Analysis of the "opt-out": Legally certain GMO cultivation bans or a weak compromise?

Critical analysis of the Directive of 11 March 2015 amending the EU Release Directive 2001/18/EC as regards the possibility of Member States to prohibit the cultivation of GMOs in their territory.

It has taken four years to negotiate a so-called "out-out" clause in Brussels. It aims to present Member States with more possibilities to prohibit or restrict the cultivation of genetically modified (GM) plants that have been authorised in Europe in their territory. This should strengthen regions' right to self-determination, something that has been demanded by many GMO critics as also the "European GMO-free Network". In addition, it should also permit further reasons, for example socio-economic or agro-political factors - not only "new scientific evidence" as in the past - to prohibit the cultivation of GMOs.

To date, the Europe-wide ban on GMO cultivation demanded by the Arbeitsgemeinschaft bäuerliche Landwirtschaft (AbL) has not be politically implemented. A truly stricter and independent risk assessment of GMOs, as asked for by the EU Environment Council since 2008, has also not become a reality. The need for such action is nonetheless recognised and changes are to be implemented at the latest 2 years after entry into force, but whether that is proportionate to the risk posed by GMOs is debatable. Therefore, critics are justified in asking for an authorisation moratorium until the environmental risk assessment is truly tightened. This is now more important than ever, so as to prevent a flood of authorisations for new GMOs, under the guise of national bans. To avoid a patchwork across Europe, governments across the continent must answer authorisation applications from GMO corporations with a clear "No". This is the safest way to protect our GMO-free organic and conventional agriculture and environment.

The AbL analysis of the amendments to the EU Release Directive 2001/18/EC shows that the EU Council of Ministers and the Commission squandered the opportunity to reinforce the Directive and its possible implementation in Member States against foreseeable complaints by corporations. For example, demands from NGOs and the European Parliament like strengthening the legal certainty for possible bans by providing a further legal basis (Environmental Law, Article 192) or creating a precise list of reasons for bans were not taken on board. It is nonetheless positive that GMOs can be prohibited at any point in time - this also applies to groups of GMOs (i.e. crops or traits). Bans can also be issued due to reasons based on environment policy, though these can complement but not be contrary to the evaluation of the European Food Safety Authority (EFSA).

The AbL critically views the fact that corporations are still part of the decision-making process and can thereby strengthen their position. Their participation nonetheless (contrary the view of the Council) is no longer binding. Such a formalised say for corporations in the authorisation procedure is albeit a first and introduces a silent paradigm shift. It undermines the sovereignty of Member States and can be a taste of what's to come in terms of greater rights for corporations in future free trade agreements like TTIP and CETA. Furthermore, the Council of Ministers also turned down the introduction of binding, effective and immediately applicable coexistence measures as also a binding liability regime, which would take the polluter to task.

Maize flowers (BioSicherheit)

<u>Analysis of the amendments to Directive 2001/18/EC:</u>

The following text analyses the document **amending the EU Release Directive as regards national bans on GMO cultivation** of 11 March 2015.[(1)]

The negotiators of the European Parliament, the Council of Ministers and the Commission agreed on

Arbeitsgemeinschaft bäuerliche Landwirtschaft e.V., Bahnhofstraße 31,
59065 Hamm/Westf., Tel.: 04131/400720, volling@abl-ev.de, www.abl-ev.de

this document in December 2014. The compromise text was formally adopted by Parliament and Council in mid-January and March 2015 respectively.

The amendments to the EU Release Directive 2001/18/EC envisage a **two-phase model** within which Member States can prohibit the cultivation of GMOs: **during the authorisation procedure and after successful authorisation**. The Directive also deals with the withdrawal of cultivation bans, transitional periods, coexistence, environmental risk assessment and research. A report on the effectiveness of the Directive is also to be published.

In continuation, you have **excerpts from the Directive (*italics*)** followed by a **critical evaluation** of the same.[(2)]

Phase 1 (during the authorisation procedure):

***During the authorisation procedure of a given GMO or during the renewal of consent/authorisation**, a Member State may **demand** that the **geographical scope of the written consent or authorisation be adjusted to the effect** that all or part of the territory of that Member State is to be **excluded from cultivation**. That **demand** shall be communicated to the Commission at the **latest 45 days** from the date of receiving the assessment report from EFSA. The Commission shall present the demand of the Member State to the notifier/applicant and to the other Member States **without delay** and shall make the demand publicly available. **Within 30 days** from the presentation by the Commission of that demand, the notifier/applicant **may adjust or confirm** the geographical scope of its **initial notification/application**. In the absence of confirmation, the adjustment of the geographical scope of the notification/application shall be implemented (Article 26b, 1, 2).*

Evaluation of Phase 1:

In Phase 1, **corporations are accorded a formal role in the authorisation procedure**, which gives them the **right to have a say**. This was strongly opposed by the anti-GMO movement but the EU Council of Ministers held their ground. A further point of criticism is the fact that **corporations are not obliged** to comply with the bans demanded by Member States, but can reject them **without justification**.

