Terres Univia's observations on TRIS notifications

2020/280/F - 2020/281/F - 2020/282/F

1. Presentation of Terres Univia

(1) Founded in 2015, as a result of the merger between ONIDOL (created in 1976, French oils seed and oil fruit sectors) and UNIP (created in 1975, French high protein plant sector), Terres Univia represents French oilseed and oil fruit sector (oil seed rape, sunflower, soya, linseed, olive) and French legume seed sector (field pea, faba bean, lupin, lentil, chickpea, alfalfa) interests.

(2) The purpose of Terres Univia is to bring together and represent the professional organisations of these sectors, from production to industrial processing: breeding activities (seed breeders, seed multipliers), crop production, storage activities, industrial transformation (crushing, refining, etc.), food manufacturers and feed industry.

(3) Terres Univia aims to facilitate interactions between professional partners like producers and processors, to undertake activities of collective interest action, and to promote the development and the use of oilseeds and associate products.

(4) Terres Univia is in charge of following market trends, regulatory and food safety information, and statistical information transfer about the French oilseed and legume sector.

(5) Terres Univia also stimulates and supports research programs with external experts, technical institutes such as Terres Inovia and ITERG, universities and national research centers such as INRAE, CNRS, INSERM. Terres Univia promotes research projects related to plant breeding, human and animal nutrition, renewable energy and renewable chemistry development. Its expertise extends from R&D actions to dissemination and promotion/communication.

(6) Terres Univia herewith intends to provide the European Commission ("**the Commission**") with its observations on French notifications 2020/280/F, 2020/281/F and 2020/282/F.

2. Presentation of the notifications

(7) On May 6th 2020, France has notified to the Commission three draft technical regulations relating to genetically modified organisms ("**GMOs**"), in accordance with the procedure laid down in Directive (EU) 2015/1535[1].

(8) These notifications include:

- a draft decree *amending the list of techniques for obtaining GMOs traditionally used without any noted drawbacks with regard to public health or the environment* (**notification 2020/280/F**);
- a draft order *laying down the list of varieties mentioned in Article 2 of Decree [xx]* (**notification 2020/281/F**);
- a draft order *amending the Official Catalogue of Species and Varieties of Cultivated Crops in France (rape seeds and other crucifer seeds)*(**notification 2020/282/F**).

(9) These draft decree and orders from the French State are supposed to implement several rulings from the Court of Justice of the European Union ("**CJEU**") and the French Council of State ("**CE**"), France's highest administrative Court, but in fact go further and put internal market at risk, as will be demonstrated below.

(10) By a ruling of 3 October 2016, the CE referred four questions to the CJEU for a preliminary ruling, aimed in particular at clarifying the scope of Directive 2001/18/EC as regards mutagenesis techniques[2]. In a ruling dated 25 July 2018[3], the CJUE clarified 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 Directive 2001/18/EC;
- on the contrary, organisms obtained by means of new techniques/ methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18/EC was adopted shall be included in the scope of that Directive.

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1 Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, OJ L 241, 17.9.2015, p. 1-15.

2 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.

3 Judgement of the Court (Grand Chamber) of 25 July 2018, *Confédération paysanne and Others*, case C- 528/16.

(11) **The CJUE therefore draw a clear line (namely a cut-off date) between the new techniques/ methods of mutagenesis and those conventionally used with a long safety record, but did not make any other distinctions based on the type of mutagenesis technique.**

(12) On 7 February 2020[4], the CE departed from that CJUE ruling by *(i)* introducing a new distinction between *in vivo* and *in vitro* mutagenesis techniques and *(ii)* by further considering that "*in vitro random mutagenesis techniques subjecting plant cells to chemical or physical mutagens*" should "*be regarded as being subject to the obligations imposed on genetically modified organisms by that Directive* [2001/18/EC]".

