



Directive (EU) 2015/412

Allowing Member States to restrict or prohibit the cultivation of GMOs in their territory

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EU legislative framework on GMOs

Directive 2001/18/EC
on the deliberate release into the environment of GMOs

Regulation (EC) 1829/2003
on GM food and feed



SAFETY

- Each GMO **MUST** be authorised to be placed on the market – **case by case risk assessment by EFSA**
- Authorisation subject to conditions
- Post-market monitoring
- Traceability/labelling requirements for all GMOs or GM food and feed

Safeguard clauses

Emergency measures

- A Member State can provisionally restrict or prohibit the use/sale of an authorised GMO when new or additional information affecting its risk assessment gives good reasons to consider that this GMO constitutes a risk to human health of the environment.
- The Member State shall inform the Commission and other Member States of its decision.
- A decision has to be taken by the Regulatory Committee on this temporary national safeguard measure.

GMO cultivation in the EU

- 1 GMO authorised for cultivation: MON 810.
Cultivated in 5 Member States: ES, PT, CZ, RO, SK
- Several Member States with safeguard measures, none of which confirmed by EFSA.
- COM proposal to withdraw safeguard measures rejected by the Council in 2009.

GMO cultivation in the EU

- In 2009, 13 Member States requested the Commission to give them freedom to decide on GMO cultivation on their territory (strong national dimensions)
- 2009 President Barroso guidelines: more subsidiarity for GMO cultivation.

2010: a new approach on GMO cultivation

A strategy in 2 steps

1- New Recommendation on coexistence

- **Provides more flexible guidance to Member States on how to avoid presence of GMOs in other products**
- Non-binding act
- Built upon the recommendation of 2003
- Supported by technical work of the European Coexistence Bureau (maize, honey, soya)

2- Proposal for an amendment to Directive 2001/18/EC

- To provide a legal base for Member States willing to ban or restrict cultivation of authorised GMOs on their territory
- Not linked to safety



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- As from 2 April 2015, Member States can decide on cultivation of EU authorised GMOs on their territory, based on reasons other than risk on health & environment.
- The EU wide risk assessment and authorisation system is preserved.

Directive (EU) 2015/412: Key features

- **Option 1: Before EU authorisation, a Member States can exclude part or all of its territory from the geographical scope of the application, with agreement of the applicant.**
 - No justification needed.
 - 6 month transitional measures for pending and authorised GMOs.
 - The Member States can reintegrate the geographical scope of the autorisation later.
- **Option 2 ("Opt out"): Any time after EU autorisation, a Member State can adopt measures to restrict or ban GMO cultivation on part of or all its territory.**
 - The decision must be based on reasoned grounds not in conflict with the EU assessment of risks on health/environment (e.g. environmental/agricultural policy objectives, town and country planning, land use, socio-economic impacts, coexistence, public policy, etc.)
- **Coexistence measures at borders of Member States that cultivate GMOs.**

European GMO Socio-Economic Bureau

A technical working group composed of experts from 17 Member States (+NO) and the JRC. Terms of Reference endorsed by Competent Authorities in May 2013, and stakeholders consulted.

Mission: organize and facilitate the exchange of technical and scientific information on socio-economic implications of cultivation and use of GMOs between MS and EC.

Scope: impacts of GM crop cultivation in all sectors of the EU economy. Focus on crops of relevance currently approved or in the regulatory pipeline.

Expected Outputs

➤ Reference Documents

First: "General methodological framework to investigate the socio-economic impacts of GM crop cultivation" - final drafting stage after public consultation
Publication Q3 2015

Next: by sets of indicators for socio-economic impacts at country/EU level (per crop/trait combinations: Bt maize (ongoing), HT maize, HT soya, HT sugarbeet) – deadline 2017.

➤ Research/analysis

If necessary, analyze socio-economic data generated by MS or other source and make analysis available via public reporting.



Thank you for your attention.