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Information on implementation of GMO legislation as regards GMOs produced using directed mutagenesis techniques

Dear Colleagues,

During the meetings of SCOPAFF on September 11th, 2018 and the Regulatory Committee under Directive 2001/18 on October 18th, 2018, Member States Competent Authorities were requested to provide any information relevant to the implementation of the Court ruling.

The following information was requested in particular[1]:

1. Communicate ongoing and future applications for field trials
2. Communicate products readily available in third countries and specify, if possible, if they are patented
3. Communicate experience with contained uses
4. Information on intellectual property
5. Liaise with the national competent authorities responsible for seeds to discuss the means (and potential challenges) to ensure that all registered varieties fulfil the legal requirements
6. Regarding official controls: to share information on the difficulties they are confronted with (including impact on resources) for both inspections and analytical testing, and to share good practices on inspections
7. Provide or describe specific examples of products or specific situations where the implementation of the legislation would be challenged
8. Provide available information on areas of common interest such as new techniques other than mutagenesis techniques, economic and trade impacts, ongoing research and research needs at national or EU level
9. To discuss with national laboratories to provide timely input to EURL GMFF/ENGL in view of finalising the draft report, and provide to the JRC and reference laboratories any questions and information concerning analytical issues.
10. Information on how the Member States see the implementation at national level and any forthcoming official Government position.

[1] The listed requests are, for the most part, paraphrased from the Summary Report of the Regulatory Committee 2001/18/EC meeting on 18 October 2018 and complemented by personal notes of the meeting of SCOPAFF on 9 September 2018.

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Part of the requested information was provided in our e-mail of October, 5th following the information requests during SCOPAFF in September. In order to maintain oversight and provide answers in a structured manner, our answers to all of the requests described above are listed below. Answers that were copied from the earlier NL input are indicated with a *.

1. Field trials

* In the Netherlands, there are no ongoing field trials with plants or gene therapy applications with organisms obtained by new mutagenesis techniques. Neither are such trials in the pipeline.

2. Products readily available in third countries, and available patented products

* We keep a close eye on developments like the import of gm food (plants) and products derived from it (food and feed), like the developments regarding placing on the market of gene-edited animals, but also developments in (international) research. There is a database EUginius (German&Dutch) to which we add products that are being placed on the market. We do see that developments with new mutagenesis techniques in third countries continue very fast (e.g. mushrooms from the US). When it comes to animals, the developments in China are going fast.

* We do have an overview of the known NBT-plants that might occur at the world market (see attachment). Extra information about the overview:

* The plants in the overview have been authorized by different authorities in de USA and in Canada. These plants are already at an advanced stage of pre-market development or have already been commercialized, the latter at least for 1 herbicide-tolerant rapeseed (5715 from Cibus) in Canada and the USA.
* In the USA it concerns crops that have been declared as 'non-regulated' by their USDA-APHIS[2] under their rules, i.e. crops that are field-tested, imported and that can be transported between states within the USA. This means that they also have to meet additional requirements of the EPA and FDA, if they have plant-incorporated protectants (eg disease resistance genes) at the EPA, and for use as food and feed at the FDA, at least as those rules apply.
* For the two Canadian authorizations of "plants with novel traits" it concerns the cultivation of herbicide-tolerant rapeseed (5715 and CLB-1). These two are also permitted as "novel foods" in Canada[3].

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[2] USDA APHIS: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/Regulated_Article_Letters_of_Inquiry
Canada: http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236 ; https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.htmlv
[3] commercial NPBT rapeseed: https://www.grainews.ca/2016/11/30/cibus-develops-sulfonylurea-tolerant-su-canola/

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* Not included are transgenic plants and intragenic potatoes from the same lists. The Canadian lists also do not include the plants that have been developed by using classical or in-vitro mutagenesis techniques that are not regarded as new plant breeding techniques (NBTs). If the Commission is interested in these lists (such as Clearfield), we can of course send you these. Companies themselves, such as Cibus, also indicate that more NBT crops will enter the market within a few years[4].
* Finally, we found that "high-oleic" soy with altered fatty acid composition is also commercially grown[5].

3. Experience with contained uses

NL has consistently considered applications of NBTs in the Netherlands as GMOs, except for the use of "traditional" mutagenesis techniques (induced by exposure to chemical substances or irradiation). Dutch national authorities have applied the EU GMO legislation to these organisms and their products in accordance with Directive 2009/41 and in conformity with relevant elements of the Court Ruling in this regard.

4. Intellectual property

* In the Netherlands we have no issues with intellectual property. Furthermore, new breeding techniques, patenting, and essential biological processes are also discussed with member states in the GGP group of dgGROW. We consider it would be useful if the Commission coordinates these matters internally.

5. National seed register

After consulting with the responsible authority for the national seed register, NL confirms that there are no products of directed mutagenesis listed in that register.

