Council of the European Union

Brussels, 19 November 2024
(OR. en)

15813/24

Interinstitutional File:
2023/0226(COD)

AGRI 804
AGRILEG 434
ENV 1125
CODEC 2147

NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	WP Innovation in Agriculture – Meeting of 19 November 2024 – Item 1b: Presentation of the European Food Safety Authority

Following the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) of 19 November 2024, delegations will find in annex the presentation given by the representative of the European Food Safety Authority.

20241119_WP on NGTs

SCIENTIFIC OPINION ON THE ANSES ANALYSIS OF ANNEX I OF THE NEW GENOMIC TECHNIQUES PROPOSAL

Nikoletta Papadopoulou
Team Leader Nutrition and Food Innovation Unit

efsa
EUROPEAN FOOD SAFETY AUTHORITY

CATEGORIES OF PLANTS DEVELOPED BY NGT

- **Category 1**

Plants that could occur naturally or be produced by conventional breeding techniques

Require a verification procedure to confirm that they are equivalent

- **Category 2**

Plants characterised by more complex sets of genetic modifications

Remain subject to the requirements of the EU GMO legislation

ANNEX 1 CRITERIA

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.

ANSES OPINION

1. The need to clarify the definitions and scope in the EC proposal
2. The scientific basis for these equivalence criteria
3. The need to take potential risks of category 1 NGT plants into account

EFSA'S WORK ON NGT

- To support the development of the scientific opinion on the ANSES analysis of Annex I, the GMO panel leveraged EFSA published work on targeted mutagenesis, cis-genesis and intragenesis (EFSA GMO Panel, 2012a, 2012b, 2020, 2022).


efsa JOURNAL OPEN ACCESS

Opinion | Open Access

Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function

EFSA Panel on Genetically Modified Organisms (GMO)

First published: 25 October 2012 | https://doi.org/10.2903/j.efsa.2012.2943 | Citations: 75


efsa JOURNAL OPEN ACCESS

Scientific Opinion | Open Access

Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis

EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel), Hanspeter Naegeli, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst, Michelle M Epstein ... See all authors

First published: 24 November 2020 | https://doi.org/10.2903/j.efsa.2020.6299 | Citations: 3


efsa JOURNAL OPEN ACCESS

Scientific Report | Open Access

Overview of EFSA and European national authorities' scientific opinions on the risk assessment of plants developed through New Genomic Techniques

European Food Safety Authority (EFSA), Konstantinos Paraskevopoulos, Silvia Federici

First published: 29 April 2021 | https://doi.org/10.2903/j.efsa.2021.6614 | Citations: 1


efsa JOURNAL OPEN ACCESS

Scientific Opinion | Open Access

Evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology

EFSA Panel on Genetically Modified Organisms (GMO), Hanspeter Naegeli, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst, Michelle M Epstein, Leslie George Firbank ... See all authors

First published: 05 February 2021 | https://doi.org/10.2903/j.efsa.2021.6301 | Citations: 3


efsa JOURNAL OPEN ACCESS

Opinion | Open Access

Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis

EFSA Panel on Genetically Modified Organisms (GMO)

First published: 16 February 2012 | https://doi.org/10.2903/j.efsa.2012.2561 | Citations: 86


efsa JOURNAL OPEN ACCESS

Scientific Opinion | Open Access

Updated scientific opinion on plants developed through cisgenesis and intragenesis

EFSA Panel on Genetically Modified Organisms (GMO), Ewen Mullins, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst, Michelle M Epstein, Leslie George Firbank ... See all authors

First published: 20 October 2022 | https://doi.org/10.2903/j.efsa.2022.7621 | Citations: 1


