Genetically modified organisms GMO and EU agricultural law – certain aspects in the light of ECJ judgement C-528/16

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A. Introduction

In EU agricultural law legal norms concerning agricultural production are combined with those aiming to protect environment and guarantee safe food and feed.

By GMO is meant genetically modified organisms – like plants, animals, bacteria, virus – whose genome has been artificially modified to get new characteristics. These goals can be better resistance to a malady, weed or insect. GMO can also raise production, quality and nutritional value of cultivated plants and food stuffs. By means of GMO has also been raised tolerance of some plants towards herbicide.[1] New plant breeding techniques such as Crisp/Cas have the potential to improve sustainability in agriculture. On the other side there can be risks for humans, animals and environment when very old complicated genetic inheritance of an organism is changed rapidly.

[1] Bianci, p. 535-536

The central EU legal norms relating to GMO are TFEU 191 article (precautionary principle) and also 34-36 articles (free movement of goods, restrictions based on human and animal health). Several international agreements like Cartagena agreement and specially WTO-agreements (GATT, SPS and TBT) relate essentially to the sector.

The central derived EU legislation on GMO consist of Council directives 2001/18/EC and 2009/41/EC. Special feature in these directives is that they aim to reach safety by regulating complex methods and techniques. To the central context of GMO regulation belong also Parliament and Council regulations (EU) N:o 1829/2003 and 1830/2003.[2] Key regulation in this respect is also Parliament and Council regulation (EU) 178/2002 by which general principles on food law were coded and European food safety authority EFSA was founded. These horizontal rules organizing the use of genetically modified organisms can be divided to three phases: research and contained use – risk evaluation and authorization – cultivation and placing on market.

Traditionally and still at the beginning of first decade of this millennium EU market organization measures were made product by product approach. GMO is today also governed vertically by product sector measures.[3] This sort of regulation is in following directives: Council directive 2002/53/EC (cataloque of varieties of agricultural plant species), Council directive 2002/54/EC (marketing of beet seed), Council directive 2002/55/EC (marketing of vegetable seed), Council directive 2002/56/EC (marketing of seed potatoes), Council directive 2002/57/EC (marketing of oil seed and fibre plants), Council directive 2008/72/EC (marketing of vegetable propagating and planting material, other than seed) and Council directive 2008/90/EC (marketing of fruit plants and propagating material). From older relating regulation can be named Council directive 66/401/EEC (marketing of fodder plant seed), Council directive 66/402/EEC (marketing of cereal seed), Council directive 68/193/EEC (marketing of vegetative propagation material of vine), Council directive 98/56/EC (marketing of propagating material of ornamental plants) and Council directive 1999/105/EC (marketing of forest reproductive material).

To GMO context belong also Parliament and Council regulations (EU) 1107/2009 (placing on market of plant protection products) and (EU) 726/2004 (authorization of medicinal products for human and veterinary use).

Council regulation (EC) N:o 2100/94 concerns plant variety rights and Council regulation (EU) N:o 834/2007 deals with organic farming in which production method GMO is not allowed. When agricultural products and food stuffs are prosessed as important connected elements can also be named Parliament and Council regulations (EU) 1332/2008 (food enzymes), (EU) 1333/2008 (additives) and (EU) 1334/2008 (aromes).

At GMO sector we do not suffer from the lack of definitions. In EU law there are important production borderlines between GMO, conventional and organic agriculture. According to Council regulation (EU) N:o 834/2007 organic farming cannot be GMO. If a plant variety is GMO it can be cultivated, marketed and used as food stuff or feed after administrative authorisation meant in Council regulation (EU) N:o 1829/2003 and Council directives 2001/18/EC and 2002/53/EC. If a product clearly turns out to be GMO or unauthorized GMO, it can mean considerable economic

[2] Blumann (and others) p. 347
[3] Bianchi, p. 6 and 36

setback in organic and conventional agriculture by loss of sales income and public subvention. Mixed products may also cause liability for damages both in marketing and farming.[4]

Central concepts and definitions concerning GMO and mutagenesis are in Council regulation (EU) N:o 1829/2003 and Council directive 2001/18/EC. These concepts need to be clear enough and in line with each other in sector legislation in order to guarantee that production market (plant cultivation) and food & feed market are safe and function in EU. Uncertainty is a bad scenario at market, if it is unclear how a plant variety should be classified.

