

# News from GMOs??

## existing legislation (1)

### A. Starting point is the **existing EU-GMO-legislation**

1. The European Union has established a legal framework to ensure that the development of modern biotechnology, and more specifically of GMOs, takes place in safe conditions.
2. **The legal framework aims to:**
  - Protect human and animal health and the environment by introducing a safety assessment of the highest possible standards at EU level before any GMO is placed on the market.
  - Put in place harmonized procedures for risk assessment and authorization of GMOs that are efficient, time-limited and transparent.
  - Ensure clear labelling of GMOs placed on the market in order to enable consumers as well as professionals (e.g. farmers, and food feed chain operators) to make an informed choice.
  - Ensure the traceability of GMOs placed on the market

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## existing legislation (2)

### 3. The **building blocks** of the GMO legislation are:

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

New Directive (EU) 2015/412 from EP and Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 13. March 2015

Regulation (EC) 1829/2003 on genetically modified food and feed

New proposal on use of GMOs from the EC on 24. April 2015

Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms

Directive 2009/41/EC on contained use of genetically modified micro-organisms. Regulation (EC) 1946/2003 on transboundary movements of GMOs

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## existing legislation (3)

B. Following **evaluation recommendations**, the Commission has launched following actions since 2011:

- ✘ A proposal for increased flexibility on GMO cultivation
- ✘ Technical information on the socio-economic implications of GMO cultivation
- ✘ Reviewing and transforming the risk assessment guidelines for food and feed and environmental release into legal documents approved by EU countries
- ✘ Reinforcing of the environmental monitoring
- ✘ Harmonized sampling, testing for low level presence in food
- ✘ Assessing of new plant breeding techniques
- ✘ Stepping up communication on GMO issues

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## existing legislation (4)

### C. Authorisations of GMO

1. In general, authorisations are valid throughout the EU and may be for cultivation and/or marketing of GM-food and feed and derived products

#### 2. More information

3. Regulation (EC) 1829/2003 on GM food & feed

4. Directive 2001/18/EC on deliberate release into the environment

5. Commission Implementing Regulation (EU) 503/2013 on applications for authorization of genetically modified food and feed in accordance with Regulation (EC) 1829/2003

6. Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.

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## existing legislation (5)

### 3. GMO authorizations for cultivation

The process for authorisation of cultivation of GMOs in the EU takes place under Directive 2001/18/EC or Regulation (EC) 1829/2003 (if the scope covers also food and feed).

How to apply for authorisation?

Under Directive 2001/18/EC, an application for authorisation of a GMO for cultivation must be submitted to a national competent authority. The summary of the notification has to be forwarded to the Commission which makes it available for public consultation, the lead country prepares an assessment etc....until a final decision in the Regulatory Committee by qualified majority

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## existing legislation (6)

### 4. **NEW: Amended Directive No. 2015/412** - Restricting or banning GMO cultivation

Under the new Directive (EU) 2015/412, Member States have 2 possibilities/ options to restrict **or** prohibit GMO cultivation on their territory:

**Option 1:** During the authorisation procedure, a Member State may ask to amend the geographical scope of the application to exclude part of or all its territory. The applicant has 30 days to adjust or confirm the scope of its application. Member States are allowed to ask for their territory to be reintegrated into the geographical scope of the authorization after the GMO authorization has been granted; or

**Option 2:** Member State may adopt national opt-out measures restricting or prohibiting the cultivation of a GM crop, by invoking **compelling grounds**

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## existing legislation (7)

Member States will still be able to adopt safeguard clauses to address new risks on health or the environment that may be identified after a GMO is authorized.

Only one type of GM maize – MON810 – is grown commercially in the EU, Spain is by far the biggest grower with 137.000 hectares (1.56% of the EU's total maize-growing area), maize is modified to be resistant to the European corn borer, a damaging insect pest. MON810 is banned in 7 EU-MS by safeguard clauses: AT, BUL, FR, FRG, GR, HU and LUX.

The new concept is intended to find the **right balance** between maintaining an EU approval system and giving the EU-MS the opportunity to freely decide on the use and/or cultivation of GMOs within their own territory

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## Cultivation – Implementation of 2015/412 in AT (1)

Discussions between the federal and the regional levels have started. A joint working group has coordinated the technical work so far

A **first draft** of a national law by the **Federal Ministry for Health** is tabled (Änderung des Gentechnikgesetz), **for Option 1 of the procedure** (Art 26b and c) dealing with the “geographical scope”. Delegation of powers (from the Länder) to the Minister of Health is given.

The AT-Gentechnikgesetz has already implemented rules so far – on a federal level - for authorisation, use and placing into the market of GMOs and bans for specific GM-products for cultivation (maize MON810, maize T25) or use in food and feed and processed feed etc.