efsa JOURNAL OPEN ACCESS

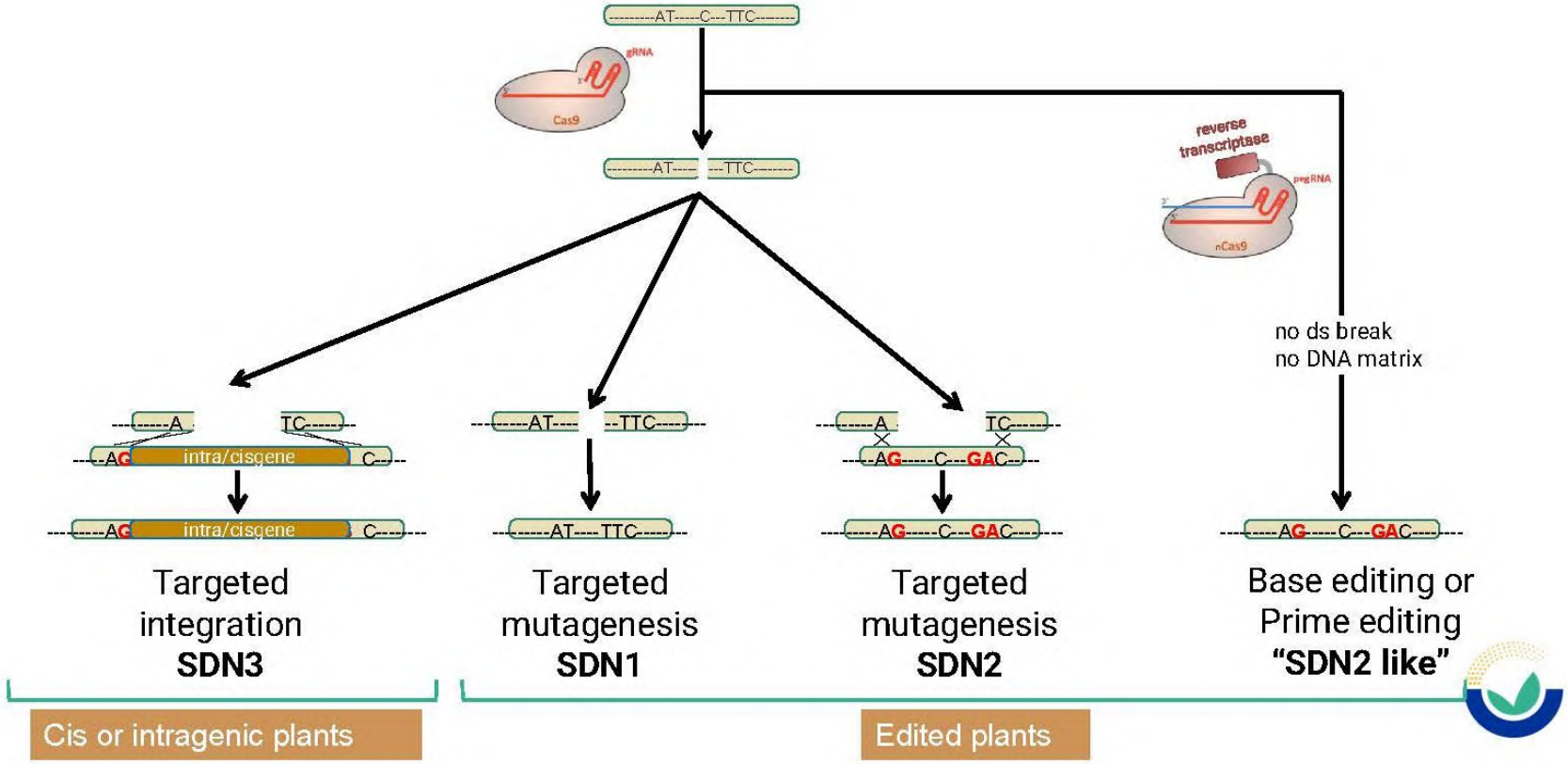
Statement | Open Access

Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis

EFSA Panel on Genetically Modified Organisms (GMO), Ewen Mullins, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst, Michelle M Epstein, Leslie George Firbank ... See all authors

