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Overview of EU legislation on genetically modified organisms (GMOs)

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union

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DG SANTE, Biotechnology Unit

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Outline

1. Scope
2. Requirements
3. Procedures
4. Controls
5. Emergency measures and opt-out for cultivation
6. International obligations
7. Summary and practical information

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Main pieces of legislation

- **Directive 2001/18/EC** on the deliberate release of GMOs
- **Regulation (EC) No 1829/2003** on GM food and feed
- **Regulation (EC) No 1830/2003** on traceability and labelling of GMOs
- **Directive 2009/41/EC** on the contained use of genetically modified microorganisms (GMMs)

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Overview

Deliberate release

- Experimental releases
- Placing on the market

GM food and feed

- Placing on the market

Contained use

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Main objectives

- Protection of human life and health, animal health and welfare, environment and consumer interests in relation to GMOs
- Ensuring the effective functioning of the internal market

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1. SCOPE

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Scope

- GMOs (product): organism in which the genetic material has been altered in a way that does not occur naturally
- Technique (process): lists of techniques
  - Leading to genetic modification
  - Not leading to genetic modification
  - Exempted

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Directive 2001/18/EC

- Living organisms (e.g. grains, live plants, animals, micro-organisms)
- Deliberate release into the environment (intentional introduction)
  - Experimental releases (part B)
  - Placing on the market (part C)

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Regulation (EC) No 1829/2003

Food and feed uses

GM FOOD
- containing or consisting of GMOs

-produced from GMOs

GM FEED
- containing or consisting of GMOs

-produced from GMOs

GM SEED
GMOs which may be used as food and feed

OTHER
GMOs which may be used as food and feed

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Common aspects

- Cultivation applications under Dir. 2001/18 or Reg. 1829/2003
- Environmental risk assessment under Regulation in accordance with Annexes to Directive 2001/18
- Parts A and D of Directive 2001/18 applicable to GMOs authorised under the Regulation

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Directive 2009/41/EC

- Micro-organisms (e.g. bacteria, viruses, fungi)
- Contained use: activities for which containment/safety measures are used to limit contact with the general population and the environment

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2. REQUIREMENTS

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Placing on the market

Directive 2001/18/EC and Regulation 1829/2003

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1. Safety

- MS must ensure appropriate measures to avoid adverse effects on health or the environment
- Pre-market authorisation for each GMO
  - 10-year validity + renewal
- Unauthorised GMOs cannot be placed on the market
- Once authorised:
  - Post-market monitoring
  - Traceability

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2. Information

- **To consumers (labelling)**
  - Labelling of GM products is mandatory
  - Exemption: labelling threshold for GM food and feed (if adventitious or technically unavoidable presence below 0,9%)
  - No labelling threshold for seeds
- **To the public (public registers)**
  - On releases (MS and COM)
  - On GM food and food authorisations (COM)

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3. Coexistence

- Member States <u>may</u> take measures to avoid the unintended presence of GMOs in other product
- Member States in which GMOs are cultivated <u>must</u> take action in border areas to avoid contamination of neighbouring EU countries where the cultivation of those GMOs is prohibited.
- Notification of measures to other MS and the Commission under Directive (EU) 2015/1535
- Guidelines (Recommendation 2010/C 200/01)

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Contained use of GMMs

Directive 2009/41/EC

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Contained use
Obligations of users

- Assessment and classification of risks (Classes 1 to 4)
- Notification of premises (first use)
- Notification of class 2 contained uses or above
- Emergency plan for accidents

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3. PROCEDURES

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Directive 2001/18/EC

- **Field trials** (Part B): Member States' competence

- **Placing on the market** (Part C): two-step procedure

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Part B of Directive 2001/18/EC

- Notification to national competent authority
- Content of the notification:
  - Technical dossier
  - Environmental risk assessment
- Reply from the authority within 90 days
- Information requirements
  - Public consultation
  - Information to Commission and other MS
  - Public register of experimental releases

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Part C of Directive 2001/18/EC

Standard (national) procedure

- Notification to national competent authority (MS rapporteur)
- Assessment report within 90 days
- If no reasoned objections from the Commission or Member States, written consent by MS rapporteur

