Memorandum

On the question of the applicability of the statements of the European Court of Justice in case C-528/16 to the area of regulation of Directive 2009/41/EC on the contained use of genetically modified micro-organisms

Commissioned by the
Federal Agency for Nature Conservation (BfN)

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I. Subject of the analysis

Following the judgment of the European Court of Justice (ECJ) in Case C-528/16, the question was raised as to whether the findings can be applied to work involving contained uses. The possibility of such a spill-over effect of the judgment was denied, with a reference to the fact that the sole subject of the judicial appraisal was the regulatory regime of Directive 2001/18/EC on deliberate release. It was further pointed out that the European Court of Justice based its judgment very substantially on recital 17 of Directive 2001/18/EC, and that no comparable recital is present in Directive 2009/41/EC on contained use. This Memorandum examines the question of whether this evaluation is convincing from a legal point of view.

II. Preliminary considerations

Both German and European law assume, as a matter of principle, an inter partes effect of decisions by the specialised courts.[1] Therefore, effects extending beyond the specific case in question are not assumed per se. On the other hand, even at the level of the first-instance courts, it is apparent that certain judgments can have an impact well beyond a particular individual case. This is always so when the decision is not primarily attributable to the specific facts of the case, but rather presents

[1] Recently in this context, e.g. BVerfG, NJW 2018, 2695ff para. 132, Juris.

legal considerations which are fundamentally relevant for a number of similar cases. Consequently, judicial decisions issued by other formations of the court or cited in literature are used here to corroborate a legal deduction.

The effect described is further reinforced if the decision is issued, not by a specialised court, but by a constitutional court or judicial body of similar standing; the judgments of such courts can no longer be appealed and regularly concern highly political issues. It seems here rather presumptuous to base an argument on the inter partes effect or on the focus of a decision which arose from a matter referred for preliminary ruling.[2] These general considerations notwithstanding, this Memorandum presents the key arguments supporting the full application of the legal considerations set out in the judgment to the law under Directive 2009/41/EC on contained use.

III. Effects of the primary law provision of Article 191(2) second sentence TFEU

[2] For instance, the recent comments on the spill-over effect of the ECHR judgment by the Federal Constitutional Court (BVerfG), NJW 2018, 2695ff, para. 132, Juris: "If the rights enshrined in the Convention have no precedence over German constitutional law, but are in fact relevant as a principle of interpretation for the Basic Law, taking the judgment of the European Court of Human Rights into account beyond its inter partes effect is primarily aimed at identifying and addressing statements on the fundamental values of the Convention [...]. As far as possible, conflict with the fundamental values of the Convention must be avoided."

As is well-known, the European Union has no competence-competence,[3] but relies on the narrowly defined catalogue of authorisation bases which the member states agreed to confer, and which were therefore explicitly anchored in the primary legislation.

In its original version, and still now in its current version, Directive 2009/41/EC on contained use was and is expressly and exclusively based on Article 175(1) TEC (ex-Article 130s TEC, current Article 192 TFEU). This directive is thus without question an environmental measure. As far as can be determined, the correctness of this classification has not been contested to date.[4] For the specification of the goals to be pursued by environmental policy, Article 175(1) TEC referred to Article 174(1) TEC, which accordingly defined the following permissible goals for European environmental policy:

- Preserving, protecting and improving the quality of the environment;

- protecting human health

[3] Judgment of the Federal Constitutional Court, see e.g. recent judgment BVerfG 142, 123ff, para. 130, Juris with further references.

[4] By way of example Bakhschai, in: Fuhrmann, Klein and Fleischfresser (eds.), Arzneimittelrecht, 2nd 2014 edition, Section Gentechnikrechtliche Besonderheiten, para. 8.

- prudent and rational utilisation of natural resources

- promoting measures at international level to deal with regional or worldwide environmental problems.

The cardinal principles determining the realisation of these goals were then set out in Article 174(2) second sentence TEC: "[Community environmental policy] shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay."

