

# Genetic modification – regulation

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## EU Directive 2001/18/EC

- Authorization of environmental release of GM crops in three steps
  - Research under contained conditions
    - Greenhouse with measures against pollen & seed dispersal
  - Field trials with gene flow containment
    - Isolation distance to conventional cultivation (e.g. 400 m to maize, cf. 25-250 m in coexistence)
  - Commercial cultivation after approval based on extensive dossier
    - Research of earlier phases, location of transgene, crop composition, transgene outcrossing, effects on non-target organisms, etc.

For commercial cultivation risk assessment at EU level, subjects to be addressed according to EFSA (European Food Safety Authority) guidelines (based on analysis of possible trait effects (hazard identification) & using field trials) (also see GM debate ppt for more details on some subjects):

Molecular characterisation of transgenic inserts in GM plant genome

Persistence/invasiveness of GM plant and/or with hybridization to wild relatives

Gene transfer to microorganisms (horizontal gene flow)

Interaction with target organisms (e.g. pathogen, pest insect)

Interaction with non-target organisms (e.g. other insects, natural enemies, species with conservation status, functional groups to be selected for which lists have been drawn up)

Impact of specific cultivation management, incl. on receiving environment

Effects on biogeochemical processes (soil quality)

Effects on human & animal health

## EU Regulation 1829/2003

- Authorization of GM food and feed
  - Compositional analysis showing no adverse effects or disadvantageous nutritional changes for consumer
  - Providing detection method with standard materials by which competent authorities can trace the transgenic event in food and feed products

Effects on human & animal health (plant compositional analysis, possible allergenicity, animal feeding trials)

## Authorization procedure GM crops

- At EU level, EFSA advises based on scientific risk analysis according to 2001/18/EC and 1829/2003
- Extensive EU procedure before European Committee eventually decides about authorization for import and/or cultivation
- Member States decide about cultivation in their own country

EFSA = European Food Safety Authority

## GM crops in Netherlands

- NL adopted a reservation regarding GM cultivation until a decision framework has been established
  - Advisory report by Rathenau Institute
  
- Government advised about all aspects of GM by a special Committee, COGEM
  
- Statutory tasks performed by Bureau GGO (RIVM)
  - For example, permissions for field trials

COGEM = Commissie Genetische Modificatie (Netherlands Commission on Genetic Modification)  
RIVM = Rijksinstituut voor Volksgezondheid en Milieu (Netherlands National Institute for Health and the Environment)

## Additional EU GM regulation

- Recommendation for coexistence of GM and non-GM cultivation, for which specific measures to be developed by individual Member States
  - Preventing admixture of non-GM cultivation with GM to ascertain freedom of choice
  - Measures such as isolation distances to avoid pollen-mediated gene flow
  - Agriculture basically an open system, therefore 100% separation practically impossible: threshold value for GM adventitious presence allowed in non-GM products of 0.9%

Also see coexistence ppt for more details

## Additional EU GM regulation

### ■ Special attention to organic cultivations

- Conventional production obligatory labelling as GM above 0.9%
- Organic cultivation not allowed to use GM, admixture may lead to residual damage to markets
  - E.g. in NL for maize isolation distance with conventional 25m, with organic 250 m (against pollen-mediated GM gene flow)

## Effects of EU GM regulation

- Large number of GM crops authorized for import
  - Import mainly for feed production
  
- Authorization for cultivation is perceived as too complex, too expensive and too unpredictable
  - Only one GM crop cultivated (already admitted in 1998): Bt maize MON810, mainly in Spain & Portugal

Because of the complexities, presently in practice no applications for cultivation. The previously allowed GM carnations with altered flower colour have not been extended (or new forms applied) for cultivation, only for import. The last attempt, amylopectin potato, was withdrawn closely to planned cultivation starting season (see below). Import for feed economically important and also to avoid possible (costly) problems with admixtures (LLP = low level presence) in bulk imports, many new GM events in imported crop species are submitted for authorisation of import.