Above mentioned legislation aims to reach product safety and in directive 2001/18/EC this objective is to be reached by defining and regulating the methods and techniques editing genome. Depending on the techniques used some modified organisms can be classified GMO and some not, although from the end product you cannot tell by which techniques genome was edited. When no foreign genes are involved you cannot even differ edited genome from the fact that mutation could have occurred naturally.[5]

A practical way to focus this question is to do it via ECJ judgement C-528/16. In this case for a preliminary ruling Conseil d´Etatof France made 4 questions to the ECJ relating to the definition GMO/mutagenesis and Council directives 2001/18/EC and 2002/53/EC.

B. In ECJ judgement applied provisions of derived EU legislation

The central provisions in Council directives 2001/18/EC and 2002/53/EC are following:

Article 1 of directive 2001/18 provides:

‘In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when:

– carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community,

– placing on the market genetically modified organisms as or in products within the Community.’

Article 2 of Directive 2001/18 provides:

‘For the purpose of this Directive:

…

(2) “genetically modified organism (GMO)” means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

[4] Rosso-Grossman, p. 221 and 247; Hollo p. 179-180 and 200-201
[5] Dederer, p. 111-112

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

(3) "deliberate release": any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment;

…'

Pursuant to Article 3(1) of the directive:

'This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.'

Article 4 of Directive 2001/18 sets out general obligations for the Member States. Paragraph 1 thereof provides:

'Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. GMOs may only be deliberately released or placed on the market in conformity with part B or part C respectively.'

Article 36 of that directive provides:

'1. [Council] Directive 90/220/EEC [of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ 1990 L 117, p. 15)] shall be repealed on 17 October 2002.

2. References made to the repealed Directive shall be construed as being made to this Directive and should be read in accordance with the correlation table in Annex VIII.'

Under the heading 'Techniques referred to in Article 2(2)', Annex I A to Directive 2001/18 provides:

'PART 1

Techniques of genetic modification referred to in Article 2(2)(a) are inter alia:

(1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules …

(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism, …

(3) cell fusion (including protoplast fusion) or hybridisation techniques …

PART 2

Techniques referred to in Article 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B:

(1) in vitro fertilisation,

(2) natural processes such as: conjugation, transduction, transformation,

(3) polyploidy induction.'

Under the heading 'Techniques referred to in Article 3', Annex I B to Directive 2001/18 provides:

'Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) mutagenesis,

…'

Directive 2002/53

Article 1(1) and (2) of Directive 2002/53 provides:

'1. This Directive concerns the acceptance for inclusion in a common catalogue of varieties of agricultural plant species of those varieties of beet, fodder plant, cereal, potato and oil and fibre plant the seed of which may be marketed …

2. The common catalogue of varieties shall be compiled on the basis of the national catalogues of the Member States.'

Article 4(4) of Directive 2002/53 provides:

'In the case of a genetically modified variety within the meaning of Article 2(1) and (2) of Directive 90/220/EEC, the variety shall be accepted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment.'

Article 7(4)(a) of Directive 2002/53 provides:

'In the case of a genetically modified variety referred to in Article 4(4) an environmental risk assessment equivalent to that laid down in Directive 90/220/EEC shall be carried out.'

Article 9(5) of Directive 2002/53 states:

'Member States shall ensure that genetically modified varieties which have been accepted are clearly indicated as such in the catalogue of varieties. They shall further ensure that any person marketing such a variety clearly indicates in his sales catalogue that the variety is genetically modified.'

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C. The ECJ judgement

For a preliminary ruling Conseil d´Etat referred the following 4 questions to the ECJ.

By application of 12 March 2015, the applicants in the main proceedings, a French agricultural union and eight associations concerned with the protection of the environment and the dissemination of information on the dangers of GMOs, asked the referring court to annul the implied decision of the Prime Minister refusing their request that, inter alia, he revoke Article D. 531-2 of the Environmental Code, transposing Directive 2001/18, which excludes mutagenesis from the definition of techniques giving rise to genetic modification within the meaning of Article L. 531-1 of the code, and ban the cultivation and marketing of herbicide-tolerant rape varieties obtained by mutagenesis, and to order the Prime Minister, subject to a periodic penalty, to take all steps to introduce a moratorium on herbicide-tolerant plant varieties obtained by mutagenesis.

The applicants in the main proceedings submitted before the referring court, inter alia, that mutagenesis techniques have evolved and now make it possible to produce, as with transgenesis techniques, herbicide-resistant varieties. However, they submit, the obligations laid down in Directive 2001/18 do not apply to those varieties, even though they present risks for the environment or health arising in particular from the release of genetic material of those varieties leading to the appearance of weeds which have acquired the herbicide-resistant gene, from the ensuing need to increase the quantities and vary the types of herbicides used and the resulting pollution of the environment, or from unintentional effects, such as undesired or off-target mutations on other parts of the genome and the accumulation of carcinogenic molecules or endocrine disruptors in cultivated plants intended for human or animal consumption.

