

International Grains Council
Conseil international des céréales
Consejo Internacional de Cereales
Международный Совет по Зерну

GEN(19/20)2

Restricted

7 October 2019

TO: All members of the International Grains Council

FROM: [REDACTED], [REDACTED]

SUBJECT: Questionnaire: State of play of regulation of members' precision breeding techniques

As part of its mandate under the Grains Trade Convention, the International Grains Council (IGC) is working (a) to further international co-operation in all aspects of trade in grains, especially insofar as these affect the food grain situation; (b) to promote the expansion of international trade in grains, and to secure the freest possible flow of this trade, including the elimination of trade barriers and unfair and discriminatory practices, in the interest of all members, in particular developing members; (c) to contribute to the fullest extent possible to the stability of international grain markets in the interests of all members, to enhance world food security, and to contribute to the development of countries whose economies are heavily dependent on commercial sales of grain; and (d) to provide a forum for exchange of information and discussion of members' concerns regarding trade in grains.

In line with this mandate, information is being solicited from IGC members to support a seminar on 4 December 2019 in London on plant precision breeding innovations.

Members are requested to complete the attached questionnaire and return it to the Secretariat in word format (not pdf) **by Friday 25 October 2019**.

A summary of the replies will be circulated to members before the December seminar.

Terms and definitions:

It is worth noting that the nomenclature in these areas varies across IGC member countries, jurisdictions and cultures, including other terms such as "new plant breeding techniques", "plant breeding innovation" and "precision biotechnology". All these terms describe the continuous evolution of methods used to improve plants. One common category of these methods is gene-editing (e.g., CRISPR-Cas, and TALENs, among others), through which breeders can make precise changes to the plant's genetic material. In this survey we will use the term "**precision breeding techniques**".

Replies of the European Union

A. STATE OF PLAY OF REGULATION OF MEMBERS' PRECISION BREEDING TECHNIQUES

1. To the best of your knowledge, are products of precision breeding techniques:

	In your country Please answer Yes or No	In other countries Please answer Yes or No
Commercialized	No	Yes
Authorized (if required) but not yet commercialized	No	Yes
Waiting for authorization (if required)	No	Yes
In the R&D phase	Yes	Yes
At the conceptual stage	Yes	Yes

2. How are products of precision breeding techniques regulated in your country?

Use	Regulatory Status Please state if : - GM - Not GM - Other (please elaborate)... - Do not know/not determined
Seeds/environmental release	GM
Food	GM
Feed	GM

3. Are certain breeding techniques (e.g., Zinc Finger, CRISPR, TALEN, ODM, Cisgenesis, Reverse Breeding, Agro-infiltration...) regulated differently? If so, please explain.

A decision whether an organism falls under EU GMO legislation depends on the definition of GMO and on the exemption criteria. According to the EU legislation, any organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination is a GMO.

The only GMOs exempted from the EU GMO legislation are the following:

- organisms produced by mutagenesis techniques, which have conventionally been used in a number of applications and have a long safety record,
- organisms produced by cell fusion of plant cells of organism, which can exchange genetic material through traditional breeding methods,

provided that there is no use of recombinant nucleic acid molecule or GMOs other than those exempted.

4. Are there non-safety measures in place that would apply to products of precision breeding techniques in your country: (Please answer Yes or No)

	Yes/No
Variety registration	Yes
Traceability requirements	Yes
Identity preservation measures	Yes (only for seeds: seed certification system)
Notification of placing on the market	Yes (pre-market authorisation)
Intellectual property protection	Yes. For seeds special IP system exists (plant variety rights)
Other (please state)	Labelling requirements

5. Are you anticipating new policy, regulations or amendments to regulations in regards to products of Precisions Breeding Techniques in the next 2 years?

In 2018, the Court of Justice of the European Union clarified that organisms derived from new mutagenesis techniques are subject to the EU's legislation on GMOs. The European Commission and the Member States are implementing the legislation as interpreted by the Court.

No new policy, regulations or amendments to regulations are foreseen under the current College of the Commissioners, which is approaching the end of its mandate by the end of 2019.

B. RELEVANCE OF PRECISION BREEDING TECHNIQUES TO THE IMPLEMENTATION OF THE GRAINS TRADE CONVENTION

6. Do you see opportunities for precision breeding techniques contributing to the objectives of the Grains Trade Convention?

Yes/No: According to some stakeholders, yes.

Comment: (please elaborate on which objectives and how)

Some EU stakeholders (researchers and industry) claim that precision breeding techniques can contribute to food security by tackling challenges that agriculture is facing due to climate change and by delivering on more sustainable agriculture. It remains to be seen whether this potential will be realised.

7. Do you foresee any ways in which the use of precision breeding techniques in the future could make it more difficult to achieve the objectives of the Grains Trade Convention?

Yes/No: No

Comment: (please elaborate on which objectives and how)

It is important that all stakeholders respect the legislation in place.

8. Is greater international co-operation needed among IGC members on this issue? In what areas or on what topics?

Yes/No: Not within the IGC.

Comment: While the exchange of information within IGC is welcome, closer international co-operation between members of IGC should rather take place outside the organisation. In the view of the EU, such co-operation does not belong to the core business of the IGC and we also doubt, given the limited resources, that the organisation would have the capacity for this.

9. Should IGC provide for future exchanges of information and discussion of members' perspectives regarding this issue and the international trade in grains?

Yes/No: Yes

Comment: The European Commission is in favour of transparent flow of information.

10. Regarding liaison with the grains sector, with which partners do you currently consult on precision breeding?

- a) farmers
- b) national/regional grain trade associations
- c) grain trade companies
- d) academic research institutes working on plant breeding
- e) national/regional seed associations
- f) seed companies

The European Commission consults on the issue with all potential stakeholders listed above.

It should be noted that for the time being there is no on-going "formal" consultation on precision breeding techniques with the above-mentioned stakeholders. However, the Commission is informed of the views of these stakeholders via meetings, civil dialogues, position papers, correspondence and through government authorities of the Member States.

11. Do you need additional information or engagement from any of these partners? Please describe.

The EU would appreciate if stakeholders, in particular seed companies and seed associations, or responsible authorities of IGC members could exchange information on commercialized products developed through precision breeding techniques.