6. Official controls and analytical testing

* The Netherlands Food and Consumer Product Safety Authority (in Dutch: NVWA) carries out import controls that can consist of both a document check and a physical check on the batch to be imported. The basis for this check is a risk-based approach in which the country of origin, type of product and crop are taken into account. If necessary, when legislation or recent events require so, accents

[4] Future plants like rice, flax, potatoes: http://www.cibuscanola.com/canola-about
[5] http://www.calyxt.com/calyxt-exceeds-farmer-adoption-milestone-for-high-oleic-soybean-product-launch/

can be placed on specific products and/or specific countries. For example on Chinese rice products.

As requested during the meeting of the Regulatory Committee 2001/18/EC in October, some more information is hereby provided on the use of document checks in import controls.
Based on article 5, Regulation 1830/2003, information on the use of GMOs in a product "is transmitted in writing to the operator receiving the product". This type of information regarding imported goods can usually be obtained from the accompanying (transport) documentation. However, this is only helpful if the exporting country requires a GMO status to be mentioned in these documents.
An example of a specific combination of document checks and physical checks are the requirements for the import of Chinese rice products laid down in Commission implementing decision 2011/884.

* The Human Environment and Transport Authority in the Netherlands (in Dutch: ILT) controls import parties with a risk-based approach. This approach is based on a database that combines data on global gmo activities, the environmental risk and the transport flows.

The Dutch expert on detection and identification (from RIKILT, the Dutch national reference lab) communicates with the JRC on a regular basis to discuss any analytical issues.

7. Specific examples of products or specific situations where the implementation of the legislation would be challenged

At the moment, we are not aware of any such products or situations.

8. Available information on areas of common interest

As regards the New Plant Breeding Techniques, the Court ruling confirms the interpretation in the Dutch implementation of the GMO legislation. The Dutch authorities have always considered organisms produced by any new breeding technique as GMOs, excluding only products resulting from the use of "traditional" mutagenesis techniques (induced by exposure to chemical substances or irradiation) from the application of the GMO legislation.

Research with GMOs can be conducted according to the rules laid down in the applicable Dutch legislation implementing the EU GMO legislation. The same applies for trade: EU law is applicable, the Court ruling does not change this.

9. Provide input to EURL GMFF / ENGL and JRC

The Dutch expert on detection and identification (from RIKILT Wageningen University & Research, the Dutch national reference lab) has provided input for the EURL GMFF/ENGL report.

* RIKILT and NVWA are of the opinion that the possibilities for the NBT crops distinguished from conventional crops are currently very limited. In the future, when NBTs will also be able to bring about greater changes in plants (which is already happening now in microorganisms) this opinion can change, but at the moment in most cases we will not be able to make the distinction. Moreover, in our monitoring programs we work especially with complex products and that makes it even more difficult in practice. Conversely, it is possible to analyze risk-based: when specific new properties are known, and especially when the associated DNA sequence (more or less) is known, we can develop specific methods for this and detect these properties. This may concern properties that may pose a risk to people, animals or the environment. In single plant material (or animal material) there are more possibilities, but the development of this type of methodology is still in its infancy and needs to be dealt with even further.

10. Information on how the Member States see the implementation at national level and any forthcoming official Government position

In the Netherlands, the EU Court ruling itself has no consequences for national implementation or inspections. The Dutch authorities have always considered organisms produced by any new breeding technique as GMOs, excluding only products resulting from the use of "traditional" mutagenesis techniques (induced by exposure to chemical substances or irradiation) from the application of the GMO legislation. Dutch national authorities have applied the EU GMO legislation to these organisms and their products.

The Court has added significant elements to the legal interpretation of the existing GMO-legislation regarding new techniques, directed mutagenesis techniques in particular and the exemption mechanism of directive 2001/18/EC. These elements need to be addressed and are *inter alia*:

- The scope of what is to be understood by mutagenesis, is undefined and must be clarified by authorities or the EU-legislator in order to provide clarity and legal certainty;
- The scope of the existing exemption for mutagenesis is limited to products obtained by mutagenesis techniques "that have conventionally been used in a number of applications and have a long safety record" [6]

The Court has not explained what constitutes mutagenesis, nor how to determine when mutagenesis techniques or methods have traditionally been used and have proven to be safe. By consequence, the Court's ruling urges the legislator and authorities to keep the directive up-to-date in respect of technical and scientific progress. It is therefore urgent and essential that EU-authorities and the EU-legislator address these issues without undue delay in order to provide clarity and legal certainty.

The Netherlands has noted with disappointment the Commission's position that it will not tackle a revision of the GMO legislation any more as its mandate will soon

[6] Recital 17 of Directive 2001/18/EC: "This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record."

expire. The Netherlands is firmly convinced of the urgent need of a revision of the GMO legislation as appropriate, taking into consideration the consequences of the CJEU ruling for the implementation thereof.

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To that end, the Netherlands aims to promote that a revision of the EU GMO legislation and addressing the consequences of the CJEU ruling are adequately included in the mandate and Programme of Work of the incoming Commission. A more detailed description of the formal Dutch government position, including an informal courtesy translation, are provided in the attached letter to the Dutch Parliament of November 30th, 2018.

Kind regards,

On behalf of the Dutch competent authorities for directive 2001/18/EC and regulation 1829/2003,