SNIA's contribution to French notifications 2020/280/F - 2020/281/F - 2020/282/F

09 July 2020

1) PRESENTATION OF THE SNIA

(1) Created in 1971, the SNIA (Syndicat national de l'industrie de la nutrition animale) is a professional union which represents the French compound feed industrie. Its action concerns raw materials for the feeding of farm animals, the manufacture of animal feed, the delivery and technical support of farms, the search for answers for the food industry and consumers. It is a member of EUROFAC, the European representation of the French animal nutrition industry, which is a member of FEFAC, the European federation of the sector.

(2) The SNIA brings together companies (130 manufactures, 8,5 million tonnes/year) established locally throughout the French territory. It provides a platform for dialogue between animal nutrition companies, other professional sectors and the political and economic environment, at national, regional and European level.

(3) The SNIA is frequently consulted on economic, technical or regulatory issues in the fields of agriculture, agro-supply and agrifood. The SNIA focuses its actions around food and feed safety, the quality of products, the improvement and development of the livestock sector.

(4) The SNIA participates in the work of DURALIM, the first French collaborative platform for sustainable farm animal nutrition. It is a member of the OQUALIM Association, the benchmark approach in France for the quality and safety of animal feed. It is a member of several inter-professions and official consultation committees.

2) OVERVIEW OF THE DRAFT NOTIFICATIONS

(5) SNIA's observations relate to the following three notifications referred under 2020/280/F, 2020/281/F and 2020/282/F:

- 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;
- a draft order laying down the list of varieties mentioned in Article 2 of Decree [xx];
- a draft order amending the Official Catalogue of Species and Varieties of Cultivated Crops in France (rape seeds and other crucifer seeds).

(6) The draft decree intends to clarify the mutagenesis techniques which are exempt from the scope of the provisions of the French Environment Code relating to GMOs and transposing Directive 2001/18/CE. It provides for 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*".

(7) As a result of this decree, organisms resulting from "*in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents*" will fall within the scope of the GMOs regulations.

(8) The draft orders draw the consequences of the decree. They list the varieties resulting from ""*in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents*" which are :

- deleted from the French Official Catalogue of Species and Varieties of Cultivated Crops (rapeseed and other crucifer seeds) ;
- supposed to satisfy the conditions for revocation of registration in the EU catalogue.

(9) As clarified by France on the TRIS database, once the draft notifications 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, due to them not having been evaluated and authorised under the regulations on GMOs*" (emphasis added).

3) ANALYSIS OF THE FRENCH PROPOSALS PURSUANT TO EU LAW

a) French proposals breach the principle of the primacy of EU law

(10) *Principle* - According to the primacy of EU law, European law is superior to the national laws of Member States. All national acts are subject to this principle, irrespective of their nature. The judiciary is also subject to this principle, therefore meaning that Member State case-law shall comply with EU case-law[1].

(11) *Application to the French notifications* - In 2016, the French Council of State ("**CE**") asked the Court of Justice of the European Union (preliminary rulings procedure) to clarify the scope of Directive 2001/18/EC[2] as regards mutagenesis techniques.

(12) In a ruling dated 3 October 2016, the CJUE clarified that[3] :

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1 Judgement of the Court of 15 July 1964, case C-6/64, paragraph 104.

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.

- 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.

(13) The CJUE therefore drew 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 between *in vivo* and *in vitro* mutagenesis techniques, as acknowledged by the European Commission itself in its letter of 20 May 2020[4] to EFSA[5]:

"*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).

(14) By introducing a new distinction between *in vivo* and *in vitro* mutagenesis techniques, the French notified drafts go far beyond the CJEU ruling. The ruling of the French CE dated 7 February 2020[6], which the draft texts are supposed to implement, also breached that principle of primacy of EU law by making this distinction between *in vivo* and *in vitro* the key element for determining which mutagenesis technique is included in the scope of the GMOs regulation:

"*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).

