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European Commission
DG Growth
Unit B2 "Prevention of technical barriers"

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01/07/2020
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Re : Draft decrees submitted by France on GMO rules with respect to mutagenesis
Y. ref. : TRIS Notification Numbers 2020/280/F, 2020/281/F, 2020/282/F

Dear Sirs,

BASF hereby submits to the European Commission its comments on the above-mentioned notifications of three draft decrees filed by France under Directive 2015/1535 laying down a procedure for the provision of information in the field of technical regulations ("TRIS"). The French draft decrees are, in BASF's view, not compatible with EU law as they create unjustified barriers to trade within the internal market.

BASF's interest in the (French) mutagenesis discussion

BASF is a global, innovation-based company with activities in a wide range of industries. Agricultural Solutions is one of the key areas of BASF's business activity. BASF provides a comprehensive portfolio of agricultural inputs and solutions to farmers worldwide, including seeds and traits, chemical and biological crop protection, soil management, plant health, pest control and digital farming. BASF makes significant investments in research and development in all those areas, contributing to a healthy and affordable food production globally.

Over decades, BASF has developed a broad portfolio of non-transgenic herbicide tolerant traits in a range of crops such as oilseed rape, sunflower and rice. Those traits are commercialized in various parts of the world through a network of licensed seed companies, to the benefit of farmers and with no observed negative effects on health or the environment. One of those traits, Clearfield® oilseed rape, is the primary target of the French draft decrees. Thus, BASF's interests are significantly affected by the mutagenesis discussion in general and in France in particular.

BASF is disappointed that the French government intends to deny French farmers the benefit of this powerful weed management tool that has been successfully used by farmers for years. The French proposal will have significant negative effects in the short and long term on agricultural innovation and trade in many areas and territories, and in particular in the EU.

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The French draft decrees constitute unjustified barriers to free trade within the EU

BASF submits that the French draft decrees constitute an unjustified attempt to create barriers to free trade within the EU for the following reasons:

Creation of barriers to free trade

The French draft decrees rest on the assertion that, in contrast with *in vivo* random mutagenesis, *in vitro* based random mutagenesis, would not qualify for exemption from GMO legislation. Put differently, the French draft decrees propose that organisms obtained through *in vitro* random mutagenesis be regulated in France exactly in the same way as transgenic events have been regulated in the EU since the adoption of the first GMO directive.

However, organisms obtained through random mutagenesis have never been regulated in the EU as GMOs and have never been split up in different groups with deviating requirements for registration. The distinction between *in vivo* and *in vitro* random mutagenesis is irrelevant for the purposes of regulatory classification, as *in vitro* is nothing more than an alternative application to *in vivo* random mutagenesis but without influencing the range of possible outcomes in terms of achievable mutations. Consequently, plants resulting from *in vitro* random mutagenesis cannot be considered GMOs.

By imposing different rules for products from random mutagenesis, France would introduce an individual national GMO regulation that interfere with the harmonized GMO regime at EU level and create significant negative effects on trade within the EU:

- Sales into France of seeds or grains derived in other EU Member States from *in vitro* random mutagenesis would become subject to prior authorization as a GMO, whereas it is unclear how such authorization should be obtained in the first place under the applicable regulatory framework for an exempted organism. The same would apply to exports from France to other EU Member States;
- Moreover, trade between France and other EU Member States in seeds or grains that are not derived from *in vitro* random mutagenesis would also be negatively impacted to a significant extent, as a result of the typical trade disruptions associated with low level presence of regulated material in non-regulated material and the substantial technical limitations and high economic cost incurred by industry and governments to implement systems for monitoring such low level presence across the entire value chain.

The above described negative effects are likely to occur in all potentially affected agricultural crops in the EU. Should France proceed with the adoption of its proposals as planned, BASF expects that the list of affected agricultural crops will ultimately get longer than it currently is.

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That said, even if the French proposals remained limited to oilseed rape, their potential negative economic impact on free trade would be particularly harmful for the European agri-food chain. This is because oilseed rape plays a vital role in the EU's efforts to become less dependent on protein imports, and France has traditionally served as a major cluster with a high concentration of activities across the entire value chain from breeding and seed production up to downstream processing.