(13) In the same ruling, the CE further enjoined:

- the Prime Minister to fix by decree, taken after the opinion of the *High Council of Biotechnology*, the restrictive list of mutagenic techniques or methods exempt from the scope of the French regulations on GMOs, *i.e.* those conventionally used in a number of applications and which have a long safety record;

- the competent authorities to identify, within the common catalogue of varieties of agricultural plant species, those varieties that would have been registered without having been evaluated and authorised under the GMOs regulations.

(14) The draft decree notified under **2020/280/F** provides its own interpretation of the techniques of mutagenesis exempt from the scope of the provisions of the French Environment Code relating to GMOs[5] and transposing Directive 2001/18/CE. It foresees the exemption of "*random mutagenesis, with the exception of in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents*".

(15) As clarified by France on the TRIS database, "*This provision means that plant organisms resulting from in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents fall within the scope of the regulations relating to GMOs*" (emphasis added).

(16) The draft decree also provides for transitional measures for those varieties which have already been sown or planted on the date of application of the above orders.

(17) The draft order notified under **2020/281/F** identifies the varieties originating from *in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents*.

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4 Conseil d'Etat, *Confédération paysanne et autres*, séance du 20 janvier 2020 et lecture du 7 février 2020, No. 388649.

5 Title III of Book V of the legislative part and Articles L.125-3 and L.5313-15.

(18) As a consequence, the order lists those varieties *(i)* whose registration in the French Official Catalogue of Species and Varieties of Cultivated Crops has been revoked and *(ii)* **those which France considers as supposed to satisfy the conditions for revocation of registration in the EU catalogue**.

(19) As indicated in the TRIS notification, the varieties listed "*are the herbicide-tolerant varieties of rapeseed, marketed under the name Clearfield rapeseed, whose method of production described in the bibliography corresponds to this technique*"

(20) The draft order notified under **2020/282/F** lists the varieties that are removed from the French Official Catalogue of Species and Varieties of Cultivated Crops (rapeseed and other crucifer seeds), as being the result of *in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents*.

(21) In the text accompanying these notifications, France clarified that once the decree and the orders will be published, "*it will be prohibited in France to cultivate or sell the varieties resulting from in vitro random mutagenesis, consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents*" (emphasis added).

3. French proposals will distort the functioning of the EU internal market

3.1.1 French proposals are in breach of the CJEU's ruling of 25 July 2018 (C-528/16)

(22) In order to ensure a proper functioning of the internal market, while complying with the primacy of EU law, the CE's ruling and the subsequent decree and orders should have been compliant with the CJEU's ruling of 25 July 2018, which is not the case. Indeed:

- the CJUE did not distinguish between *in vivo* and *in vitro* mutagenesis techniques;
- *in vitro* mutagenesis is not a new technique/ method as defined by the CJUE.

3.1.1.1 The CJUE did not distinguish between *in vivo* and *in vitro* mutagenesis

(23) As explained above, in case C-528/16, **the CJEU did not make any distinction between *in vivo* and *in vitro* mutagenesis techniques**. The CJUE indeed only distinguished between "*techniques conventionally used in a number of applications and which have a long safety record*" and "*new techniques/methods of mutagenesis, which have appeared or have been mostly developed since Directive 2001/18 was adopted*", to conclude that only the former shall be exempted from the scope of GMOs regulations.

(24) This has been clearly highlighted by the European Commission in its letter of 20 May 2020 requesting the European Food Safety Authority ("**EFSA**") for a scientific opinion on *in vitro* random mutagenesis techniques (ARES(2020)2651289):

"*The CJEU in its reasoning referred to the "application of conventional methods of random mutagenesis" without distinguishing further between in vivo and in vitro*

random mutagenesis and distinguished them from "new techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18 was adopted"" (emphasis added).