If corporations do comply with the demands of Member States, the **authorisation is granted Europe-wide, with the exception of Member States or regions x, y, z**. It is however not clear if the concerned Member States must vote "in favour" or "abstain" when they wish to prohibit a Europe-wide authorisation within their territory. **A clear decoupling of this step**, as demanded by GMO critics, **has not been implemented.**

It is **positive** that Member States are not obliged to consult with corporations about a cultivation ban in Phase 1, but can **prohibit cultivation after authorisation has been received (Phase 2), independent of Phase 1**. For a long time, *only* Member States who had asked for a ban in Phase 1, but were unsuccessful, could impose bans in Phase 2. This condition has been deleted. **Member States can now** prohibit the cultivation of a GMO **at any point.**

Phase 2 (post EU cultivation authorisation):

***Where no demand was made in Phase 1, or where the notifier/applicant has confirmed** the geographical scope of its initial notification/application, **a Member State may adopt measures post authorisation** restricting or prohibiting the cultivation in all or part of its territory of a GMO, or of **a group of GMOs defined by crop or trait,** provided that such measures are in conformity with Union law, **reasoned, proportional and non-discriminatory** and, in addition, are based on **compelling grounds** such as those related to:*

(a) environmental policy objectives;
(b) town and country planning;
(c) land use;
(d) socio-economic impacts;
(e) avoidance of GMO presence in other products without prejudice to Article 26a;
(f) agricultural policy objectives;
(g) public policy.

*Those grounds may be invoked **individually or in combination**, with the exception of the ground set*

out in point (g) which cannot be used individually, ***but shall, in no case, conflict with the environmental risk assessment carried out by EFSA*** *(Article 26b, 3).*

A Member State which intends to adopt measures shall first communicate a ***draft of those measures and the corresponding grounds invoked to the Commission****. During a period of* ***75 days****, the Commission may make any comments it considers appropriate. During this study period, the Member State concerned shall refrain from adopting and implementing those measures and ensure that operators refrain from planting the GMO or GMOs concerned.* ***The comments from the Commission are non-binding.*** *If the measures are adopted in original or amended form, they shall be communicated to the Commission, the other Member States and the authorisation holder* ***without delay****. Member States shall make publicly available any such measure to all operators concerned, including growers (Article 26b, 4).*

The Directive is amended "having regard to the Treaty on the Functioning of the European Union, and in particular ***Article 114*** *thereof" (TFEU) (p. 1).*

Evaluation of Phase 2:

It is good that **Member States can prohibit the cultivation of GMOs at any point** during the entire authorisation period - independent of Phase 1. Furthermore, **similar GMO traits or crops** (e.g. all GMO rapeseed varieties) can be banned.

The **grounds for prohibition** may be related to environmental or agricultural policy objectives, regional planning or land use as also socio-economic reasons. Those grounds must be in conformity with Union law as also reasoned, proportional and non-discriminatory. These **vague legal terms leave much room for interpretation.**

The demand to base cultivation bans on Environmental Law (Article 192) has sadly not been implemented. The Council has based the grounds for prohibition on Internal Market Law (Article 114). Environmental Law would have led to greater legal certainty and would have strengthened the precautionary principle.

The European Parliament's **precise list of grounds for prohibition** was also **substantially shortened and weakened.** The fact that the stated **environmental grounds** cannot be in conflict with the environmental risk assessment carried out by EFSA is problematic. They **can, however, differ from and "complement" the EFSA assessment.** NGOs view EFSA's assessment quite critically as it does not evaluate many risks or do so in sufficient depth. Furthermore, the raw data that is the basis of industry studies referred to in the assessment is not published.

This leads us to conclude that **the legal certainty for the bans is not clearly established** - quite the contrary. Future complains from corporations will show which grounds for prohibition actually have a legal basis.