According to the Prime Minister and the Minister for Agriculture, the Food Processing Industry and Forestry, that application should be dismissed on the ground that the pleas raised by the applicants in the main proceedings are unfounded. The risks alleged are, it is submitted, the result not of the properties of the plant obtained through genetic modification, but of the growers' cultivation practices. Moreover, the mutations obtained by the new techniques of directed mutagenesis are similar to spontaneous or randomly introduced mutations and unintentional mutations can be eliminated in the varietal selection by crossing techniques.

According to the referring court, the conventional in vivo mutagenesis methods were used for several decades without creating identified risks for the environment or health. By contrast, since the adoption of Directive 2001/18, new varieties, in particular those resistant to herbicides, have been obtained through random mutagenesis techniques applied in vitro to plant cells and through directed mutagenesis techniques/methods applying new genetic engineering techniques, such as oligonucleotide-directed mutagenesis or directed nuclease mutagenesis. It is, in the view of the referring court, impossible to determine with certainty the existence and extent of the risks presented by those new herbicide-resistant varieties for the environment and human and animal health, the only risk assessments thus far being carried out in the context of the marketing authorisation procedure for the plant protection products to which those varieties have been made resistant.

The referring court considers that those risks are in part similar to those that might result from seeds produced by transgenesis. As regards, in particular, the mutations obtained by the new directed mutagenesis techniques, the direct modification of the genome that they involve would result in the

same effects as the introduction of a foreign gene, specific to transgenesis. In addition, since the development of the new techniques of mutagenesis allows the production of modifications of the genetic heritage to increase at a rate out of all proportion to the modifications likely to occur naturally or randomly, the possibility of harm occurring as a result of unintentional modifications of the genome or of the properties of the plant thus obtained would be increased.

For a preliminary ruling Conseil d´Etat referred 4 questions to the ECJ and following 3 questions were answered.

1. Do organisms obtained by mutagenesis constitute [GMOs] within the meaning of Article 2 of Directive 2001/18, although they are exempt under Article 3 of and Annex I B to the directive from the obligations laid down for release and placing on the market of [GMOs]? In particular, may mutagenesis techniques, in particular new directed mutagenesis techniques implementing genetic engineering processes, be regarded as techniques listed in Annex I A, to which Article 2 refers? Consequently, must Articles 2 and 3 of and Annexes I A and I B to Directive [2001/18] be interpreted as meaning that they exempt from precautionary, impact-assessment and traceability measures all organisms and seeds obtained by mutagenesis, or only organisms obtained by conventional random mutagenesis methods by ionising radiation or exposure to mutagenic chemical agents existing before those measures were adopted ?

2. Do varieties obtained by mutagenesis constitute genetically modified varieties within the meaning of Article 4 of Directive [2002/53] which would not be exempt from the obligations laid down in that directive? Or, on the contrary, is the scope of that directive the same as that under Articles 2 and 3 of and Annex I B to [Directive 2001/18], and does it also exempt varieties obtained by mutagenesis from the obligations laid down for the inclusion of genetically modified varieties in the common catalogue of agricultural plant species by [Directive 2002/53]?

3. Do Articles 2 and 3 of and Annex I B to Directive [2001/18] on the deliberate release into the environment of [GMOs] constitute, in so far as they exclude mutagenesis from the scope of the obligations laid down in the directive, a full harmonisation measure prohibiting Member States from subjecting organisms obtained by mutagenesis to all or some of the obligations laid down in the directive or to any other obligation, or do the Member States, when transposing those provisions, have a discretion to define the regime to be applied to organisms obtained by mutagenesis?

To these questions ECJ ruled following answers:

1. Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC must be interpreted as meaning that organisms obtained by means of techniques/methods of mutagenesis constitute genetically modified organisms within the meaning of that provision.

Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive and in the light of recital 17 thereof, must be interpreted as meaning that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive.

2. Article 4(4) of Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, as amended by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003, must be interpreted as meaning that genetically modified varieties obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are exempt from the obligations laid down in that provision.

3. Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive, in so far as it excludes from the scope of that directive organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record, must be interpreted as meaning that it does not have the effect of denying Member States the option of subjecting such organisms, in compliance with EU law, in particular with the rules on the free movement of goods set out in Articles 34 to 36 TFEU, to the obligations laid down in that directive or to other obligations.