As is known, the Lisbon Treaty led to a redrawing of the foundations of the primary law of the European Union, which now had the status of a legal entity. Environmental policy is now set out in Article 191ff. TFEU, and this has certainly not resulted in any weakening of the fundamental principles described above.[5] In particular, the precautionary principle continues to define all measures of European environmental policy. Article 191(2) second sentence TFEU thus maintains, in full and virtually word-for-word, the content of Article 174(2) second sentence TEC.

Regarding the significance of the precautionary principle in the use of new genetic engineering

[5] The inclusion of climate change in the catalogue of environmental policy goals is not relevant here.

techniques, the ECJ has pointed out on various occasions that the precautionary principle permeates the entire body of legislation governing deliberate release, in order to prevent possible adverse effects on human health and the environment arising from the use of new genetic engineering techniques.[6]

Understood thus, the precautionary principle can only be given due consideration in the use of new genetic engineering techniques if the legal appraisals apply not only to deliberate release and placing on the market, but also to work involving contained use. Otherwise, gaps in protection would become apparent which cannot be reconciled with the precautionary principle and the statements relating to it issued by the ECJ.

IV. Directive 2001/18/EC on deliberate release and Directive 2009/41/EC on contained use as a complementary system

Notwithstanding all regulatory differences in the finer points, it is clear that Directive 2001/18/EC on deliberate release and Directive 2009/41/EC on contained use stand in a direct relationship to each other which extends far beyond a purely referential function. Even their history of a "coupled" adoption as Directives 90/219/EEC and 90/220/EEC points to the approach being pursued with the two regulatory instruments: from the beginning, the goal of the European legislator was the seamless regulation of

[6] ECJ judgment of 25.07.2018 in case C-528/16, paras. 50, 52, and 53, Juris.

genetic engineering techniques, from the laboratory through to placing on the market.[7]

Thus, the two directives complement each other, a fact that – as far as can be determined – is undisputed.[8] This means that, subject to specific sectoral exemptions, either Directive 2009/41/EC on contained use or Directive 2001/18/EC on deliberate release must apply; only provisions containing safety and precautionary standards which are as stringent in every way as those of the directives can even be considered as a substitute under specialist legislation.[9]

For this complementary system to function, it is vital that the directives are in lockstep, not only with regard to their key terminology, but also in the uniformity of their underlying regulatory philosophy and basic core principles. Thus, functionality could no longer be guaranteed if, for example, organisms defined as GMOs under Directive 2001/18/EC on deliberate release were deemed not to be GMOs under Directive 2009/41/EC on contained use,

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[7] Also explicitly noted by Herdegen and Dederer (eds.) in Internationales Biotechnologierecht, Folder 1, 54 updated version of November 2018, EU law/clarifications I 2, para. 49.

[8] Schröder, Freisetzung von gentechnisch veränderten Organismen, in: ZUR 2011, 422 (425) with reference to Voß, Die Novelle der Freisetzungsrichtlinie – Richtlinie 2001/18/EG, 2006, p. 183; Herdegen and Dederer (eds.), in: Internationales Biotechnologierecht, Folder 1, 54 update of November 2018, EU law/clarifications I 2, para. 49.

[9] Herdegen and Dederer (eds.), in Internationales Biotechnologierecht, Folder 1, 54 update of November 2018, EU law/clarifications I 2, para. 49.

or if measures serving to implement the precautionary principle were considered appropriate in cases of application under Directive 2001/18/EC on deliberate release, but were viewed as unnecessary in work involving contained use.

Applying the principles established by the European Court of Justice solely to issues relating to deliberate release would cause the complementary system under EU law to break down to such an extent that the functioning of the reciprocity described above would not be merely marginally affected, but completely undermined.

V. The lack of provision corresponding to recital 17

Recital 17 of Directive 2001/18/EC states: "This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record." In fact the text of Directive 2009/41/EC on contained use includes no corresponding provision. However, it cannot be concluded from this purported "gap" that the statements of the ECJ would not apply to work involving contained use. This evaluation is essentially based on two lines of argument.