The grounds for prohibition in detail (Article 26b, 3):

Environmental policy objectives *may include:*

a) the maintenance and development of agricultural practices which offer ***better sustainability****, b) maintenance of* ***local biodiversity****, including certain habitats and ecosystems, or c)* ***certain types of natural and landscape features****, as well as* ***specific ecosystem functions*** *and* ***services*** *(Recital 14).*

Socio-economic grounds *may include:*

a) the ***high cost****, b)* ***impracticability or impossibility*** *of implementing coexistence measures due to c) specific* ***geographical conditions****, such as small islands or mountain zones, or d)* ***the need to avoid GMO presence in other products such as specific or particular products****, or e) in light of the outcome of the Commission report on socio-economic effects of GMO cultivation (Recital 15).*

Maize harvest (Pixelio)

Agricultural policy objectives *may include:*

a) the need to ***protect the diversity of agricultural production*** *and b) the need to ensure* ***seed and plant propagating material***

***purity**. c) **Land use, town and country planning, or other legitimate factors including those relating to cultural traditions** may also be used (Recital 15).*

Evaluation of the grounds for prohibition:

In spite of various examples for grounds for prohibition, they still remain **legally vague**. In addition, they are not part of the main text but are mentioned only in the **recitals**. This is to be seen as an open list, which can be creatively added to. The European Parliament proposal should serve as inspiration.[3]

Withdrawal of a cultivation ban:

*Where a **Member State wishes all or part of its territory** to be **reintegrated** into the geographical scope of the consent/authorisation, it may make a request to that effect to the **competent authority,** who shall **amend** the **geographical scope** of the consent or of the decision of authorisation accordingly. The Member States and the authorisation holder shall be **informed accordingly without delay** (Article 26b, 5-7).*

Evaluation:

The fact that a government may lift an existing cultivation ban **without any defined deadlines or grounds** is problematic. Merely informing the competent authority, the authorisation holder and the other Member States is enough. **This is an issue for GMO-free organic and conventional farming and food production** as they have no transitional periods **to prevent contamination.** This leads, furthermore, to **a massive curtailment of planning security.**

Research (*Recital 19, 20*):

*(Cultivation bans)... **should not prevent biotechnology research from being carried out provided that**, in carrying out such research, **all necessary safety measures** relating to human and animal health and environmental protection are observed and that the activity **does not undermine** the respect of the **grounds on which the restriction or prohibition has been introduced**.*

*EFSA and the Member States should aim to establish **an extensive network of scientific organisations** representing **all disciplines.** They should **cooperate** to identify at an early stage any **potential divergence** between scientific opinions with a view to resolving or clarifying contentious scientific issues. The Commission and the Member States should ensure that the **necessary resources for independent research** on the potential risks are made available. Moreover, **independent researchers should be given access to all relevant material, while respecting intellectual property rights.***

*The Authority should **collect and analyse the results of research** and inform the risk managers and **the public** of any emerging risks.*

Evaluation:

The Directive makes it clear that research is considered important. Safety measures must be respected and the research may not conflict the grounds for prohibition. One of the issues is that research is not well-defined in this text. In Germany, there is still no way to stop releases in the Gatersleben Gene Bank or in the Üplingen Show Garden, which solely for display purposes. Even the propagation of seed potatoes over 115 hectares has been declared as cultivation for research. Civil society objections have been turned down by the authorities.

It is nonetheless positive that **independent researches should be given access to all relevant material**, while respecting intellectual property rights. There is also a mention of funding for independent research. Nonetheless, the Directive remains vague: Neither notifiers nor biotechnology corporations that sell GMOs should provide the funds, rather it is up to the Commission and the Member States to make the necessary provisions. **Funding provided by research funds that are supported by industry have not been included. There is no mention of funding volumes.**

Coexistence and liability (Article 26a):

As from 2 years after entry into force**, Member States in which GMOs are cultivated **shall take appropriate measures in border areas of their

territory *with the aim of* ***avoiding*** *possible cross-border contamination into neighbouring Member States in which the cultivation of those GMOs is prohibited,* ***unless such measures are unnecessary in the light of particular geographical conditions****. Those measures shall be* ***communicated to the Commission****.*

Evaluation:

The negotiators squandered the opportunity to implement **proportionate, binding, effective and strict coexistence measures** (without exceptions) **as also liability rules.** Some EU Member States (like Spain) have not even so much as introduced such rules. The measures are worded very weakly - contamination should be **"avoided" and not prevented** - and they become applicable **only 2 years after entry into force**. What happens in the interim period is not addressed. There is **no mention of sanctions.** There is also **no "opt-out clause"** for when coexistence is not possible.

Maize flowers (BioSicherheit)

Moreover, **a binding liability regime,** as demanded by the European Parliament, **was not implemented**

Even in Germany, the liability rules are insufficient - for example, only "added market value" must be compensated, whereas other losses and precautionary measures taken to ensure GMO-free production are not included. **Implementing the "polluter pays principle" would have been significant progress.**

Report on effectiveness and damages (Article 2):

No later than 4 years after *the date of entry into force of this Directive,* ***the Commission*** *shall present* ***a report*** *regarding the use of provisions to restrict or prohibit the cultivation of GMOs, including* ***the effectiveness of these provisions.*** *That report may be accompanied by appropriate* ***legislative proposals****.*

By the same date, the Commission shall also report on the actual remediation of environmental damages that might occur due to the cultivation of GMOs.