ECJ main grounds in the preliminary ruling

First answer (chapter numbers from the judgement):

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28 Account being taken of the information provided by the referring court, it must be noted, first, that the mutations brought about by techniques/methods of mutagenesis such as those at issue in the main proceedings, the implementation of which is intended to produce herbicide-resistant varieties of plant species, constitute alterations made to the genetic material of an organism, for the purposes of Article 2(2) of Directive 2001/18.

29 Secondly, since, as is apparent from the order for reference, certain of those techniques/methods involve the use of chemical or physical mutageneous agents, and others involve the use of genetic engineering, those techniques/methods alter the genetic material of an organism in a way that does not occur naturally, within the meaning of that provision.

30 It follows that organisms obtained by means of techniques/methods of mutagenesis must be considered to be GMOs within the meaning of Article 2(2) of Directive 2001/18.

31 That interpretation is supported by the general scheme of that directive, which is one of the factors to be taken into account for the purpose of its interpretation.

32 It should be noted that the definition of a GMO in Article 2(2) of Directive 2001/18 is made clear by a distinction between techniques the use of which results in genetic modification and techniques which are not considered to result in such genetic modification.

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34 Although part 1 of Annex I A to that directive does not explicitly refer to techniques/methods of mutagenesis, that fact is not such as to exclude organisms obtained by means of those techniques/methods from coming under the definition of a GMO in Article 2(2) of the directive.

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36 Secondly, it must be noted that the EU legislature has not included mutagenesis in the exhaustive list of techniques not resulting in a genetic modification, referred to in Article 2(2)(b) of Directive 2001/18, read in conjunction with part 2 of Annex I A to that directive.

37 On the contrary, mutagenesis is expressly cited, in Annex I B to that directive, as one of the techniques/methods of 'genetic modification' referred to in Article 3(1) of that directive, relating to organisms that have to be excluded from the scope of the directive.

38 In the light of the foregoing considerations, Article 2(2) of Directive 2001/18 must be interpreted as meaning that organisms obtained by means of techniques/methods of mutagenesis constitute GMOs within the meaning of that provision.

The exclusion of certain techniques/methods of mutagenesis from the scope of Directive 2001/18

39 It is apparent from Article 3(1) of Directive 2001/18, relating to exemptions, that that directive does not apply to organisms obtained through the techniques of genetic modification listed in Annex I B to that directive.

40 In that regard, Annex I B lists the techniques/methods of genetic modification yielding organisms which, on condition that they do not involve the use of recombinant nucleic acid molecules or GMOs other than those produced by one or more of the techniques/methods listed in that annex, are to be excluded from the scope of that directive. Among those techniques/methods, point 1 of that annex refers to mutagenesis.

41 At the outset, it should be pointed out that, as a provision derogating from the requirement to subject GMOs to the obligations laid down in Directive 2001/18, Article 3(1) thereof, read in conjunction with point 1 of Annex I B to that directive, must be interpreted strictly (see, by analogy, judgment of 17 April 2018, Commission v Poland (Białowieża Forest), C 441/17, EU:C:2018:255, paragraph 189 and the case-law cited).

42 Furthermore, for the purpose of interpreting a provision of EU law, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part (judgment of 27 April 2017, Pinckernelle, C 535/15, EU:C:2017:315, paragraph 31).

43 As regards, first of all, the wording of Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto, it must be noted that, by referring generally to mutagenesis, that provision does not, on its own, provide any conclusive guidance as to the types of techniques/methods that the EU legislature intended specifically to exclude from the scope of the directive.

44 As regards, next, the context in which that exclusion is made, it should be noted that the EU legislature set out in recital 17 of Directive 2001/18 the conditions under which certain GMOs should be excluded from the scope of the directive.

45 Recital 17 states that Directive 2001/18 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.

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47 In that regard, it should be pointed out that the referring court is called upon to rule, in particular, on the techniques/methods of directed mutagenesis involving the use of genetic engineering which have appeared or have been mostly developed since Directive 2001/18 was adopted and in respect of which the risks for the environment or for human health have not thus far been established with certainty.

48 As the referring court states in essence, the risks 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.

49 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.

50 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.

51 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.

52 That finding is supported by the objective of Directive 2001/18, which seeks, as is apparent from Article 1 thereof, in accordance with the precautionary principle, to protect human health and the environment when, first, GMOs are deliberately released into the environment for any purpose other than placing on the market within the European Union and, secondly, when GMOs are placed on the market within the European Union as or in products.