No underlying justification

In its "Brief statement of grounds", as published in the TRIS database, the French government appears to position the draft decrees as inevitable consequence of the French *Conseil d'Etat* ("Council of State") decision of February 2020 in a court case brought by nine associations. This view is not shared by BASF. According to the "Brief statement of grounds", the Council of State "concludes that the techniques of *in vitro* random mutagenesis (...) are not conventionally used techniques which have a long safety record, having appeared or having mainly been developed since the adoption of Directive 200/18. It follows that the organisms obtained via these techniques must be subject to the regulations on GMOs. Consequently, the Council of State enjoined the Prime Minister to amend the regulations specifying the techniques of mutagenesis exempt from the regulations on GMOs in order to distinguish them from those which, according to its analysis, fall within the scope of this regulation". BASF respectfully submits that the French government puts undue emphasis on the Council of State's conclusion with respect to the status of *in vitro* random mutagenesis and omits a critical element in the dictum of the decision, notably that the government is enjoined to seek the scientific advice from the *Haut Conseil des Biotechnologies* ("High Council of Biotechnologies") to determine which exact mutagenesis techniques are exempted from GMO regulation, in application of the principles as clarified by the CJEU in its preliminary ruling in Case C-528/16. If the draft decrees were an inevitable consequence of the court ruling, the High Council of Biotechnologies' consultation would be rendered useless.

In any event, the existence of an injunction imposed by a national court could not be relied upon to overcome the need for a legitimate objective that is met by the measure. It is well established that an EU Member State measure creating obstacles to free trade within the EU may be justified under Article 36 of the Treaty on the Functioning of the European Union ("TFEU") and other mandatory requirements specified in the applicable case law, provided, always, that such measure complies with the proportionality principle. The proportionality principle, in summary, requires that a measure must be confined to what is necessary to safeguard a legitimate objective and must be proportional to the said objective.

BASF submits that the draft French decrees do not meet the above requirements for the following reasons:

- The TRIS notifications filed by France remain vague as to the precise objective of the draft decrees. No reasoning is provided to what extent the proposal could in particular be justified by the objective of public health protection under Art. 36 TFEU. The French government obviously aims to respond to concerns voiced by the nine associations on alleged risks associated with the

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cultivation of tolerant crops in France. However, random mutagenesis techniques have been used in plant breeding for decades without safety concern.

- Further, subjecting organisms obtained through *in vitro* random mutagenesis to GMO regulation in France would neither be suitable nor appropriate to address the alleged risks associated with the cultivation of herbicide tolerant crops in France:
 - o the French decrees would introduce an arbitrary distinction, with no basis in science, between *in vivo* and *in vitro* mutagenesis, which renders it unenforceable to the extent it is not possible to determine whether a given mutation derives from *in vivo* versus *in vitro* mutagenesis, or even from spontaneous mutation;
 - o if adopted as proposed, the measures not only provide for a framework around cultivation of herbicide tolerant crops in France but go far beyond that objective. Subjecting *in vitro* mutagenesis to GMO regulation triggers restrictions on other parts of the value chain that do not involve commercial cultivation (research and development, supply chain, downstream processing) as well as on trade of seeds and grains in both directions between France and other EU Member States, both in respect of the herbicide tolerance based value chains and even non-herbicide tolerance based value chains through low level presence of non-authorized materials in authorized materials. The economic costs resulting from managing low level presence as well as from trade disruption are expected to be substantial and would be disproportionate, considering that these are merely side-effects of a measure to address alleged risks associated with cultivation of herbicide tolerant crops in France.

For those reasons, BASF requests that the European Commission provides a detailed opinion under Directive 2015/1535 on the incompatibility with EU internal market rules to obtain the maximum possible extension of the current standstill period, and engages in a dialogue with France to safeguard a proper functioning of the internal market in seeds and its derived products.

We remain at your disposal should you have further questions.

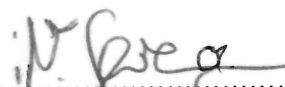
Best regards,

BASF SE



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