**WHAT IS THE APPROVAL PROCESS FOR IMPORT OF GMOs IN THE EU?**

**RISK ASSESSMENT OF GM PLANTS**

1. **RESEARCH & DEVELOPMENT**
   - **OBJECTIVE:** Select the best performing plant with the lowest likelihood of adverse effects
   - **UP TO 2 YEARS**

2. **SAFETY ASSESSMENT**
   - **COMPARATIVE ASSESSMENT:** IS THE GM AS SAFE AS ITS CONVENTIONAL COUNTERPART?
     - Agronomic characteristics (yield, height, etc.)
     - Phenotype (appearance)
   - **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?
     - Characterise the insert on a 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**
     - Feeding on animals
       - Rate: 90 days of feeding to rule out adverse effects
     - Digestibility study
     - Bioinformatic analysis
     - Animal feeding trials
     - Chickens: 42 days of feeding for nutritional assessment in case of compositional changes case-by-case
   - **POTENTIAL ENVIRONMENTAL IMPACT**
     - Evaluate potential adverse effects on the environment
   - **REGULATORY DOSSIER**

3. **EFSA REVIEW**
   - **SCIENTIFIC OPINION**
     - EFSA declares the GM product safe
   - **EVALUATION OF RISK FOR HEALTH AND ENVIRONMENT**

4. **RISK MANAGEMENT PHASE**
   - **AUTHORISATION BY EUROPEAN COMMISSION**
   - **VOTING BY EU MEMBER STATES**
   - **DRAFT PROPOSAL FOR AUTHORISATION**

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

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**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

**SCIENTIFIC OPINION**
- EFSA declares the GM product safe

**EVALUATION OF RISK FOR HEALTH AND ENVIRONMENT**
- During this process applicants are often asked to provide more information for clarification

**AUTHORISATION BY EUROPEAN COMMISSION**
- 10 MONTHS ON AVERAGE

**VOTING BY EU MEMBER STATES**
- DRAFT PROPOSAL FOR AUTHORISATION

**DRAFT PROPOSAL FOR AUTHORISATION**
- 8 YEARS ON AVERAGE

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**POTENTIAL ENVIRONMENTAL IMPACT**
- Evaluate potential adverse effects on the environment

**MOLECULAR CHARACTERISATION**
- What DNA was put into the crop?
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**APPLICATIONS**
- Dossier on non- GM crop
- 6 Applications
- 30 Months on average