53 As laid down in Article 4(1) of Directive 2001/18, it is for the Member States to ensure, in accordance with the precautionary principle, that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs. This implies, in particular, that such deliberate release or the placing on the market may take place only on completion of procedures of assessment of the risks referred to in part B and part C of that directive respectively. However, as set out in paragraph 48 of the present judgment, the risks for the environment or human health linked to the use of new

techniques/methods of mutagenesis to which the referring court refers might be similar to those which result from the production and release of a GMO through transgenesis. It follows that an interpretation of the exemption in Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto, which excludes organisms obtained by means of techniques/methods of mutagenesis from the scope of that directive, without any distinctions, would compromise the objective of protection pursued by the directive and would fail to respect the precautionary principle which it seeks to implement.

Second answer (chapter numbers from the judgement):

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56 In that regard, it should be recalled that Directive 2002/53 concerns, as is apparent from Article 1(1) thereof, the acceptance, for inclusion in a common catalogue of varieties of agricultural plant species, of certain agricultural species the seed of which may be marketed, that common catalogue being compiled, in accordance with paragraph 2 of that article, on the basis of the national catalogues of the Member States.

57 Article 4(4) of Directive 2002/53 provides that, with regard to a genetically modified variety within the meaning of Article 2(1) and (2) of Directive 90/220, that variety is to be accepted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment.

58 As regards, in the first place, the scope of the concept of ‘genetically modified variety’, referred to in Article 4(4) of Directive 2002/53, it should be noted that that provision, without explicitly referring to varieties obtained by means of techniques/methods of mutagenesis, refers to the definitions set out in Article 2(1) and (2) of Directive 90/220.

59 In that regard, as stated in Article 36 of Directive 2001/18, Directive 90/220 having been repealed, references to that directive are to be construed as references to Directive 2001/18. Therefore, according to the correlation table in Annex VIII to that directive, the reference made in Article 4(4) of Directive 2002/53 should be construed as referring to Article 2(1) and (2) of Directive 2001/18.

60 As established in paragraph 30 of the present judgment, organisms obtained by means of techniques/methods of mutagenesis such as those at issue in the main proceedings must be regarded as coming within the concept of a GMO in Article 2(2) of Directive 2001/18. Consequently, varieties obtained by means of techniques/methods of mutagenesis, such as those to which the referring court refers, must also be regarded as coming within the concept of ‘genetically modified variety’ referred to in Article 4(4) of Directive 2002/53.

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64 As the Advocate General has noted in point 161 of his Opinion, it would be inconsistent to impose obligations, with regard to the environmental risk assessment, on genetically modified varieties within the meaning of Directive 2002/53 from which they are explicitly exempted by Directive 2001/18.

65 Consequently, the reference made in Article 4(4) of Directive 2002/53 to the concept of a GMO in Article 2(2) of Directive 2001/18, with a view to determining whether a variety is genetically modified, must be interpreted as covering the exemption relating to organisms obtained

by mutagenesis laid down in Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive.

66 In that regard, it should be recalled that, as concluded in paragraph 54 of the present judgment, the exemption in Article 3(1) of Directive 2001/18 concerns only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record.

67 It follows that genetically modified varieties obtained by means of techniques/methods of mutagenesis such as those at issue in the main proceedings, with the exception of varieties obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record, come within the scope of Article 4(4) of Directive 2002/53 and the obligations with regard to the protection of health and the environment laid down in that provision for the purpose of acceptance for inclusion of the varieties in the common catalogue.

Third answer (chapter numbers from the judgement):

Admissibility

70 As a preliminary point, the European Commission queries the admissibility of the third question, since, in the proceedings pending before the referring court, the applicants in the main proceedings challenge the lawfulness of the national provision at issue in the main proceedings, in the present case Article D. 531-2 of the Environmental Code, not because that provision subjects organisms obtained by mutagenesis to obligations not laid down in Directive 2001/18, but because Article D. 531-2 exempts those organisms from the regulatory framework laid down in the national measures transposing the directive.

71 According to the Commission, in so far as Directive 2001/18 excludes from its scope organisms obtained by mutagenesis, it does not prohibit Member States from adopting measures regulating those organisms, provided that other rules arising from EU law, such as, in particular, those relating to the free movement of goods, are respected. Consequently, it submits, the question whether Member States may adopt measures regulating those organisms is hypothetical.

72 In that regard, it is necessary to state at the outset that, in accordance with the settled case-law of the Court, in proceedings under Article 267 TFEU, it is solely for the national court before which the dispute has been brought, and which must assume responsibility for the subsequent judicial decision, to determine, in the light of the particular circumstances of the case, both the need for a preliminary ruling and the relevance of the questions which it submits to the Court. Consequently, where the questions submitted concern the interpretation of EU law, the Court is bound, in principle, to give a ruling (judgment of 22 February 2018, Kubota (UK) and EP Barrus, C 545/16, EU:C:2018:101, paragraph 18 and the case-law cited).