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## Cultivation – Implementation of 2015/412 in AT (2)

A **second draft** of a national law by the **Federal Ministry for Agriculture** is tabled (Gentechnik-Anbauverbots-Rahmengesetzes), for the **second option of the procedure** (Art 26b § 3) dealing with “EU-MS may adopt measures restricting or prohibiting...based on compelling grounds”

### Reaction by the Länder in the consultation procedure:

**No go**, for the content (i.e. 2 new Committees) and the general approach proposing this!

Because of Art 10 § 1 lit. 12 B-VG (national constitution law)

The restrictions or prohibition of GM-cultivation will be implemented in the (existing) “Länder - Vorsorgegesetze”

# News from GMOs??

## Cultivation – Implementation of 2015/412 in AT (3)

Upper Austria wants to ensure the **5 guiding objectives and principles**:

**Taking** (political, regional and legal) **responsability** on a good governance policy level

**Right of self - determination = subsidiarity principle** to ensure – if possible – coexistence for every farming system and introduce regional measures (following Art 26a of directive 2001/18/EC) to avoid the presence of GMO on/in other products;

**Precautionary principle**: most important to avoid irreversible damages to ensure biodiversity, lively ecosystems without contamination and biological diversity of species + (legal) framework conditions on coexistence between farming systems + ensure the future of our common living conditions

**Polluter-pays-principle**: to secure food and feed is a matter of right distribution, not of production + liability responsibility

**Freedom of choice**: realistic chances for all farmers, seed producers, proceeders, retailers, consumers, Regions

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## Cultivation – Implementation of 2015/412 in AT (4)

Gentechnik–Vorsorgegesetzes der österreichischen Länder - **Precautionary laws**

Austrian legal bans for import or cultivation (MON 810 and T25), which leads de facto to zero cultivation of GM-plants ("**First level safety net**")

Oö. Gentechnik - Vorsorgegesetz 2006 (precautionary law 2006) = **2nd „safety net“**, cultivation only after indication for permit/GM-register possible and strict rules of coexistence

**3rd „safety net** = Oö. Sicherheitsabstandsverordnung 2009: Regulation introducing security zones/buffer zones with minimum distances: 4km to rapeseed, 1km to maize seed areas, 600m to GM-maize cultivation areas.

**GMO–monitoring:** "Saatgutgentechnik-Verordnung" done by AGES (Federal agency for Health and Nutrition security) + Bundesamt für Ernährungssicherheit (1.400, - controls) – and enterprise self-controls 920 Analysen, seed controlling: 150 field trails (Feldproben) Rapeseed, Maize, Soya; 2.200 feed trials, all per one year

**Verbindungsbüro Oberösterreich**



# News from GMOs??

## Implementation of 2015/412 in general (1)

**Possibilities** for EU-MS to **restrict or prohibit** cultivation of GMOs in their territories

How to keep GM crops out of the fields, effectively, legally sound and solid, in addition to the EFSA-assessment in the authorization procedure, in conformity with Union law, reasoned, proportional, non-discriminatory, based on compelling grounds

EU-Member States and Regions **do not have any experience** so far in this exercise of banning or prohibition

### Exceptions

- 1.If Coexistence rules are already in place (and notified to the EC services, ie. the Region Bruxelles-Capitale has formally notified its Coexistence rules to the EC = Accepted!)
- 2.Additional grounds, using the safeguard clause for i.e. banning MON 810 in 7 EU-MS, notified to the EC
- 3.The Region of Upper Austria requested the ban of cultivation of GMOs on 12.000 km<sup>2</sup> in 2003, notification draft law 2002, A/720030 on 25.3.2003 (under Art. 95 § 5 of the Treaties, as exception using the safeguard clause in Art. 23 of Directive 2001/18/EC).

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## Implementation of 2015/412 in general (2)

3. Action against the negative decision of the EC before the European Court of First Instance, case No. C-439/05P and C-454/05P, Negative Decision ECJ First Instance on 5.10.2005: requirements for Art 95(5) are not applied, no new scientific evidence, no proof for the existence of a **specific problem** in the whole Region with GE.

Formal notification of the precautionary GM-cultivation laws from Austrian Regions to the EC under the procedure of Directive 90/34/EC (new rules regarding standards = Comments from the EC services (and the consulted EU-MS)).

### **No legislation or “best practices” so far**

**Exception:** the Island of Madeira (POR) notified in May 2010 to the EC via Directive 94/34/EC (defining the information system between EU-MS if new rules for standardization are put into place....) Result: No (negative) reaction and no comments from the EC services = Accepted.

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## **Implementation of 2015/412 in general (3)**

**Opt-out possible, provided that such measures are:**

In conformity with Union law

Reasoned

Proportional (proportionality check is tricky and difficult)

Non-discriminatory

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## Directive 2015/412 - compelling grounds (1)

### a) Environmental policy objectives

national and /or regional different politics and policy strategies to secure biodiversity  
Nature protection objectives for secure and safe diversity of fauna and flora  
SPA- and FFH Directive reserved/defined areas  
specific ecosystem functions and services, maintenance of local biodiversity  
other nature protection interests (UN heritage, avoiding implications for non-target organism, biosphere and landscape protection schemes, protection of certain types of natural and landscape features)

### b) Town and country planning (Art 192 TFEU)

spatial planning overarching objectives

# News from GMOs??

## Directive 2015/412 - compelling grounds (2)

### c) Land use

impossibility of coexistence (small fields)