Firstly, it is important to understand the overall regulatory context in which the ECJ places recital 17. The full wording of the relevant passage of the judgment is as follows:

"Moreover, as stated in recital 4 of Directive 2001/18, living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers, thereby affecting other Member States. The effects of such releases on the environment may be irreversible. In the same vein, recital 5 of that directive states that the protection of human health and the environment requires that due attention be given to controlling risks from such releases.

Furthermore, it has been emphasised, in recital 8 of that directive, that the precautionary principle was taken into account in the drafting of the directive and must also be taken into account in its implementation. Emphasis is also placed, in recital 55 of Directive 2001/18, on the need to follow closely the development and use of GMOs.

In those circumstances, Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive, cannot be interpreted as excluding, from the scope of the directive, organisms obtained by means of new techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18 was adopted. Such an interpretation would fail to have regard to the intention of the EU legislature, reflected in recital 17 of the directive, to exclude from the scope of the directive only organisms obtained by means of techniques/methods which have

conventionally been used in a number of applications and have a long safety record."[10]

In this light, recital 17 is a direct expression of the precautionary principle. Its central function is to clarify that only techniques that "have a long safety record" can be excluded from the scope of the directive, with reference to Article 3(1) of Directive 2001/18/EC on deliberate release in conjunction with point 1 of Annex I B. However – as explained under III – since Directive 2009/41/EC on contained use is an instrument of European environmental policy and therefore already committed to comprehensive compliance with the precautionary principle through the primary law provision of Article 191(2) second sentence TFEU, no further clarification in the sense of recital 17 of Directive 2001/18/EC is needed in Directive 2009/41/EC.[11] For this reason alone, and despite the lack of a provision comparable to recital 17, the statements of the ECJ are also applicable to work involving contained use.

Secondly, the ECJ's understanding of the risk makes the statements in judgment C-528/16 applicable to Directive 2009/41/EC on contained use as well. The ECJ states as follows:

"As the referring court states in essence, the risks

[10] ECJ, ECJ judgment of 25.07.2018 in case C-528/16, C-528/16, para. 49ff. Juris.
[11] See also, however, recitals 2, 3, 5, 13 and Article 1 of Directive 2009/41/EC on contained use.

linked to the use of those new techniques/methods of mutagenesis might prove to be similar to those which result from the production and release of a GMO through transgenesis. It thus follows from the material before the Court, first, that the direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects as the introduction of a foreign gene into that organism and, secondly, that the development of those new techniques/methods makes it possible to produce genetically modified varieties at a rate and in quantities quite unlike those resulting from the application of conventional methods of random mutagenesis."[12]

These risks assumed by the ECJ[13] may have particularly drastic impacts in the case of deliberate release, but obviously are not limited to this scenario. Particularly in conjunction with the ECJ statements on the effects of the precautionary principle, compliance with primary law when dealing with the risks of new genetic engineering techniques requires that relevant provisions be extended to the scope of Directive 2009/41/EC on contained use, even

[12] ECJ, ECJ judgment of 25.07.2018 in case C-528/16, para. 48, Juris.

[13] In this context, some hold the erroneous view that these were not the conclusions of the ECJ itself, but that the ECJ adopted the findings of the referring court. Irrespective of the fact that this in itself would not preclude any binding nature of the statements, the unambiguous language of the judgment shows the assertion to be wrong, as the ECJ makes a clear distinction between the referring court (not capitalised) and its own findings - i.e. those of the Court (capitalised).

though this directive contains no provision comparable to recital 17.

VI. Summary

In conclusion, it can be established that the arguments put forward against extending the statements of the ECJ to the area of application of Directive 2009/41/EC on contained use are not persuasive. On the contrary, their postulated non-application to work involving contained use would lead to a violation of the standards enshrined in primary law, to irreparable systemic distortions and to unjustifiable risks to human health and the environment.