Deutsche Forschungsgemeinschaft
German Research Foundation

Statement by the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) on the Draft Legislation to Reform the Law on Genetic Engineering

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General Aspects

This draft legislation is intended to implement EU Directive 2001/18/EU on the deliberate release into the environment of genetically modified organisms [referred to below as GMOs]. The Directive requires member states to take the precautionary principle into account (Article 8) when implementing the "appropriate control of risks" when GMOs are released. However, this requirement does not free the German federal government and the legislature from considering general principles of appropriateness, particularly in so far as the draft legislation affects legal matters subject to constitutional protection, such as freedom of research and freedom of occupational practice.

As part of the regulation of the release and placing on the market of GMOs, the draft legislation introduces an extension of the objectives of the law (Article 1 clause 2 new version), namely the principle of "co-existence", which is defined as co-existence of "agriculture using genetic engineering with conventional and ecological agriculture." The vast majority of the following individual regulations nevertheless contradict the stated objective of the law. They present obstacles due to disproportionate conditions, which in practice–as the sum of the direct and indirect consequences of the planned regulations–will affect only one of these three forms of agriculture, namely the use of genetic engineering. Not only the agricultural use of "green genetic engineering", but also its use in research will be excluded, not according to the law, but by the predictable effects of the new regulations.

The scientific goals of "green genetic engineering" include the acquisition of new knowledge and the development of new applications. There is a wide variety of possible new applications, including the protection of the ecological balance in habitats subject to agricultural use, by reducing the application of substances which also have toxic effects. Other objectives include increased efficiency in agricultural practice, for example, by improved protection against loss of harvest, and the cultivation of new varieties that are specially adapted to local conditions in countries where increased yields are urgently necessary to ensure that the population can be fed. There is no evident attempt in this draft legislation, or in its official explanation, to balance these goals with the supposed risks of exploiting "green genetic engineering". The opportunity to incorporate the scientific findings introduced into the discussion on green genetic engineering–in which the Federal Ministry of Consumer Protection, Food and Agriculture has played a decisive role–has been missed.

The effects of the draft legislation would be a major restriction in the freedom of research, particularly by equating the conditions and legal consequences (e.g., liability) of releases for scientific purposes with placing on the market for commercial reasons. Constitutional law requires freedom of research to be weighed up against other legal objects protected by constitutional law, but this has not been done.

The draft legislation almost exclusively contains regulations to protect against dangers, although the very existence of these dangers is unproven. Rather, reference is made to Directive 2001/18/EU and to the fact that, according to this directive, certain risks

cannot be excluded with certainty. Current knowledge in this area–including the knowledge gained since the Directive 90/220/EEC came into force, since replaced by Directive 2001/18/EU–has not been considered. There is also no counterpart in the draft legislation and its official explanation to the aspects discussed in Article 20ff of Directive 2001/18 EU related to the harmonisation of tests of environmental compatibility, the necessity for risk assessment, etc.

Details

Procedure and Deadline

Directive 2001/18/EU had to be implemented by 17 October 2002. The letter by the Federal Ministry of Consumer Protection, Food and Agriculture offered the opportunity to make comments on the draft legislation. This letter was dated 16 January 2004 and specified a deadline of 14 days. This is inappropriate and disproportional, since it is not possible to perform a thorough examination within this period. This letter is therefore inconsistent with their own previous procrastination and gives the impression that the hearing is to be regarded as a formality. Later comments are therefore to be anticipated.

No. 2

In Article 1 clause 1 “the consideration of ethical values” is introduced for the first time as the protective objective of the legislation. This is not convincing. The protection aimed at in the law is, in itself, an ethical value. “The consideration of ethical values” in the wording of the law is an undefined legal concept. The reference in the official explanation to the draft legislation to the “express emphasis” of the German Law on Animal Protection is misplaced, as it is not mentioned in the text of the law.

The current version of the Genetic Engineering Act states that it should provide “protection against hazardous substances and the environmental impacts of genetic engineering.” Instead of this, the new text mentions “harmful effects“, as if these were not only possible, but probable, or even proven. This is however not the state of current knowledge. The law should return to the previous wording in this respect.

No. 4 c)

The definition of “placing on the market” contains a new restriction. This is not explained in the official explanation and will restrict research. Art. 2 clause 4 of Directive 2001/18/EU is implemented here in such a way that only the preparation of work in genetic engineering units or for releases which have already been approved should not count as placing on the market. This is not what the Directive calls for. This starts a vicious circle, as approval for release then requires experience with placing on the market, which is in turn linked to more demanding conditions.

What is required instead is a regulation which unambiguously states that exchange of GMOs between scientific institutes for scientific purposes does not count as placing on the market.

No. 5

Article 4 clauses 1 and 5a provide for the creation of a separate “committee for releases and placing on the market.” This is inappropriate for a number of reasons.