(15) Even when applying the distinction drawn by the CJEU, neither the draft decree and orders nor the CE's ruling comply with the CJEU ruling insofar as "*in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents*" date from well before 2001 as acknowledged in the Rapporteur public's conclusions preceding the CE's ruling:

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4 Request for a scientific opinion on in vitro random mutagenesis techniques ; Ref. Ares(2020)2651289 - 20/05/2020.

5 European Food Safety Agency.

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

"*in vitro reconstitution methods were indeed experimented in the late 1960s and in connection with random mutagenesis in the early 1980s*" and "*the marketing of the Clearfield® rapeseed in France* [date] *from 1995*".

(16) **For these reasons, there is a serious breach of the principle of the primacy of EU law. Also by not asking for a new preliminary reference to the CJEU before imposing prohibitions to *in vitro* established practices, France should be regarded as in breach of both articles 267 TFEU[7] and Article 4(3) TEU[8].**

b) French proposals breach the principle of the uniform application of EU law

(17) *Principle* - Pursuant to the CJUE, the uniform application of EU law is a fundamental requirement of the EU legal order as it aims at ensuring that citizens are uniformly protected by EU law throughout all EU territories[9].

(18) *Application to the French notifications* - As explained above the notified decree and orders, but also the ruling of the French CE, breach the principle of uniform application of EU law by introducing a distinction between *in vivo* and *in vitro* techniques that has never been made by the CJUE as regards the scope of the GMOs regulations to mutagenesis.

(19) In addition, as acknowledged by the European Commission, the distinction between *in vivo* and *in vitro* mutagenesis techniques has neither been made by EFSA, nor by Member States when implementing the seed legislation, the plant propagating material legislation or the GMO legislation[10].

(20) The breach of the principle of the uniform application of EU law will be further aggravated by the fact that other regulations directly or indirectly refer to Directive 2001/18/EC as far the exemptions to the GMO regulations is concerned. This is for example the case of Regulations (EC) 1830/2003[11], (EC) 1946/2003[12], (EC) 1107/2009[13] and (EU) 2018/848[14].

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7 Pursuant to that provision, Court of last resort have an obligation to bring any matter relating to the interpretation of EU law before the CJUE.

8 Pursuant to that provision, Member States shall facilitate the achievement of the Union's tasks and refrain from any measure which could jeopardise the attainment of the Union's objectives.

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

10 Request for a scientific opinion on in vitro random mutagenesis techniques ; Ref. Ares(2020)2651289 - 20/05/2020.

11 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.

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

13 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.

14 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.

(21) **As a result, the draft decree and orders will undermine an harmonized area of EU legislation. This is all the more detrimental since the European Council[15] has recently concluded that an harmonized approach should prevail in drawing the consequences of the CJEU's ruling in case C-528/16.**

(22) This is the reason why the European Council 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*".

(23) In this 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.

c) French proposals will impede the EU internal market for the whole supply chain

i) Barriers to the free movement of goods

(24) *Principle* - Pursuant to Articles 34 and 35 TFEU, any restriction on imports or exports shall be prohibited between Member States. Any prohibition in this respect is considered as the most extreme form of restriction.

(25) *Application to the French notifications* - The draft decree and orders will create barriers to the free movement of goods within the EU **by having the direct effect of prohibiting both the cultivation and sale** of varieties resulting from "*in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents*", as clarified by France on the TRIS database:

"*it will be prohibited in France to cultivate or place on the market the varieties resulting from in vitro random mutagenesis, consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents*" (emphasis added).

(26) **As a result, the functioning of the EU internal market will be seriously impeded both upstream and downstream as the notified texts will prohibit the sale in France of both seeds and resulting products (varieties, animal feed etc.) lawfully marketed in other Member States.**

(27) **In addition, by also prohibiting the cultivation of some varieties stemming from *in vitro* mutagenesis techniques, the notified texts will further impact the**

[15] Decision (EU) 2019/1904 of 8 November 2019.

export of both these varieties and the resulting products (such as animal feed), although they could be lawfully marketed in other Member States.

