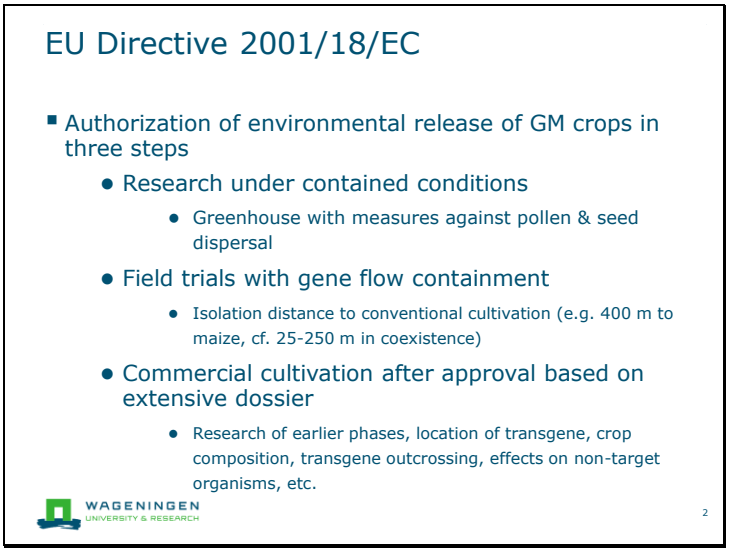
Slide 1

Genetic modification – regulation

Clemens van de Wiel, Jan Schaart & Bert Lotz

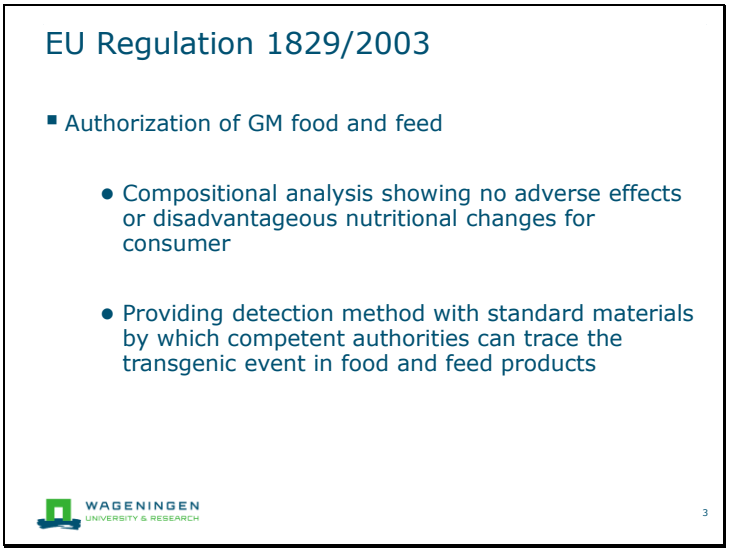
WAGENINGEN
UNIVERSITY & RESEARCH

Slide 2



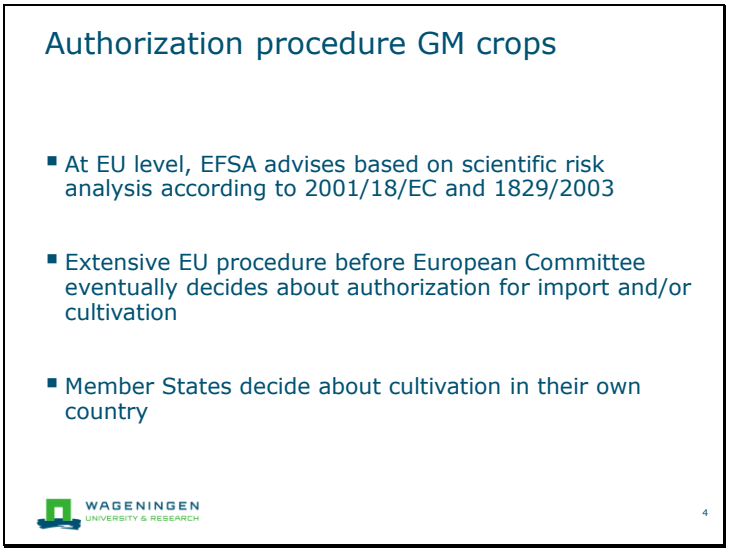
For commercial cultivation risk assessment at EU level, subjects to be addressed according to EFSA (European Food Safety Authority) guidelines (based on analysis of possible trait effects (hazard identification) & using field trials) (also see GM debate ppt for more details on some subjects):
Molecular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