- The Central Commission for Biological Safety in its current membership and manner of work has convincingly proved its value. There is no persuasive reason to alter the existing structures.
- It is not totally clear whether there are enough qualified experts available in Germany to occupy two separate statutory bodies with related responsibilities. [The appointment of foreign nationals to the Central Commission for Biological Safety is still only expedient to a limited extent.]
- The objective context of the responsibilities still speaks for their treatment by a single statutory body. This applies, for example, to the scientific questions, the safety problems and to the legal issues, which involve both federal and state jurisdiction.
- Article 5a amends the requirements for membership of the committee. This is now to include the same number of experts and subject experts. Expertise in genetic engineering is no longer a requirement for at least some of the members. This fails to fulfil the standards which can be expected of an expert statutory body.

No. 6 a)

The wording in paragraph 1 Sentence 3 (resistance to antibiotics) differs here unnecessarily from the wording in Art. 4 clause 2 of Directive 2001/18/EU and is, as a result, incomprehensible. The wording of the Directive should be used here, if better wording cannot be found.

No. 11 (together with No. 26)

There has been a demand for many years that the procedure for work in safety grade 1 (as in Article 8 new version) and for additional work in safety grade 2 should be facilitated. The overall effect of the planned amendments in Article 12 and Article 26 is to make these amendments null and void, by equating the requirements and legal consequences of the registration and notification procedures in almost every respect.

This can be seen by looking at the example of the new paragraph 6a. This provides the authorities with very wide discretionary powers for sweeping measures, which could, for example, have the practical consequence of delaying a research project for a full year, as the window of opportunity for the planned study will already have closed once the legal steps have been successfully taken. This is unacceptable for constitutional reasons.

No. 12 a)

The amendment in the new No. 4 of Article 14 clause 1 Sentence 1 is not reasonable in its present form. The wording of the law and the official explanation should be consistent.

The reference to “No. 2” is incorrect. The claim by the official explanation that no. 4 “forbids” something is incorrect.

Apart from these inconsistencies, the wording used here – “Products extracted or manufactured from organisms modified by genetic engineering“ – is totally unacceptable. According to food law regulations, sugar is still sugar, irrespective of the genetic makeup of the beet from which it was extracted.

No. 14 a)

Article 16 clause 1 No. 2 (new version) extends the safety precautions by adding the

obligation to demonstrate “that hybridisation has been reduced to the lowest possible level.” This is too vague to guarantee legal security. It is also true that not every hybrid presents a risk.

Paragraph 4 of the new version gives the German Federal Agency for Nature Conservation as the consent agency for the first time. This is, at most, appropriate for the cases in Article 16 of the new version. This responsibility should, in general, remain with the Federal Biological Research Centre for Agriculture and Forestry (BBA), as only this agency has the necessary expertise.

No. 15

The definition of justified interest in information in Article 16 a clause 5 is inappropriate. For example, it is not stated anywhere whether the applicant has the usage right for the plot of land in question.

The regulations in Article 16 b violate the rule of reasonableness. They allow the responsible state authority practically the unrestricted right to prevent the use of any products which contain or could contain GMOs, even if they have legally been placed on the market. The conditions for approval have been expressed so broadly that legal steps would appear futile from the outset. There is no problem in including the protection of ecologically sensitive areas in the conditions for approval in Article 16.

At present, it is not possible to assess the scope of the new Article 16 c. It is doubtful whether the elements of “good technical practice” as summarised here can be implemented in practice in a sensible way and, if so, whether the necessary effort would be appropriate.

No. 19

There is a discrepancy between the wording of the law and of the official explanation. Even the current wording of Article 18 clause 2 of the Genetic Engineering Act fulfils the requirements of Directive 2001/18/EU. The new wording can only be reasonably understood as an intentional displacement of the balance between what is the rule and what is the exception with respect to the conditions for a hearing. This is not acceptable.

No. 29

The text and official explanation for clauses 1 and 2 of Article 28a are not logical. (The provisions for what is compulsory and what is permissible have been transposed.)

No. 34

The consideration of the relevant parties’ interests in different situations of neighbour law in the new Article 36 is imbalanced and this must be corrected. The exclusion of local custom as a defence in section 3 can, for example, privilege a party who acquires a plot of land that is largely or even exclusively dominated by the cultivation of GMO (if this were possible) and then claims to cultivate it “free of genetic engineering.”

All in all, and particularly in their unilateral character, the extension in the liability regulations in Article 32 et seqq., together with the precautionary obligations in Article 16 c, represent an encroachment on professional freedom. The required weighing up of competing fundamental rights has not been performed. From this point of view, it is

doubtful whether the draft legislation is in accordance with constitutional law. This also applies to the legally fictional definition of economic acceptability for the, as yet, vague requirements of Article 16 c of the draft in paragraph 2 and for the liability for the overall debt in paragraph 4. There is no basis at all for such a definition.

The use of the term “damage” as a synonym for “impairment” in paragraph 4 is inappropriate.

No. 35 a

The amendment contravenes both constitutional principles (requirement for clarity) and current knowledge obtained from studies on the danger from working with safety grade 1 (there are no such studies). The regulation is also hostile to research. It should therefore be stopped.