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ANNEXES 1 to 3

SENSITIVE*

ANNEXES

to the

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on plants obtained by certain new genomic techniques and their food and feed, and amending Directives 68/193/EEC, 1999/105/EC, 2002/53/EC, 2002/55/EC, and Regulation (EU) 2017/625

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ANNEX I

Criteria of equivalence of NGT plants to conventional plants

An NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than [20] genetic modifications of the types referred to in points 1 to 5, in predictable DNA sequences. A predictable DNA sequence is any DNA sequence that shares sequence similarity with the targeted site.

(1) Substitution or insertion of no more than [20] nucleotides ;

(2) Deletion of any number of nucleotides;

(3) On the condition that the genetic modification does not result in an intragenic plant:

  (a) Targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;

  (b) Targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

(4) Targeted inversion of a sequence of any number of nucleotides;

(5) Any other targeted modification of any size, on the condition that the resulting DNA sequences already occur (possibly with modifications as accepted under points 1 and/or 2) in a species from the breeders' gene pool.

ANNEX II

Risk assessment of category 2 NGT plants and their NGT food and feed

Part I - General principles for the risk assessment of category 2 NGT plants and their food and feed

This Annex describes the general principles to be followed to perform the environmental risk assessment referred to in Articles X, Y and the food and feed risk assessment referred to in Articles Z, Z.

The risk assessment shall be carried out in accordance with the principles set out in the introductory part and in sections A and B of Annex II to Directive 2001/18/EC.

Given the wide variety of NGT plants, food and feed the type and amount of information necessary for the risk assessment will vary on a case-by-case basis. Factors to be considered are, *inter alia*:

(a) the trait(s) introduced,

(b) the function of the modified or inserted genome sequence(s),

(c) the function of any gene disrupted by the insertion of a cisgene/intragene or parts thereof,

(d) prior experience with the consumption of similar plants or their products

(e) prior experience with the cultivation of the same plant species or plant species exhibiting similar traits or in which similar genome sequences have been modified, inserted or disrupted.

The information specified under Part I shall always be required for the risk assessment of NGT plants. Any information specified under Part II and III shall only be required for the risk assessment if the specific characteristics and the intended use of the NGT plant give rise to a plausible risk hypothesis that can be addressed utilising the specified information. Technical guidance shall be developed by the European Food Safety Authority for the implementation of this Annex.

1. Hazard identification and characterisation

In order to identify potential adverse effects resulting from the release of a NGT plant or the consumption of NGT food and feed, the following information shall be provided by collating already available data from scientific literature or from other sources or generating scientific data where necessary by performing appropriate experimental or bioinformatic studies.

(a) General information

1. Information relating to the recipient plant or, where appropriate, to the parental plants
2. Information relating to the release
3. Molecular characterisation

2. Exposure assessment

The likelihood of each identified potential adverse effect occurring shall be evaluated taking into consideration the characteristics of the receiving environment(s) and the scope of the application.

3. Risk characterisation

The risk shall be characterised by combining, for each potential adverse effect, the magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi quantitative estimation of the risk. Where relevant, the uncertainty for each identified risk shall be described.

Part II - Hazard identification and characterisation: specific information for environmental risk assessment of category 2 NGT plants and their food and feed

1. Analysis of agronomic, phenotypic and compositional characteristics
2. Persistence and invasiveness
3. Potential gene transfer
4. Interactions of the NGT plant with target organisms
5. Interactions of the NGT plan with non-target organisms
6. Impacts of the specific cultivation, management and harvesting techniques
7. Effects on biogeochemical processes
8. Effects on human and animal health

Part III – Hazard identification and characterisation: specific information for food and feed risk assessment of category 2 NGT plants and their food and feed

Analysis of agronomic, phenotypic and compositional characteristics

1. Toxicology
2. Allergenicity
3. Nutritional assessment

ANNEX III

Traits referred to in Article 24(1) and Article 5(1)

Part 1

The type of traits referred to in Article 24(1) are:

1. Tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, other pests
2. Tolerance/resistance to abiotic stresses, including climate adaptation
3. Improved quality or nutritional characteristics
4. Improved utilisation of resources
5. Increased yield, including yield stability and yield under low input conditions
6. Improved storage performance

Part 2

The type of traits referred to in Article 24(1) excluding the application of the incentives listed in Article 24(2) and (3), and referred to in point (a) point (ii) of Article 5(1) are:

1. Tolerance to herbicides