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Part C of Directive 2001/18/EC

EU procedure (in case of objections)

- EFSA reviews the risk assessment
- Commission decision under comitology procedure
- Written consent by rapporteur MS

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Regulation (EC) No 1829/2003

Applicant
- Product development and application

EFSA
- Risk assessment

COM
- Risk management

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Regulation (EC) No 1829/2003 application

- Applicaiton submitted to national competent authority of a Member State (requirements in Implementing Regulation (EU) No 503/2013)
- National competent authority transmits to EFSA
- EFSA informs the other MS and the Commission
- Commission's Joint Research Center (JRC) validates the methods of detection and identification proposed by the applicant

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Regulation (EC) No 1829/2003 risk assessment

- EFSA has 6 months to carry out the risk assessment and issue an opinion
  - Can ask a national competent authority to carry out the risk assessment
  - Must ask a competent authority to carry out the risk assessment when the GMO is for cultivation
- Member States are consulted and can send comments to EFSA

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Regulation (EC) No 1829/2003 risk management

- Commission proposes a decision on authorisation within 3 months after EFSA opinion
- Public consultation on EFSA opinion
- Commission draft decision can include risk management measures
- Decision by comitology

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Directive 2009/41/EC

- Notification by the user: contains a risk assessment based on the conditions set out in the legislation – proposes classification of the contained use (class 1 to 4)
- National authority examins the conformity of notifications with Directive + emergency plan
- Reporting and exchange of information with the Commission and the other Member States

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4. CONTROLS

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Controls
General rules

- General EU rules on Official Controls apply to GMOs (Regulations (EC) No 882/2004 and 2017/625/EU)
- Member States are responsible for the enforcement of EU agri-food chain legislation (national competent authorities must monitor and verify through official controls that relevant requirements are effectively complied with and enforced)
- Products from the EU and third countries

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Controls

Directive 2001/18/EC

- Member States shall ensure that the competent authority organises inspections and other control measures to ensure compliance with the Directive
- In case of a release of unauthorised GMOs, the Member State concerned shall ensure that necessary measures are taken to terminate the release and take remedial action if necessary

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Controls
Directive 2009/41/EC

Member States shall ensure that the competent authority organises inspections and other control measures to ensure that users comply with the Directive

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5. EMERGENCY MEASURES AND OPT-OUT FOR CULTIVATION

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Emergency measures/ safeguard clauses

- National emergency measures : if new risk identified after the authorisation, Member States can take measures – notify it to the Commission and other MS
- EU emergency measures: if new risk identified after the autorisation, the Commission can adopt measures (comitology procedure)
- EU emergency measures against non authorised GMOs (e.g. non-authroised rice originating from China)

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Opt-out for cultivation

- Member States can ban or restrict GMO cultivation under certain conditions (Directive (EU) 2015/412):
  - as part of the authorisation procedure of a GMO a MS can ask to amend the geographical scope of the authorisation;
  - after a GMO has been authorised, a MS may ban or restrict its cultivation provided that measures adopted conform to EU law and are reasoned, proportional, non-discriminatory and based on compelling grounds.
- 19 Member States have opted-out from (all demands were made under transitional regime of Art 26c of Dir. 2001/18).

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6. INTERNATIONAL OBLIGATIONS

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International obligations

- Cartagena protocol on the prevention of biosafety
  - Regulation No 1946/2003 (transboundary movements)
  - Obligations on GMO exports
- Convention of Aarhus on the right to information public participation and access to justice in the field of environment
  - Regulation (EC) No 1367/2006
  - Requests for internal review of autorisations

7. SUMMARY AND PRACTICAL INFORMATION

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Summary

- **Scope, requirements and procedures** in national law must be in line with EU law
- **Controls** must be performed as required by EU law
- **Administrative body** - to be responsible for the implementation of the legislation
- **Scientific body** - to carry out the risk assessment
- **Public registers** with information on GMOs

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Practical information

- Commission's website:

https://ec.europa.eu/food/plant/gmo_en

- Register of GM food and feed authorisations:

https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

- Register of releases under Directive 2001/18/EC:

http://gmoinfo.jrc.ec.europa.eu/

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Thank you

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