73 In the context of the procedure for cooperation between the Court of Justice and national courts that is established by Article 267 TFEU, questions concerning EU law enjoy a presumption of relevance. The Court may refuse to give a ruling on a question referred by a national court for a preliminary ruling under Article 267 TFEU only where, for instance, the requirements concerning the content of a request for a preliminary ruling, set out in Article 94 of the Rules of Procedure of the Court of Justice, are not satisfied or where it is quite obvious that the interpretation

of a provision of EU law, or the assessment of its validity, which is sought by the national court, bears no relation to the actual facts of the main action or to its purpose, or where the problem is hypothetical (judgment of 22 February 2018, Kubota (UK) and EP Barrus, C 545/16, EU:C:2018:101, paragraph 19 and the case-law cited).

74 In the present case, as stated by the referring court, the examination of the action brought by the applicants in the main proceedings involves determining the discretion enjoyed by the Member States when transposing Directive 2001/18, with a view to establishing whether or not, in the present case, the French authorities had, with regard to organisms obtained by means of techniques/methods of mutagenesis excluded from the scope of that directive, the option of subjecting such organisms to the obligations arising from Directive 2001/18 or to other obligations.

75 It is apparent from the order for reference that that action seeks, in essence, an order requiring the French authorities to subject plant varieties made herbicide resistant by mutagenesis to the provisions of the Environmental Code concerning GMOs, irrespective of the technique/method of mutagenesis used.

76 It follows that the third question referred for a preliminary ruling is not hypothetical and must, accordingly, be considered admissible.

Substance

77 As held in paragraph 54 of the present judgment, organisms obtained by means of techniques/methods of mutagenesis which have not conventionally been used in a number of applications and do not have a long safety record come within the scope of Directive 2001/18 and are, therefore, subject to the obligations arising from that directive.

78 By contrast, organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record do not come within the scope of that directive, in accordance with Article 3(1) of that directive, read in conjunction with point 1 of Annex I B thereto.

79 Consequently, and to the extent to which the EU legislature has not regulated those organisms, Member States have the option of defining their legal regime by subjecting them, in compliance with EU law, in particular the rules on the free movement of goods set out in Articles 34 to 36 TFEU, to the obligations laid down by Directive 2001/18 or to other obligations.

80 The EU legislature excluded from the scope of that directive organisms made by techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record, without specifying in any way the legal regime to which they may be subject. In particular, it does not follow from Directive 2001/18 that the fact that those organisms are excluded from its scope means that persons concerned could proceed freely with their deliberate release into the environment or with the placement on the market of such organisms as or in products within the European Union.

81 Therefore, the exemption in Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive, cannot be interpreted as preventing Member States from legislating in that area.

82 In those circumstances, the answer to the third question is that Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive, in so far as it

excludes from the scope of that directive organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record, must be interpreted as meaning that it does not have the effect of denying Member States the option of subjecting such organisms, in compliance with EU law, in particular with the rules on the free movement of goods set out in Articles 34 to 36 TFEU, to the obligations laid down in that directive or to other obligations.

D. Concluding remarks

1. Observations on the judgement

All judgements are bound to their context and details of the case. ECJ has not on its own given the judgement in question, but it is the result of process of preliminary ruling. From a national court made questions and given facts form the foundation of the judgement. This dialogue between national court and ECJ aims to interpret EU law and it has certain key element rules.

According to ECJ recommendation 2016/ C 439/01 for national courts for preliminary ruling contradictory procedure in national court is recommended before the ECJ preliminary ruling. The national court needs to give the facts in the case and hypothetical or too general questions are not allowed. The referring national court is also supposed to give grounds to the questions asked in preliminary ruling and the national court can also tell its own point of view towards the case at that stage of process.