## Effects of EU GM regulation: Amflora case

- Authorisation process for GM amylopectin potato cultivation
  - Amflora from BASF application for authorisation in 1996, final approval only in 2010
  - AVEBE had also been working since 1989 finally leading to their improved Modena and had merged this programme with BASF by 2010

From 1998-2004, in practice there was a de facto moratorium on new GM approvals. Amflora safety eventually assessed by EFSA in 2005, after that several rounds of votes about authorisation in EU Standing Committee without qualified majority and another request by EC (European Commission) to EFSA for a new consolidated scientific opinion in 2009. In the end, also under pressure from requests by BASF (incl. European Court), final approval by EC in 2010.

AVEBE had already started on GM amylopectin potato in 1989 (by silencing GBSS gene with transgenic construct as generating the mutant before that was inefficient, see NPBT ppt) and even had two GM varieties on the variety list in 1998 (Apriori & Apropos) but these have not had any cultivation completed as final approval of cultivation was not forthcoming in 1999 (also see de facto EU moratorium above, already delivered or even planted tubers had to be destroyed at the time). Modena was a marker-free GM variant using the plant's *GBSS* promoter (so actually intragenic in NPBT terms, except for use of a nos terminator sequence).

## Effects of EU GM regulation: Amflora saga

### ■ Authorisation process for GM amylopectin potato cultivation

- The intended Amflora seed potato cultivation in NL in 2012 was halted shortly before its start, and beginning of 2013 BASF withdrew from introducing GM in EU and transferred GM research to the US
  - Potato breeding & seed companies were reluctant to start cultivation for fears of losing valuable non-GM markets
  - Presently, only small amylopectin cultivation based on classical mutant obtained with much effort in 1980s

Amflora cultivation was halted in 2012 in NL because potato breeding companies withheld growers from cultivation by not delivering GM seed potatoes and/or asking guarantees of GM-free status for all other deliveries of seed potatoes for fear of possible damage to the important national & international potato market with consumer sensitivities around GM. Shortly before that, in 2010, an admixture of an Amflora seed potato cultivation with another transgenic potato variety, Amadea, had been reported for a BASF field site in Sweden, accidentally reminding of the role of human error and that complete separation of production chains calls for extensive measures (see Coexistence ppt). In 2012, BASF decided to withdraw GM from EU market and focus on US and Asia; beginning of 2013 it also announced to withdraw GM research because of negative GM climate in Europe accompanied by risks of field trials destructions. Presently, the last episode of the EU Amflora saga was at the end of 2013, when the EU General Court annulled the EU Amflora authorisation for procedural reasons in a case by Hungary against the EC (the 2009 consolidated EFSA Opinion together with previous decisions drafts had not been submitted to Competent Committees). At the moment, there is only a small cultivation area of amylopectin potato in N Germany based on the mutant obtained with much effort by classical mutagenesis in 1980s (see NPBT ppt), for processing by AVEBE (Eliane™ potato).

## GM regulation: conclusions

### ■ Paradoxes to regulation

- EU developed a highly refined system of safety assessment, yet it does not appear to have increased trust in GM implementation
  - Usually no qualified majority in favour of EU GM authorisations
- Even though there appears to be a good market for applications such as amylopectin and late blight-resistant potatoes, companies are reluctant to introduce them
  - Obstacles are perceived burdens of regulation and fears of losing markets

Over the years, EFSA developed a large body of Scientific Opinions on GM crops and Guiding Documents for applicants how to perform field trials for environmental safety assessments etc.

## GM regulation: conclusions

### ■ Paradoxes to regulation

- Paradoxes intensified with the new plant breeding techniques (NPBTs)
  - Often developed to address specific worries about GM but likely not implemented under present regulatory regime
  - The use of GM in the process of obtaining NPBT products often not recognizable as no transgene present anymore in the final plant lines
    - The plant could as well have come about in another manner, albeit with more efforts

Also see NPBT ppt