Evaluation:

It is positive that **the Commission has to report on the effectiveness of the Directive and on the environmental damages of GMOs.** However, there is no mention of what would deem the Directive as "ineffective" and what direction potential changes should then take. There is also no clarity on what happens if environmental damages have not been sufficiently remedied.

Transitional measures (Article 26c):

Within 6 months of date of entry into force *of the Directive (October 2015), a* ***Member State*** *may* ***demand*** *that the geographical scope of an authorisation granted be* ***adjusted****. The Commission shall present the demand of the Member State to the notifier/applicant and to the other Member States without delay. If the notifier/applicant confirms or does not respond* ***within 30 days****, the geographical scope of the notification/application shall be adjusted accordingly (Paragraphs 1-3).*

Environmental risk assessment (Article 3):

No later than 2 years from the date of entry into force, the Commission shall update the ***Annexes to Directive*** *as regards the* ***environmental risk assessment****, with a view to incorporating and building upon the strengthened 2010 Authority guidance.*

According to Recital 3, it is necessary to look for improvement of the implementation of the legal framework for the authorisation of GMOs. In this context, ***the rules on risk assessment should be, where needed, regularly updated*** *to take account of continuous developments in* ***scientific knowledge and analysis procedures****, in particular regarding the* ***long-term environmental effects*** *of genetically modified crops as well as their potential effects on* ***non-target organisms****, the characteristics of* ***receiving environments*** *and the*

geographical areas in which genetically modified crops may be cultivated, and the criteria and ***requirements for assessing GMOs producing pesticides and herbicide tolerant GMOs****.*

Evaluation:

Though it is recognised that there is room for improvement in terms of the environmental risk assessment, this will **only be addressed 2 years after entry into force** of the Directive and the **wording** ("where needed") **is very vague**. Moreover, it only refers to the woolly EFSA guidance document and **no real strengthening is demanded**. GMO critics are thus justified in asked for an **authorisation moratorium** until environmental risk assessment is truly tightened.

What comes next?

The Directive now has to be transposed into national law if Member States wish to have recourse to these new grounds for prohibition. The debate has advanced further in Germany and Austria.

The sticking point in Germany is whether bans should be issued at the centre or at Länder level and whether the Federal or the Länder governments should be in-charge of cultivation bans. If the responsibility is passed on to the Länder and the regions, a patchwork solution is a given as it will lead to potentially 16 different rules to prohibit cultivation and will pose a significant contamination risk.

To effectively protect both the GMO-free agricultural and food industries, a uniform cultivation ban from the Federal government is a must.

Conclusion:

As shown by the AbL background document "Authorise... and then prohibit?" (in German), **the possibility of prohibiting GMO cultivation nationally is a double-edged sword, when trying to keep Europe safely GMO-free.** The transposition in EU Member States must be critically and very actively monitored. Only time will tell if the Directive presents enough legal certainty. **A European or national patchwork approach must be avoided at all costs.** GMO authorisation applications should not be issued and should receive a clear "No" from all EU governments. **It would be the simplest and cheapest way for us to keep agriculture and food production - as it is even today - GMO-free across the EU.**

---

1 Directive (EU) 2015/412 of the European Parliament and the Council of 11 March 2015 amending Directive 2001/18/EC; cf. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2015:068:TOC

2 An in-depth analysis of the Council proposal of June 2014 and the Parliament proposal of November 2014 can be found in the AbL background document: "Authorise... and then prohibit? National GMO bans - straddling sovereignty and corporate dependence" (in German), http://www.abl-ev.de/fileadmin/Dokumente/AbL_ev/Gentechnikfrei/Anbau_u_Freisetzungen/AbL-Hintergrundpapier_opt_out_Nov._2014_klein.pdf

3 Draft report of the Committee on the Environment, Public Health and Food Safety of the European Parliament by Corrine Lepage, 20.04.2011, A7-0170/2011.

Author and further information:
Annemarie Volling, Arbeitsgemeinschaft bäuerliche Landwirtschaft (AbL) e.V., Tel: 04131/ 400720; volling@abl-ev.de, www.abl-ev.de

For their friendly support, we would like to thank:

STIFTUNG GEKKO
Für eine biologisch vielfältige, sichere und nachhaltige Welt

FaNaL Verein zur Förderung einer Nachhaltigen Landwirtschaft

Would you like to support our work?
We welcome **donations** to our association "Verein zur Förderung einer nachhaltigen Landwirtschaft – FaNaL e.V.":
Recipient: FaNaL e.V. Rheda-Wiedenbrück
IBAN: DE68478535200002029379
Credit institution: Kreissparkasse Wiedenbrück