Referring court in this case is Conseil d`Etat, Supreme administrative court of France. The process in this national court is either administrative appeal or rather administrative litigation. The contested decision of prime minister of France is implicite – nèe du silence – by which means demands of environmental and agricultural organisations are rejected in administration. A normal contested administrative decision with grounds and motivation does not exist in case which probably limits the amount of enlightening facts in this administrative case. In their action environmental and agricultural organisations demand inter alia that it should be forebidden to cultivate and market via mutagenesis made rape seed varieties. In its request for preliminary ruling Conseil d´Etat among other things states as grounds for request that new mutagenesis techniques would result in the same effects as the introduction of a foreign gene, specific to transgenesis. In interim decision of Conseil d´Etat (3rd of October 2016, N:o 388649) relating to the case mutagenesis is described as new techniques without introduction of foreign gene (chapter 23). One bothering question in the present case is the fact that what the rape seed varieties in guestion are made of. According to material in case the rightowners of these varieties have not been heard before preliminary ruling process in ECJ, which is not in line with contradictory principle. Rightholders as an interest party could have enriched facts of the case by opening up structure of genomes of rape seed varieties in question. There is no evidence that genes from foreign species would have been attached to plant varieties in question. All interest parties should have the possibility to influence the outcame, which is bound to have great significance given by ECJ grand chamber judgement. In preliminary ruling process asked questions are on a too general level if details are not bound to the actual case. It is risky that guestions asked and answered relate somewhat too widely to the phenomenon itself than to actual cleared facts and characteristics of the case. In court work there tends to be enough concrete problems. On the other hand in EU court context, when in preliminary ruling asked questions are

somewhat general but not too general, the ruled answer can give you more effective EU law coverage. According to democratic principles it belongs to legislator to solve general real problems in society by giving legal norms after careful preparation. Agrilaw is a large context, one change concerning interpretation and actual contents of one or few legal norms may have large effects. Already chairman the first chairman of Haut Authoritè (Comission) Jean Monnet stated in the 1960´s that commission underestimated the complexity of issues in common agricultural policy.[6] After that era regulation of agriculture has increased considerably in 60 years by many program period reforms.

Second bothering guestion is the fact that what is the concrete risk in the actual case to trigger application of precautionary principle contrary to the wording in legislation. According to appellants the use of herbicide tolerant rape seed varieties has caused that weeds have acquired herbicide tolerant gene which has led to excessive use of herbicides with negative impacts to humans and environment. French authorities commented that this is due to cultivation practices. In the actual case there is no information on how largely these rape seed varieties are cultivated in France. Moreover there is no evidence at the present case on gene flow from rape seed varieties to weed plants. According to principles of integrated plant protection farmers should use various means and methods to protect cultivated plants. The usual reason for a herbicide tolerant weed is the fact that the same herbicide with same effective components have been used too long.[7]

2. Market consequences

Conserning international trade there has been estimations that into EU imported with novel genome technics developed food and feed should be evaluated and registered as GMO because of the judgement.[8] This is one alternative but probably too dramatic. One ECJ judgement alone can hardly form a generally applicable binding legal provision when various gene edited food&feed are placed on market in EU. In accordance with SPS-agreement of WTO member states shall ensure that all sanitary and phytosanitary regulations which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them. By regulation is meant legal norms such as laws, decrees or ordinances which are applicable generally.

SPS-agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. According to article 2 of the agreement members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

Article 4 in SPS-agreement provides that Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from

[6] Monnet, p. 753
[7] ProAgria, p. 62
[8] Dederer, p. 102

those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection.

Article 5.7 in the agreement provides that in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

When with novel mutagenesis genome edited food&feed products are placed on market in EU the central legislation is in parliament and council regulation 1829/2003 which contains definition of GMO. According to article 2 in mentioned regulation: (---) 5. "genetically modified organism" or "GMO" means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC. Mutagenesis is one of the techniques mentioned in the Annex 1 B. Because of regulation 1829/2003 definition and WTO-agreements (SPS) it seems quite possible that for instance with Crisp/Cas9 (mutagenesis) techniques outside EU produced and cultivated rape seed – fulfilling the criteria in directive 2001/18 annex 1B - can be placed on EU market without administrative authorization process meant in regulation 1829/2003. With this legislation novel genome edited food&feed products importing operators can reach bona fides. Moreover with novel mutagenesis technics produced varieties cannot be distinguished from varieties produced with traditional mutagenesis technics when foreign genes are not used. Without scientific evidence on risk big enough for humans, animals or environment market positioning cannot be forbidden or administratively restricted by authorization.

In accordance with grounds in recital 16 in regulation 1829/2003 processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this regulation.

Based on directive 2001/18 EU member states can forbid cultivation of gene edited novel varieties on their territory if these varieties can be classified as GMO. That may have negative impacts on EU production and market if at the same time from similar novel varieties more effectively produced food&feed products can be imported into EU market.