Slide 3



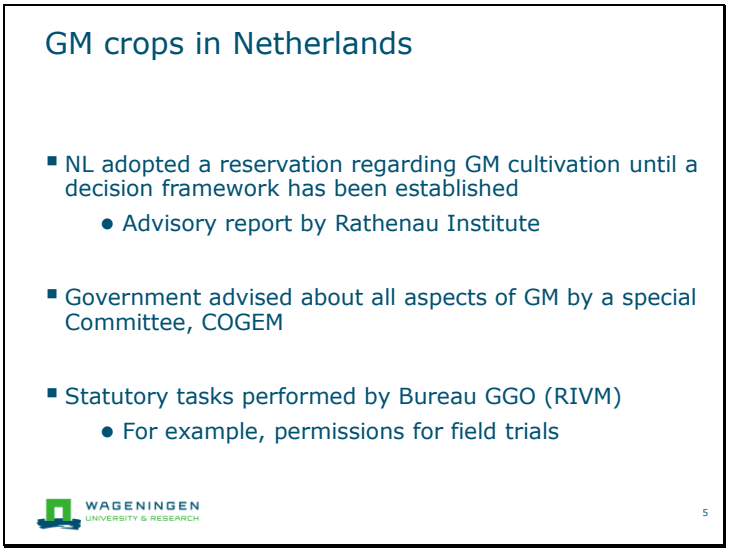
Effects on human & animal health (plant compositional analysis, possible allergenicity, animal feeding trials)

Slide 4



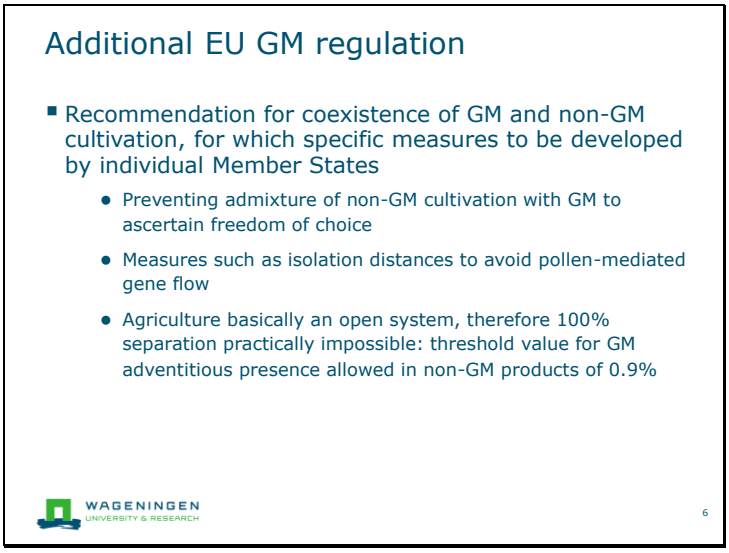
EFSA = European Food Safety Authority

Slide 5



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

Slide 6



Also see coexistence ppt for more details

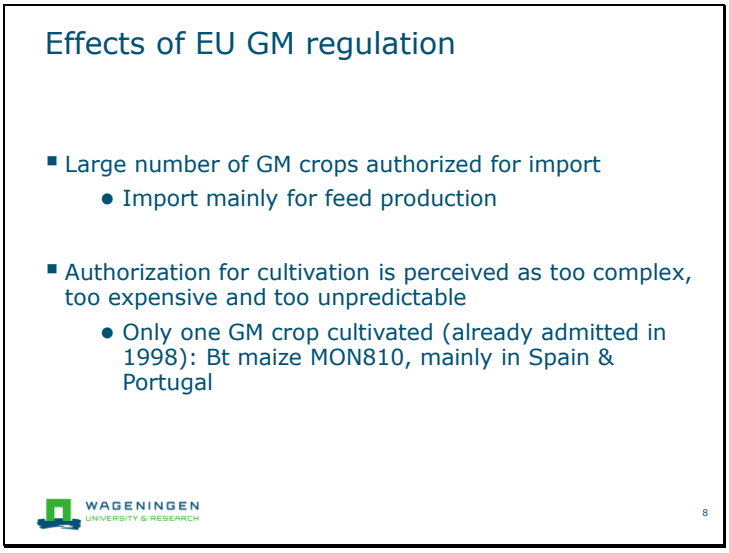
Slide 7

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)