(25) That letter from the Commission further indicates that this distinction between *in vitro* or *in vivo* mutagenesis techniques/ methods has neither been made by EFSA, nor by Member States:

- "*While EFSA explains the various modes of action depending on the chemical mutagens or the type of radiation used, the Authority makes no distinction between the application of the techniques in vitro or in vivo*" (emphasis added);

- "*Member States have never made a distinction between in vitro and in vivo either when implementing the seed legislation, the plant propagating material legislation or the GMO legislation*" (emphasis added).

(26) It is the French CE which decided on its own, without any further request for a preliminary reference as it should do in case of doubt on the interpretation of EU Law and **without any clear legal or scientific justification**, to distinguish between *in vivo* and *in vitro* mutagenesis techniques as regards the scope of the GMOs regulations:

"*both the so-called "directed" or "genome editing" techniques or methods and the in vitro random mutagenesis techniques subjecting plant cells to chemical or physical mutagens* […] *appeared after the date of adoption of Directive 2001/18/EC or have mainly developed since that date*" and should therefore "*be regarded as being subject to the obligations imposed on genetically modified organisms by that Directive*" (emphasis added).

(27) Such a distinction between *in vitro* and *in vivo* mutagenesis techniques, implemented in the draft decree and orders, is therefore manifestly wrong in law. It is also scientifically flawed as no robust scientific analysis has been provided in support of such a distinction, as acknowledged by the Commission in its letter to EFSA:

"*It is therefore important to provide a robust scientific understanding of random mutagenesis techniques and a robust scientific analysis as to whether the distinction between in vitro and in vivo is scientifically justified*" (emphasis added).

(28) Leaving it to a Member State, namely France via its CE and the notified drafts, to clarify the distinction drawn by the CJEU as regards the list of techniques/methods which should be considered as conventional or new (and therefore excluded or included in the scope of Directive 2001/18/EC) will breach the uniform application of EU law, "*which is a fundamental requirement of the Community legal order*"[6].

[6] Judgement of the Court of 6 December 2005, *ABNA e.a.*, case C-453/03, paragraph 104.

(29) This will further impede the proper functioning of the internal market, although the core purpose of Directive 2001/18/EC is to "*approximate the laws, regulations and administrative provisions of the Member States*" in the field of GMOs (article 1).

3.1.1.2 *In vitro* mutagenesis is not a new technique/ method as defined by the CJEU

(30) Pursuant to the CJEU, new techniques/ methods of mutagenesis, which are included in the scope of Directive 2001/18/EC, shall encompass techniques "*which have appeared or have been mostly developed since Directive 2001/18 was adopted*", *i.e.* since 12 March 2001.

(31) The draft decree and orders further breach the CJEU ruling as *in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents* date from before 2001.

(32) In this respect, the conclusions of the Rapporteur public preceding the French CE's ruling of 7 February 2020 highlighted that "*in vitro reconstitution methods were experimented in the late 1960s and in connection with random mutagenesis in the early 1980s***"** and that "*the marketing of the Clearfield® rapeseed in France* [date] *from 1995*".

(33) For these reasons, the draft decree and orders should not include *in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents* in the scope of the GMOs regulations. By violating the CJEU ruling, the draft decree and orders will further impede the uniform application of EU law and the proper functioning of the internal market.

(34) The breach of the EU internal market will be all the more important that **other EU regulations directly refer to Directive 2001/18/EC as far as the definition of GMOs is concerned**. For instance, Regulation (EC) 1830/2003[7] and Regulation (EC) 1946/2003[8] state that:

"'*Genetically modified organism' or 'GMO' means 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 IB to Directive 2001/18/EC*" (emphasis added).

(35) Regulation (EU) 1107/2009[9] also defines "genetically modified organisms" as "*organisms in which the genetic material has been altered within the meaning of*

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7 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

8 Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms

9 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

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".

(36) Regulation (EU) 2018/848[10] further considers that *"'genetically modified organism' or 'GMO' means a genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council which is not obtained through the techniques of genetic modification listed in Annex I.B to that Directive*" (emphasis added).

