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.
The regulatory system in the EU

European agency produces scientific opinions & advice that form basis for European decisions

Import - food/feed assessment

Hazard identification = identification of potential harmful characteristics

Data sources:
- molecular data
- compositional data
- agronomic & phenotypic data
- scientific literature

PAT, β-carotene 50% ↓, seed loss ↑ → CFTs

CFTs = compositional, functional, toxicological, environmental
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.’

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.”
**Data sources:**

- Gene transfer to m.o.
- Persistence & invasiveness potential
  - Biology crop, behaviour EU
  - Agronomic & phenotypic data
  - Existing knowledge + info on trait
  - CFTs & lab studies

**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.


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