(28) **This will in particular affect EU producers of animal feed whose products are based on agriculture resources from various parts of the European union and which will no more be able to do so in France, nor to sale any EU products to French breeders.**

(29) **In addition, France will create confusion at EU level regarding the varieties and resulting products which are regulated as GMOs or not. Indeed, depending on the EU countries, the same *in vitro* varieties and resulting products will fall within the scope of the GMOs regulations or be exempted. This will disorganise the "OGM-free" sectors and affect the consumers' confidence in both *(i)* the products sold in the EU market as GMOs or not and *(ii)* in the EU regulation in general. The internal market will therefore be further impeded.**

ii) Absence of justifications

(30) *Principles* - Pursuant to EU law, any breach of the EU internal market rules may be justified by an overriding reason of public interest, such as the ones listed in Article 36 TFEU. The CJEU further clarified that these justifications have to be interpreted strictly as they constitute "*a derogation from the fundamental principle of the elimination of all obstacles to the free movement of goods between Member States*"[16].

(31) *Application to the French notifications* - In the "*Brief Statement of Grounds*" accompanying the notifications, **France does not provide any justification for the impeding of the internal market that would result from the notified texts.**

(32) Such lack of justification is consistent with the fact that the distinction between *in vitro* and *in vivo* mutagenesis techniques **is not substantiated by scientific evidence since no robust scientific analysis has been provided in support of such a distinction.** This is precisely the reason why the European Commission has recently asked EFSA "*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*"[17] (emphasis added).

(33) **As a result of this inconsistent distinction, it will be impossible to detect and control whether seeds (and the products derived thereof) have been obtained via *in vitro* mutagenesis techniques,** which will further breach the principle of

[16] Judgment of the Court of 25 January 1977, *W. J. G. Bauhuis v The Netherlands State*, Case 46/76.

[17] Request for a scientific opinion on in vitro random mutagenesis techniques ; Ref. Ares(2020)2651289 - 20/05/2020.

legal certainty, which is one of the general principles of EU law as stated by the CJEU[18].

(34) The practical consequences that would result from the notified texts have been acknowledged by the European Council in its recent decision requesting the Commission to submit a study in light of the CJEU's ruling:

""*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*". (emphasis added)

d) French proposals further impede the EU sovereignty for food and feed

(35) *Principles* - In April 2018, the European Parliament adopted a resolution calling from a European strategy for the promotion of protein crops. In that resolution, the Parliament notably stressed out that[19]:

- the European Union was suffering from a major deficit in vegetable proteins due to the needs of its livestock sector, which is dependent on feed imports from third countries;
- it was vital to reduce the Union's massive dependency on imports of protein crops, which are mainly used for animal feed;
- the current situation carried major risks especially for the EU livestock sector, as price volatility on international markets had substantially increased;
- vegetable proteins were at the core of the challenges of food security and sovereignty (for food and feed), environmental protection, global warming and renewable energy.

(36) **Based on these considerations, the European Parliament concluded, among other things, that it is necessary to implement at EU level a long-term strategy aiming at reducing the EU dependence on imported vegetable proteins.**

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

[19] European Parliament resolution of 17 April 2018 on a European strategy for the promotion of protein crops – encouraging the production of protein and leguminous plants in the European agriculture sector (2017/2116(INI)).

(37) In November 2018, the European Commission published a report on the development of plant proteins in the European Union[20]. In that report, the Commission reviewed the supply and demand situation for plant proteins in the EU and explored the possibilities to further develop their production in an economically and environmentally sound way.

(38) The Commission notably identified options for further strengthening the development of EU-grown plant proteins so as to:

- support farmers growing plant proteins ;
- continue to boost competitiveness through R&I;
- promote the benefits of plant protein for nutrition, health, climate and environment.

(39) *Application to the French notifications* - By **prohibiting both the cultivation and sale** of varieties resulting from "*in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents*", **the notified texts will prevent the proper achievement of the above-described objectives, in particular regarding the necessity to strengthen the EU sovereignty for food and feed, and the necessity to boost competitiveness through R&I.**

4) CONCLUSIONS

(40) In light of the legal analysis made above, the SNIA 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;
  - do not respect EU primary and secondary law and its duty to cooperate in view of a solution at EU level ;
  - will further impede the EU sovereignty for food and feed.
- 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.

[20] COM(2018) 757 final.