(37) For these reasons, by misapplying the CJEU ruling, France should be considered in breach of its duty of sincere cooperation (article 4(3) of the TEU[11]). Also, by not asking for new preliminary reference to CJEU before imposing prohibitions to *in vitro* established practices and thus going beyond CJUE first ruling, the French CE was in breach of its duty to do so as Court of last resort (Article 267 TFUE)[12] and to Article 4(3) TUE accordingly.

3.1.2 The notified drafts are in breach of both articles 34 and 35 of the TFEU

(38) Pursuant to article 34 of the TFEU[13] "*Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States*". The CJEU clarified that "*it is clear that this provision includes a prohibition on imports inasmuch as this is the most extreme form of restriction*"[14] (emphasis added).

(39) Article 22 of Directive 2001/18/EC further states that "*Without prejudice to Article 23* [*i.e.* safeguard clause in case of human health or the environment], *Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive*" (emphasis added).

(40) In addition, pursuant to article 35 of the TFEU "*Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States*". Again, a prohibition on exports is considered as the most extreme form of restriction.

(41) In the present case, France clearly explained in the TRIS database that, as a result of the decree and orders, "*it will be prohibited in France to cultivate or place on the market the varieties resulting from in vitro random mutagenesis, consisting in*

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10 Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007.

11 Treaty of the European Union.

12 Court of last resort can be found in breach of the Treaty for this reason as CJUE found regarding the French Conseil d'Etat in its ruling Commission c./ France, 4 October 2018, case C-416-17.

13 Treaty on the Functioning of the European Union.

14 Judgment of the Court of 14 December 1979, *Regina v Maurice Donald Henn and John Frederick Ernest Darby*, case 34/79, paragraph 12.

subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents" (emphasis added).

(42) For this reason, the notified draft decree and orders are in breach of :

- article 34 of the TFEU by prohibiting the import in France of those varieties which will be lawfully cultivated and marketed in other Member States;
- article 35 of the TFUE by prohibiting the cultivation and thus the export of those varieties which could be lawfully marketed in other Member States.

(43) These breaches would neither be justified by a clear public interest, nor by strong scientific evidence as the distinction between *in vivo* and *in vitro* has no scientific justification.

(44) For the same reasons, the French proposals will also create important and unjustified obstacles to international trade for goods imported in France from outside the European Union. In 2018, France indeed imported 718 000 tonnes of rapeseed from outside EU notably from Ukraine, Canada and Australia where Clearfield rapeseed varieties are cultivated.

3.1.3 The notified drafts will give raise to legal uncertainty

(45) The CJEU has ruled that a national regulation constitute an unjustified obstacle to the free movement of goods when it creates an *"ambiguous factual situation by maintaining, for economic operators, a state of uncertainty as regards the possibilities for marketing* [in a Member State products] *which are lawfully manufactured and/or marketed in other Member States*" (emphasis added).

(46) The CJEU further considers that "*The principle of legal certainty - which is one of the general principles of European Union law - requires that rules of law be clear and precise and predictable in their effect, so that interested parties can ascertain their position in situations and legal relationships governed by European Union law*"[15].

(47) In the present case, the draft decree and orders will give raise to legal uncertainty as they are based on a pure legal distinction (between *in vitro* and *in vivo*) which is wrong in law and not justified from a scientific perspective. Today, it its therefore impossible :

- to know whether *in vitro* mutagenesis has been used to produce the seeds placed on the EU market as no information is available in the Common Catalogue;

[15] Judgement of the Court of 8 December 2011, *France Telecom SA. v. European Commission*, case C-453/03, paragraph 100.

- to detect and control whether seeds (and the products derived thereof) have been obtained *via in vitro* mutagenesis techniques.

(48) This legal uncertainty will create practical barriers for operators on the internal market, on the whole supply chain, not only for seed producers but also and even more for transformation and commercialisation.