3. Conditions for EU subventions of agriculture

EU agricultural subventions were before 1990´s mainly administrative prices for agricultural products. From the early 1990´s productional income subventions for farmers have been paid mainly via eligible field hectares and animal units. Conditions for these aids vary but generally speaking production needs to be carried out according to good agricultural practices. If these conditions for subvention were not followed, traditional sanction was that amount of eligible hectares or animal units were cut. It is unclear if these subventions can be cut on grounds of the use

of novel genome edited varieties. In principle at organic farming the use of GMO is forbidden and certain structural subventions like special environmental subvention for organic farming can be granted for farmers. Forbidden use of GMO may lead to rejection of this support application. Cultivated varieties need to be accepted by national authorities into national catalogue of varieties. A plant variety not included in national variety cataloque cannot be marketed and in this respect the loss of harvest sales income is an effective sanction.

At the beginning of this millennium new conditions for EU agricultural subventions were introduced in the form of cross compliance conditions. These for all EU subvention meant conditions cover different areas like good environmental condition of rural areas, food safety and animal welfare. Food law has been for 15 years a clear condition for agricultural subventions in EU. Forbidden use of a GMO variety would probably break cross compliance rules at food safety area based on parliament and council regulation 178/2002. No concrete hazard is needed to emerge and in this respect conditions are quite similar compared with negligence with missing cattle eartags or delayed animal register reports. During ongoing program period cross compliance sanctions cover all field cultivation and cattle keeping subventions and are based on parliament and council regulation 1306/2013. If these condition are broken out of negligence, subventions are usually cut 1-5 %. Negligence repeated at the same area in the period of 2 years the original sanction is multiplied by three. Non-compliance of conditions done on purpose may lead to 15-100 % sanctioning of support already on first year.

4. Future

Regulation of GMO based totally on control of methods and techniques is probably too complicated and outdated way to control sector, because science at biotechnology sector is developing fast. Already the fact that from the end product organism you cannot tell by which method it was produced - old or novel mutagenesis - demands a change. Too many moving technical components may lead to arbitrary end results when sector is controlled with either heavy or light administrative procedures with big differences in cost and consumer image. Administrative tools used cannot become technical barriers of reasonable cultivation and trade. If no with novel technics produced varieties are taken into use in fear of GMO, old via radiation and chemicals produced less efficient varieties stay in use in EU which will lower production. It is a fact that novel varieties with better nutritional value and climate change durability are needed. In organic and conventional farming it would be useful to connect plant protection characteristics into cultivated plant varieties in order to minimize work burden and reduce the use of pesticides.

It would probably be better to give up the GMO concept of today and move over to evaluate product safety of genome edited varieties. Reasonable safety aspects should be evaluated when plant varieties are registered at national catalogues. To guarantee equal treatment basic regulation of registration should be given in EU level.

SUMMARY

By GMO is meant genetically modified organisms – like plants, animals, bacteria, virus – whose genome has been artificially modified to get new characteristics. These goals can be better resistance to a malady, weed or insect. GMO can also raise production, quality and nutritional value of cultivated plants and food stuffs. By means of GMO has also been raised tolerance of some plants towards herbicide. On the other side there can be risks for humans, animals and environment when very old complicated genetic inheritance of an organism is changed rapidly.

The central EU legal norms relating to GMO are TFEU 191 article (precautionary principle) and also 34-36 articles (free movement of goods, restrictions based on human and animal health). Several international agreements like Cartagena agreement and specially WTO-agreements (GATT, SPS and TBT) relate essentially to the sector.

The central derived EU legislation on GMO consist of Council directives 2001/18/EC and 2009/41/EC. Special feature in these directives is that they aim to reach safety by regulating complex methods and techniques. To the central context of GMO regulation belong also Parliament and Council regulations (EU) N:o 1829/2003 and 1830/2003. Key regulation in this respect is also Parliament and Council regulation (EU) 178/2002 by which general principles on food law were coded and European food safety authority EFSA was founded. These horizontal rules organizing the use of genetically modified organisms can be divided to three phases: research and contained use – risk evaluation and authorization – cultivation and placing on market.

ECJ ruled in preliminary ruling 25.7.2018 that Directive 2001/18 must be interpreted as meaning that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive. Cleared facts in the present case are on somewhat general level.

Because of regulation 1829/2003 article 2 definition and WTO-agreements (SPS) it seems quite possible that for instance with Crisp/Cas9 novel mutagenesis genome editing techniques outside EU produced and cultivated rape seed – fulfilling the criteria in directive 2001/18 annex 1B - can be placed on EU market without administrative authorization process meant in regulation 1829/2003. With novel mutagenesis technics produced varieties cannot be distinguished from varieties produced with traditional mutagenesis technics when foreign genes are not used. Without scientific evidence on risk big enough for humans, animals or environment market positioning cannot be forbidden or administratively restricted by authorization. It would probably be better to give up the GMO concept of today and move over to evaluate product safety of genome edited varieties.

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