

# Regulation 1946/2003 – Transboundary movements of GMOs

- Last piece of legislation needed to implement the Biosafety Protocol.
- Objective of the Protocol: *to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms*. Special focus on transboundary movements.
- Develops new legislation for exports of GMOs from the EU, which did not exist under EC Law
- Sticks to the wording of the Protocol as far as possible, leaving margin for upcoming international discussions, e.g. Article 18.

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- For imports and movements between MSs: EC legislation in the field of Biotechnology, mainly:
  - Directive 2001/18/EC on the deliberate release of GMOs;
  - Regulation 1829/2003 on GM Food & Feed
  - Regulation 1830/2003 on labelling and traceability of GMOs
- Uniform procedures for exports in Regulation 1946/2003. Objectives and scope (Art.1 and 2):
  - Set up common export rules for GMOs implementing the CPB AIA procedure
  - Establish information and reaction mechanisms for unintentional transboundary movements of GMOs
  - Establish a common system of information sharing for transboundary movements of GMOs, using the BCH

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- **Definitions (Art.3):**
  - Technical definitions from the Community legislation have been used
  - Other definitions are taken over from relevant existing Community legislation (i.e. Custom's Code)
  - Some developed specially for Regulation 1946/2003 (i.e. “transboundary movements”)
- **Exports of GMOs intended for deliberate release (Section 1)**
  - Obligations for the exporter to notify, in writing, to the Party of Import prior to the first intentional transboundary movement
  - The notification shall contain as a minimum the information specified in Annex I of 1946/2003
  - Obligation to wait for “prior written express consent”

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- Exports of GMOs intended for food/feed/processing (Section 2)
  - Declaratory procedure for GMOs intended for food/feed/ processing
  - Respect of Parties' and non-Parties' national decisions on import
  - Coherence with Regulation (EC) 178/2202 (principles of food law)
- Chapter III- Unintentional transboundary movement of GMOs
- Chapter IV- Common provisions
  - Repartition of notification procedures between EU and MSs
  - Nomination of relevant authorities for the implementation of the CPB
  - Monitoring and reporting; confidentiality; standard penalty clause

## More information:

[http://europa.eu.int/comm/environment/biotechnology/index\\_en.htm](http://europa.eu.int/comm/environment/biotechnology/index_en.htm)

and <http://www.biodiv.org/biosafety/default.asp>

[Paula.REY-GARCIA@cec.eu.int](mailto:Paula.REY-GARCIA@cec.eu.int)