(49) Such important issues have been raised by the European Council in the Decision (EU) 2019/1904 of 8 November 2019[16] *requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16*:

"*In this respect that the Council Decision (EU) 2019/1904 of 8 November 2019 itself states that "The ruling [of the CJEU] brought legal clarity as to the status of new mutagenesis techniques, but also raised practical questions which have consequences for the national competent authorities, the Union's industry, in particular in the plant breeding sector, research and beyond. Those questions concern, inter alia, how to ensure compliance with Directive 2001/18/EC when products obtained by means of new mutagenesis techniques cannot be distinguished, using current methods, from products resulting from natural mutation, and how to ensure, in such a situation, the equal treatment between imported products and products produced within the Union*".

(50) The Council has therefore concluded that an harmonised approach should prevail for which "*a study is necessary to clarify the situation*" ; thus it requested "*the Commission to submit, by 30 April 2021, a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law*", as well as to "*submit a proposal, if appropriate in view of the outcomes of the study, or otherwise to inform the Council on other measures required as a follow-up to the study*".

(51) In such a context, by regulating what should be regarded as new mutagenesis techniques/ methods ahead and outside of any European consultation and possible subsequent EU solution, the French draft decree and orders appear premature, which further impedes the uniform application of EU law and harms the proper functioning of the Internal market.

3.1.4 The draft orders are in breach of Directive 2002/53/EC

(52) In the text accompanying notification 2020/282/F, it is indicated that "*the French authorities intend to apply Article 14 of Directive 2002/53/EC to remove the varieties of agricultural plant species registered in the French national catalogue identified as*

[16] Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study, OJ L 293, 14.11.2019, p. 103-104.

being the result of in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents" (emphasis added).

(53) Article 14(2) of Directive 2002/53/EC states that "*Member States may revoke the acceptance of a variety:*

(a) if the laws, regulations and administrative provisions adopted in pursuance of this Directive are not complied with;

(b) if, at the time of the application for acceptance or during examination, false or fraudulent particulars were supplied concerning the factors on the basis of which acceptance was granted" (emphasis added).

(54) As regards the present notifications, only the justifications provided in (a) could be relevant as there is no issue relating to the supply of false or fraudulent particulars at the time of the acceptance of the relevant varieties.

(55) The purpose of Article 14(2) of Directive 2002/53/EC is precisely to ensure the uniform and equal application of EU law in all Member States, and therefore the proper functioning of the EU internal market.

(56) **However, as explained above, the draft orders will have the opposite effects by prohibiting in France the cultivation and placing on the market of varieties resulting from some *in vitro* methods which are legally produced and marketed in other Member States.**

(57) For this reason, the draft orders notified under 2020/281/F and 2020/282/F do not comply with Directive 2002/53/EC insofar as there is no legal nor scientific justification for removing those varieties from the *Official Catalogue of Species and Varieties of Cultivated Crops in France* (rape seeds and other crucifer seeds).

(58) In addition, it is not up to France to decide on its own which varieties are supposed to satisfy the conditions for revocation of registration in the EU catalogue, all the more when such a decision is not legally and scientifically based, and puts at risk the uniform application of EU law and the proper functioning of the EU internal market.

4. CONCLUSION ON THE NOTIFICATIONS

(59) Pursuant Directive (EU) 2015/1535, Member States and the Commission may submit a detailed opinion to the Member State that has notified the draft where it emerges that the notified drafts may create barriers to the free movement of goods or to EU secondary legislation[17].

[17] Article 6 of Directive (EU) 2015/1535.

(60) **In light of the legal analysis made above, Terres Univia respectfully asks the Commission :**

- **to deliver a detailed opinion to France expressing its concerns that the proposals will create serious obstacles to the free movement of goods within the internal market, does not respect EU primary and secondary law and its duty to cooperate in view of a solution at EU level ;**

- **to ask France to remove its proposals accordingly ;**

- **to conclude that in the case France would not address the requests of the Commission, the latter would have to start a formal infringement procedure against France.**

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