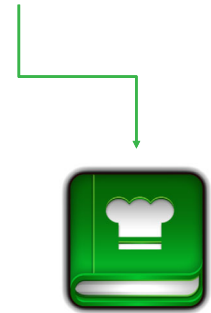


EFSA Journal 2011; 9(5):2150

SCIENTIFIC OPINION

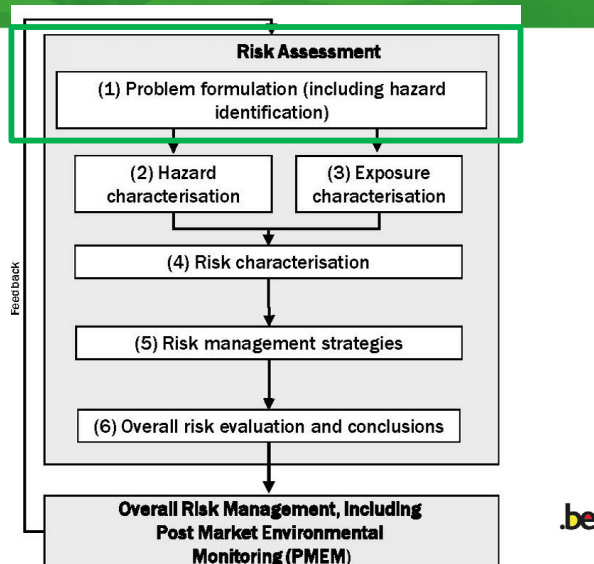
Guidance for risk assessment of food and feed from genetically modified plants<sup>1</sup>

EFSA Panel on Genetically Modified Organisms (GMO)<sup>2,3</sup>  
European Food Safety Authority (EFSA), Parma, Italy



## Import - food/feed assessment

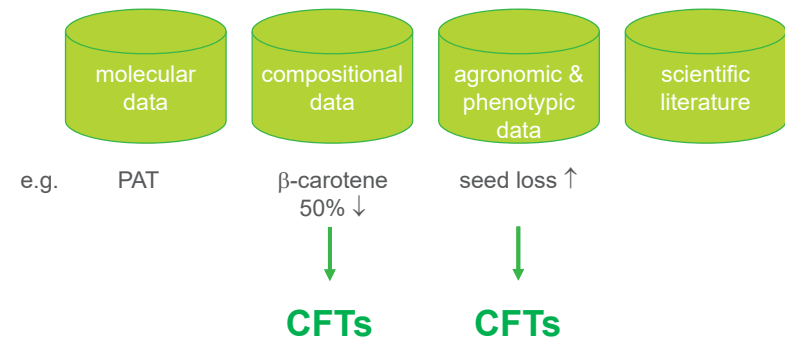
CFTs ←



## Import - food/feed assessment

Hazard identification = identification of potential harmful characteristics

Data sources:



## CFT for food/feed assessment



## CFT for food/feed assessment

CFT accepted if:

*'the geographical locations, soil characteristics, meteorological conditions and management practices of the field trials including planting, harvesting and application of plant protection products are typical for receiving environments in which the GM line and its comparator could be grown.'*

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## Import - ERA

### CULTIVATION DOSSIERS

Full  
ERA

Seven specific areas of concern						
Persistence & invasiveness of the GM plant	Plant to micro-organism gene transfer	Interaction of the plant with target organisms	Interaction of the plant with non-target organisms	Impact of cultivation, management & harvesting techniques	Effects on biogeochemical processes	Effects on human and animal health

Light  
ERA

Persistence & invasiveness of the GM plant	Plant to micro-organism gene transfer
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### IMPORT DOSSIERS

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## Import - ERA

Quote in EFSA opinions:

for a dossier *"which excludes cultivation, the ERA mainly takes into account:*

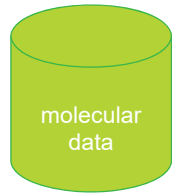
- (1) the exposure of microorganisms to recombinant DNA in the gastrointestinal tract of animals fed GM material and of microorganisms present in environments exposed to faecal material of these animals; and*
- (2) the accidental release into the environment of viable grains during transportation and processing."*

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## Import - CFT for ERA

### Data sources:

#### Gene transfer to m.o.



#### Persistence & invasiveness potential



existing  
knowledge  
+  
info on trait



CFTs &  
lab studies

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## Conclusions on use of CFTs

- CFTs studying agro/pheno characteristics of the GM plant are requested for hazard identification
- Since the early 2000s, these CFTs have been carried out, outside the EU
- These CFTs are accepted if the studies are carried out in different environments typical for the cultivation of the crop plants
- The data from these CFTs are used in the assessment of the persistence and invasiveness potential of GM plants

*(how: EFSA Journal 2010;8(11):1879 ; which data: EFSA Journal 2015;13(6):4128)*

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Arigatou gozaimasu

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