WHAT IS THE APPROVAL PROCESS FOR IMPORT OF GMOS IN THE EU?

RISK ASSESSMENT OF GM PLANTS

1. RESEARCH & DEVELOPMENT

1000 opportunities identified

OBJECTIVE: Select the best performing plant with the lowest likelihood of adverse effects

2 opportunities selected

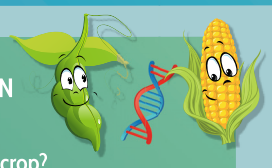
9 YEARS ON AVERAGE

2. SAFETY ASSESSMENT

COMPARATIVE ASSESSMENT: IS THE GM AS SAFE AS ITS CONVENTIONAL COUNTERPART?

› Field trials : GM vs. non-GM
- Phenotype (appearance)
- Agronomic characteristics (yield, height, etc.)
- Composition (compounds, nutrients, allergens, etc.)

MOLECULAR CHARACTERISATION



› What DNA was put into the crop?
› How many genes were put into the crop?
› Where in the host genome is the inserted DNA located?
› Is expression of the gene(s) stable?
› Characterize the insert on molecular level or analyse the product on a molecular level, such as location and stability of the inserted gene, the number of genes inserted, etc.

FOOD/FEED SAFETY

› Testing on animals
- Rats : 90 days of feeding to rule out adverse effects

› **Digestibility study**
The introduced protein is exposed to enzymes present in gastric and intestinal fluids

› **Bioinformatic analysis**
Do new compounds or altered levels of compounds in GM show similarities with known toxins or allergens ?

› Animal feeding trials
- Chickens: 42 days of feeding for nutritional assessment in case of compositional changes case-by-case

UP TO 2 YEARS

POTENTIAL ENVIRONMENTAL IMPACT

› Evaluate potential adverse effects on the environment

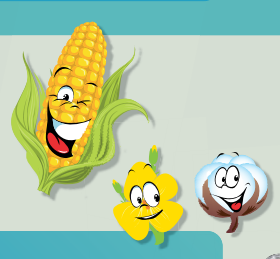
REGULATORY DOSSIER

If the product is found to be as safe as its conventional counterpart, the dossier is submitted to the European Food Safety Authority (EFSA)

6 PRINCIPLES RISK ASSESSMENT

- Science-based
- Case by case analysis
- Precautionary principle
- History of safe usage/consumption (include lessons learned from the past)
- Compliance with international quality standards (OECD, ISO, GLP)
- Weight of evidence approach

3. EFSA REVIEW



EVALUATION OF RISK FOR HEALTH AND ENVIRONMENT

During this process applicants are often asked to provide more information for clarification

29 MONTHS ON AVERAGE

SCIENTIFIC OPINION

› EFSA declares the GM product safe

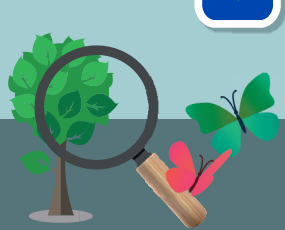
RISK MANAGEMENT PHASE

DRAFT PROPOSAL FOR AUTHORISATION

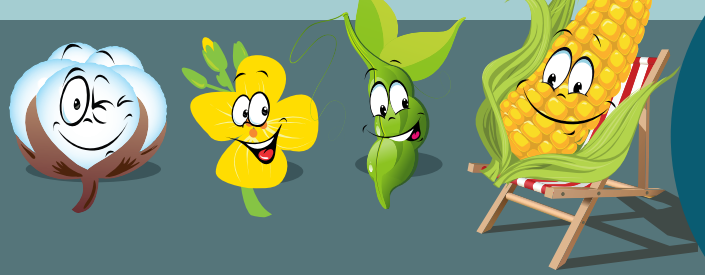
VOTING BY EU MEMBER STATES

AUTHORISATION BY EUROPEAN COMMISSION

19 MONTHS ON AVERAGE



After approval applicants are obliged to monitor and report any potential adverse effects on the environment



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