First published: 20 October 2022 | https://doi.org/10.2903/j.efsa.2022.7618

DEFINITIONS

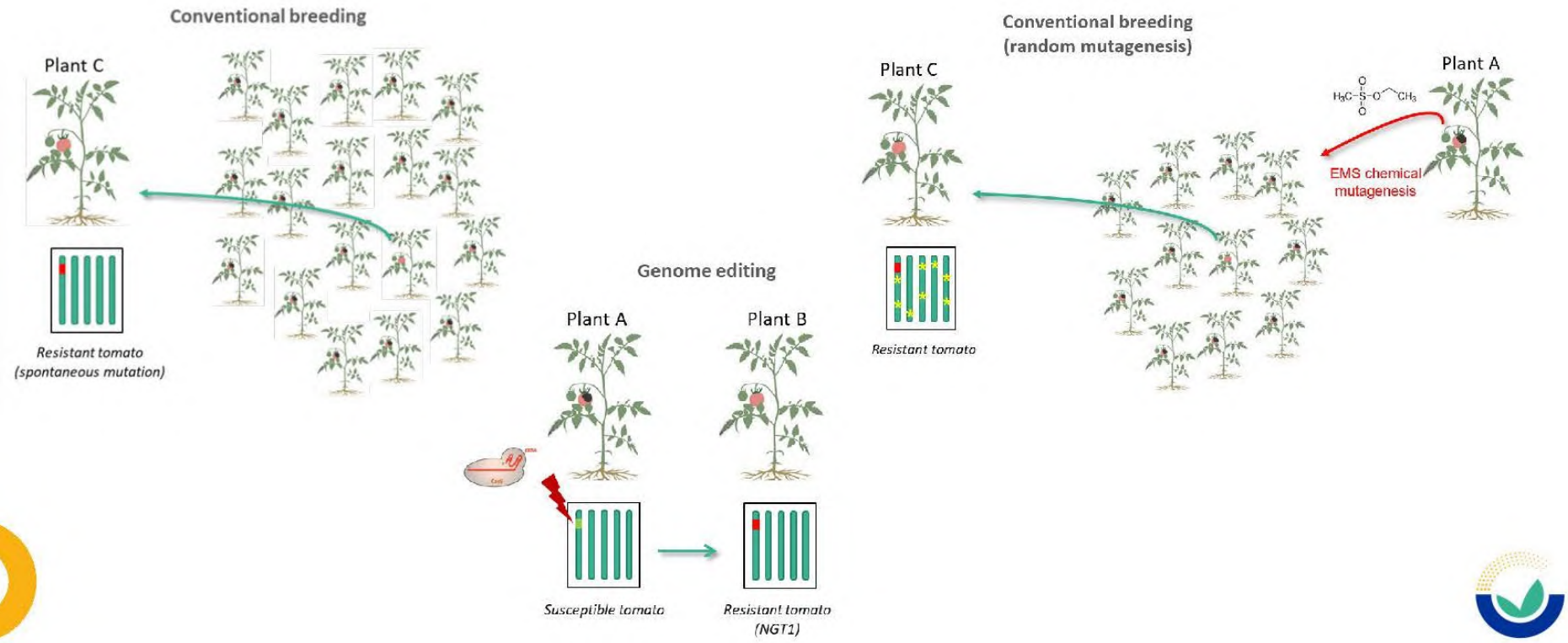


DEFINITIONS

1. The EFSA GMO Panel considered the ANSES analysis and comments on various terms used in the criteria included in Annex I of the European Commission proposal and discussed definitions based on previous EFSA GMO Panel opinions.

   With regards to the definition of the targeted site, EFSA agrees with ANSES that the term requires clarification. This definition could be revised in the legal text and/or when guidelines will be developed by EFSA.

EQUIVALENCE



EQUIVALENCE

2. The European Commission proposes a threshold of 20 genetic modifications of defined types (points 1–5 in Annex I). While the specific number is based on a risk management decision, the EFSA GMO Panel considers this number conservative given the data available in the scientific literature.

   With respect to all the equivalence criteria, the EFSA GMO Panel considers that the available scientific literature shows that plants containing the types and numbers of genetic modifications used as criteria to identify category 1 NGT plants do exist as the result of spontaneous mutations or random mutagenesis. Therefore, it is scientifically justified to consider these plants as equivalent to conventionally bred plants.

HAZARDS AND RISKS

- Off target mutations
- Unintended point mutations, deletions, insertions, inversions, and translocations
- Random mutagenesis vs Targeted mutagenesis

HAZARDS&RISKS

3. The equivalence criteria described in the European Commission proposal for category 1 NGT plants allow certain NGT plants to be classified as equivalent to conventionally bred plants with respect to the similarity of genetic modifications and the similarity of potential risks.

   The EFSA GMO Panel did not identify any additional hazards and risks associated with the use of NGTs compared to conventional breeding techniques in its previous Opinions.