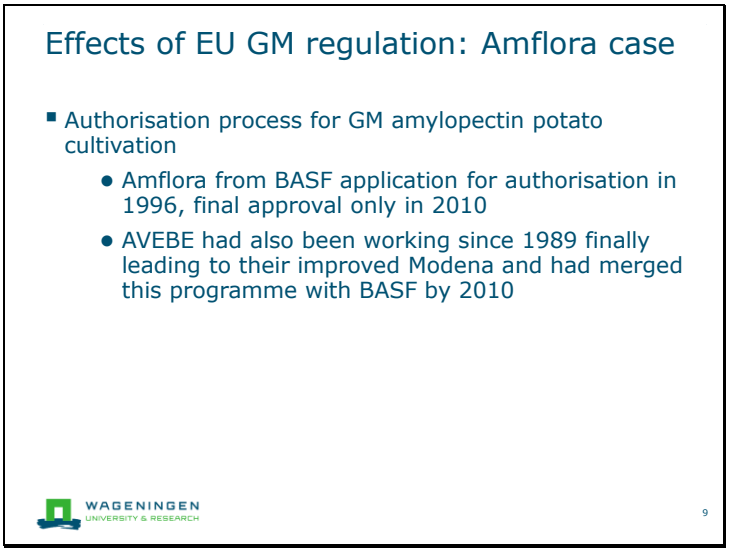
WAGENINGEN
UNIVERSITY & RESEARCH

Slide 8



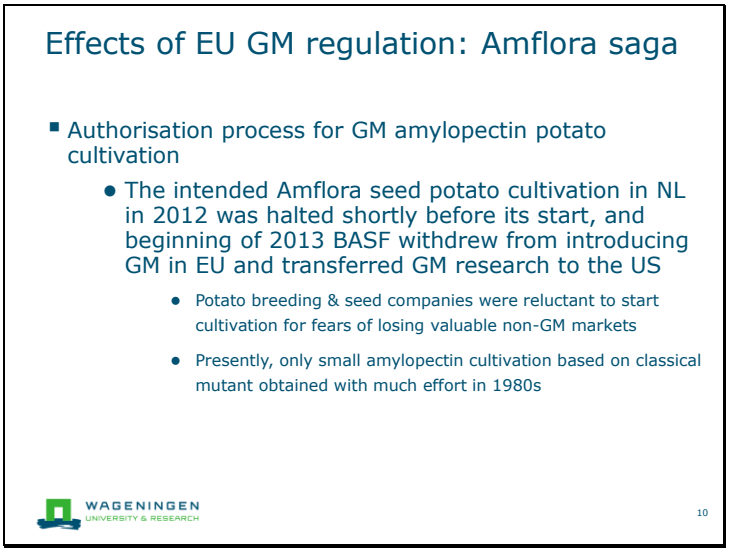
Because of the complexities, presently in practice no applications for cultivation. The previously allowed GM carnations with altered flower colour have not been extended (or new forms applied) for cultivation, only for import. The last attempt, amylopectin potato, was withdrawn closely to planned cultivation 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.

Slide 9



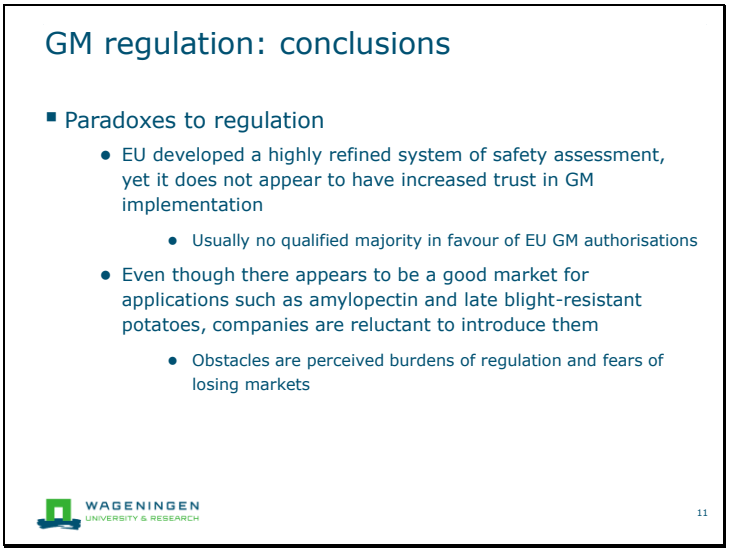
From 1998-2004, in practice there was a de facto moratorium on new GM approvals. Amflora safety eventually assessed by EFSA in 2005, after that several rounds of votes about authorisation in EU Standing Committee without qualified majority and another request by EC (European Commission) to EFSA for a 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 *GBSSI* promoter (so actually intragenic in NPBT terms, except for use of a nos terminator sequence).

Slide 10



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).

Slide 11



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.

Slide 12

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

WAGENINGEN UNIVERSITY & RESEARCH

Also see NPBT ppt