Natura 2000 defined areas to protect specific grasslands, types of plants etc.

conflicts between different land use/production models and systems

specific soil protection measures (erosion, avoiding long-term GM-soil contamination etc.)

secure traditional good practice in agriculture business

areas reserved to ensure seed and plant propagating material purity



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## Directive 2015/412 - compelling grounds (3)

### d) Socio-economic aspects (Study UBA 2010)

#### Economic criteria:

1. Profit (e.g. reduced yield, squeezing out of production of special products),
2. Prosperity (e.g. reduced employment possibilities),
3. Preservation of the environmental basis (e.g. negative effects on natural resources, ecosystem services),
4. Costs during the whole production chain (e.g. increased costs for coexistence, security & control, image loss), Indirect costs (e.g. welfare system),
5. Tourists' expectations (e.g. loss of attractiveness, landscape changes),
6. Possibility to implement regional policy (e.g. GM-free Regions as a well-known "label")

# News from GMOs??

## Directive 2015/412 - compelling grounds (4)

### Social criteria:

1. Quality of life (e.g. income, health)
2. Food availability (e.g. GM-free products)
3. Labelling regime (e.g. freedom of choice)
4. Accessibility of alternatives and dependency (e.g. costs for GM-free seed, licence costs)
5. Freedom of research (e.g. patents, patented seed)
6. Preservation of cultural heritage (e.g. traditional production, autonomy)
7. Social changes (e.g. social structure, increased conflicts, burden for future generations)

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## Directive 2015/412 - compelling grounds (5)

### **Ecological criteria** (see also Environmental policy)

1. Preservation of resources (e.g. natural resources, energy use),
2. Preservation of environmental quality (e.g. soil, water, air),
3. Preservation of biodiversity in cultivated areas (e.g. agro-biodiversity, seed diversity)
4. Preservation of uncultivated areas (e.g. protected areas, wild relatives)

### **Ethics:**

1. Population`s values & Solidarity and equality (e.g. regarding weaker groups),
2. Value of nature (e.g. species barriers)

**Third countries aspects:** Safety (legislation ensuring safety assessment), Social cohesion (e.g. distribution of burdens), Minorities` rights (e.g. indigenous people)

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## Directive 2015/412 - compelling grounds (6)

### Other relevant issues:

1. Socio-economic goals on the national level, incl. scope, baseline, Respective criteria,
2. Data incl. models (e.g. on expected coexistence costs), Assessment possibilities (ex-ante evaluation), Justification: detail degree

### Open questions:

1. Scope (Should ethical issues be included? Should the impacts on third countries be assessed?)
2. Definitions (How to define a society that may be influenced (region, country, EU)? How can ethical & cultural values be defined?)
3. Baseline (Should conventional or organic agriculture serve as a baseline? Which impacts are acceptable, desirable or avoidable?)
4. Data quality and quantity: Which spatial & temporal scale should be assessed? Which criteria and indicators should be assessed? Which data need to be generated? Which scientific methods are suitable and are to be applied? Who will collect socio-economic data and conduct relevant studies? How can ethical & cultural values be quantified? Which data should be assessed on the European level and which data are specific to certain regions and countries?

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## Directive 2015/412 - compelling grounds (7)

e) the need to **avoid GMO presence** in other products such as specific or particular products (in Art. 26a) - Coexistence rules

f) **Agricultural policy objectives**

Maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability

Protected Designation of Origin – PDO

Protected Geographical Indication – PGI

Traditional Speciality Guaranteed - TSG: highlights traditional character

High costs to secure best available Non-contamination, impracticability or impossibility of implementing coexistence measures due to specific geographical conditions (small islands, mountain zones and mountainous areas)

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## Directive 2015/412 - compelling grounds (8)

### f) Agricultural policy objectives (2)

Small-scaled structure of agricultural production systems (pollen barriers, regulation of distances between GM, traditional and organic production do not meet the requirements of Non-contamination),

Guarantee of seed purity (areas),

Specific problems such as weather conditions, island, mountain areas, wind directions, share of GM-free production, organic production vs. GM-production

Image damage, Standing of a Region as GM-free, ecological, healthy safe and secure food and feed, green tourism wealthy cooking and eating vs. GM-contamination

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## Directive 2015/412 - compelling grounds (9)

### g) Public Policy

public order aspects (religious, ethics, moral grounds?)

avoiding social conflicts between farmers in cultivation areas,

factors relating to cultural traditions, respect of societal traditions in local areas regarding long-traditional methods of agri-production

Respect of cultural heritage, combined with regional-specific non-GM-production

### Other aspects:

Legal basis is Art 114 TFEU (internal market)

WTO conformity - EC points of view:

Art 26b) does not (directly) foresee a ban or restriction, it offers (only) an opportunity to EU-MS and/or Regions to do so. Therefore no problem for European law. In case of a WTO-panel would the EC defend the measures taken by a EU-MS.

# **Danke für Ihre Aufmerksamkeit!**

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