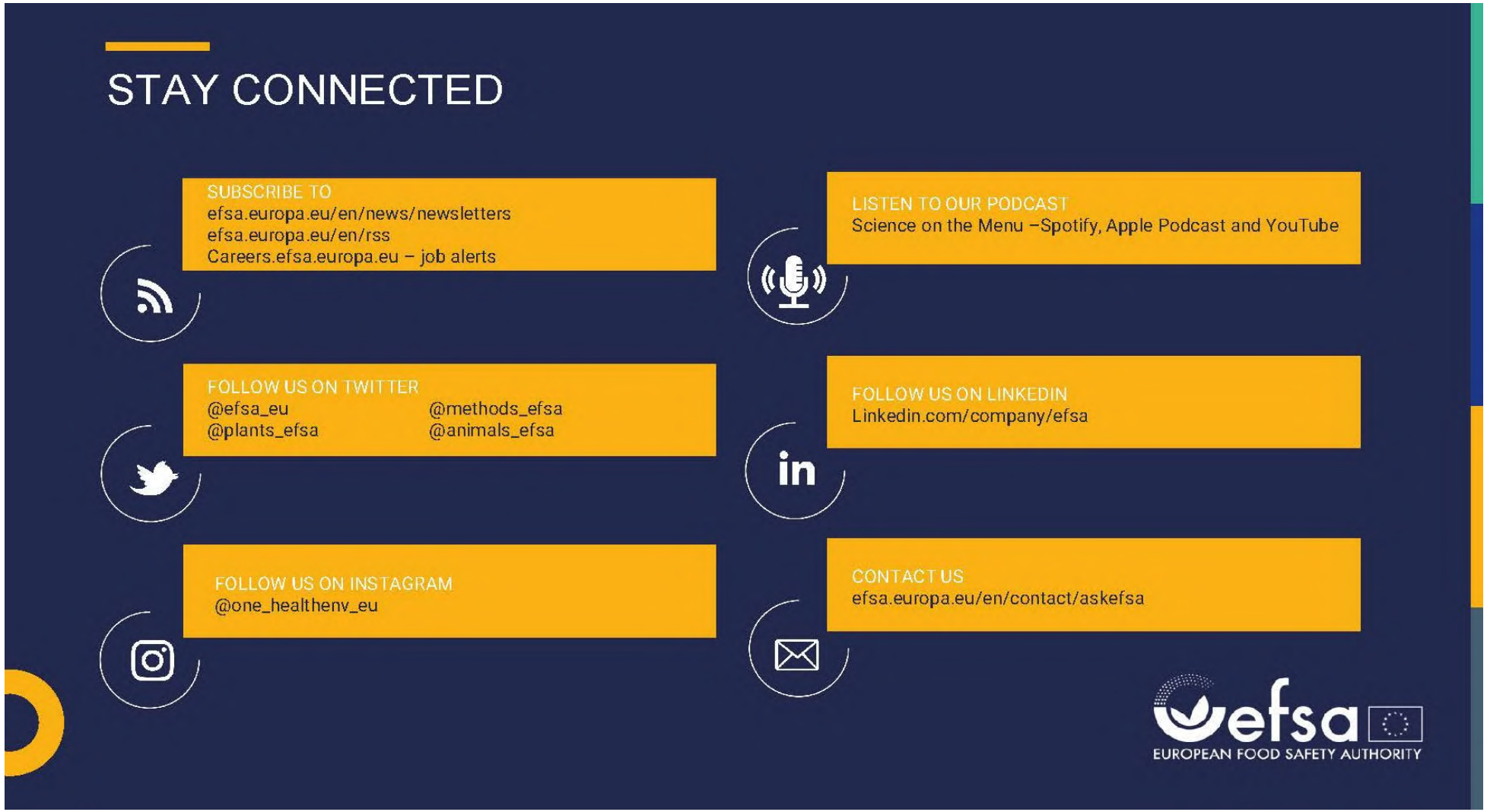
EFSA GMO PANEL FUTURE WORK

- Monitor scientific knowledge updates
- Develop fit for purpose Risk assessment methodologies
- Excellency and Transparency

ARTICLE 31

Request from the Commission to EFSA to provide scientific and technical assistance for a regular horizon scanning to assess new scientific data on plants, animals, microorganisms and products thereof obtained by new genomic techniques (EFSA-Q-2024-00643)

- Development of adequate methodology for a reproducible literature review with deliverables every 6 months. The first deliverable is expected at the end of June 2025.
- This request includes the period November 2024 - December 2026. The need for its continuation will be assessed by the end of this period.


STAY CONNECTED
SUBSCRIBE TO
efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss
Careers.efsa.europa.eu – job alerts
LISTEN TO OUR PODCAST
Science on the Menu –Spotify, Apple Podcast and YouTube
FOLLOW US ON TWITTER
@efsa_eu
@plants_efsa
@methods_efsa
@animals_efsa
FOLLOW US ON LINKEDIN
Linkedin.com/company/efsa
FOLLOW US ON INSTAGRAM
@one_healthenv_eu
CONTACT US
efsa.europa.eu/en/contact/askefsa
efsa
EUROPEAN FOOD SAFETY AUTHORITY