



Council of the
European Union

Brussels, 6 July 2023
(OR. en)

Interinstitutional File:
2023/0226(COD)

11592/23
ADD 1

AGRI 382
AGRILEG 126
ENV 824
CODEC 1316
IA 171

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	5 July 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 411 ANNEXES 1 to 3
Subject:	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 Regulation (EU) 2017/625

Delegations will find attached document COM(2023) 411 ANNEXES 1 to 3.

Encl.: COM(2023) 411 ANNEXES 1 to 3



Brussels, 5.7.2023
COM(2023) 411 final

ANNEXES 1 to 3

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 Regulation (EU) 2017/625**

{SEC(2023) 411 final} - {SWD(2023) 411 final} - {SWD(2023) 412 final} -
{SWD(2023) 413 final}

ANNEX I

Criteria of equivalence of NGT plants to conventional plants

A 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 any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

- (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 interrupt an endogenous gene:
 - (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 category 2 NGT food and feed

Part 1 of this Annex describes the general principles to be followed to perform the environmental risk assessment of category 2 NGT plants referred to in Article 13, points (c) and (d), Article 14(1), point (e), and Article 19(3), point (a), and the safety assessment of category 2 NGT food and feed referred to in Article 19(1), point (b). Part 2 describes specific information for the environmental risk assessment of category 2 NGT plants and Part 3 describes specific information for the safety assessment of category 2 NGT food and feed.

Part 1- General principles and information

The environmental risk assessment shall be carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC.

The type and amount of information necessary for the environmental risk assessment of category 2 NGT plants laid down in Annex III of Directive 2001/18/EC and for the food and feed safety assessment of category 2 NGT food and feed shall be adapted to their risk profile. Factors to be considered include:

- (a) the characteristics of the NGT plant, in particular the trait(s) introduced, the function of the modified or inserted genome sequence(s) and the function of any gene disrupted by the insertion of a cisgene or parts thereof;
- (b) prior experience with the consumption of similar plants or their products;
- (c) 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;
- (d) the scale and conditions of the release;
- (e) the intended conditions of use of the NGT plant.

The environmental risk assessment of category 2 NGT plants and the risk assessment of category 2 NGT food and NGT feed shall consist of the following:

- (a) hazard identification and characterisation;
- (b) exposure assessment;
- (c) risk characterisation.

The following information shall always be required:

- (a) hazard identification and characterisation**
 - (i) information relating to the recipient plant or, where appropriate, to the parental plants;

- (ii) molecular characterisation.

The 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.

(b) exposure assessment

Information shall be provided on the likelihood of each identified potential adverse effect. This shall be evaluated taking into consideration, as relevant, the characteristics of the receiving environment(s), the intended function, the dietary role, the expected level of use of the food and feed in the EU and the scope of the application for authorisation.

(c) risk characterisation

The applicant shall base its risk characterisation of NGT plants and foods and feed on information from hazard identification, hazard characterisation and exposure assessment. 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.

Any information on hazard identification and characterisation specified under Parts 2 and 3 shall only be required if the specific characteristics and the intended use of the category 2 NGT plant or category 2 NGT food or feed give rise to a plausible risk hypothesis that can be addressed utilising the specified information.

Part 2 - Specific information for the environmental risk assessment of category 2 NGT plants concerning hazard identification and characterisation

- (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 plant 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 3—Specific information for the safety assessment of category 2 NGT food and feed concerning hazard identification and characterisation

- (1) Analysis of agronomic, phenotypic and compositional characteristics
- (2) Toxicology
- (3) Allergenicity
- (4) Nutritional assessment

ANNEX III

Traits referred to in Article 22

Part 1

Traits justifying the incentives referred to in Article 22:

- (1) yield, including yield stability and yield under low-input conditions;
- (2) tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses and other pests;
- (3) tolerance/resistance to abiotic stresses, including those created or exacerbated by climate change;
- (4) more efficient use of resources, such as water and nutrients;
- (5) characteristics that enhance the sustainability of storage, processing and distribution;
- (6) improved quality or nutritional characteristics;
- (7) reduced need for external inputs, such as plant protection products and fertilisers.

Part 2

Traits excluding the application of the incentives referred to in Article 22: tolerance to herbicides.