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

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Background

- In November 2019, the Council of the EU requested the EC to submit a study **regarding the status of new genomic techniques (NGTs)** under Union law
  - As regards the requested study, the EC needed **an analysis of the status of NGTs that includes safety considerations**
  - The EC intended to include in the study **relevant existing scientific opinions** addressing the safety assessment of plants developed through NGTs

1. Terms of reference

ToR

- Provide an overview on the risk assessment (RA) of plants developed through NGTs
- For this overview, EFSA was not requested to develop new opinions on plants developed through specific NGTs. Rather, to take into account its previous scientific opinions, its ongoing work on the topic as well as opinions published by competent authorities and national institutions since 2012, where available

NGTs are defined as techniques capable to change the genetic material of an organism and that have emerged or have been developed since the adoption of the GMO legislation in 2001

2. Data

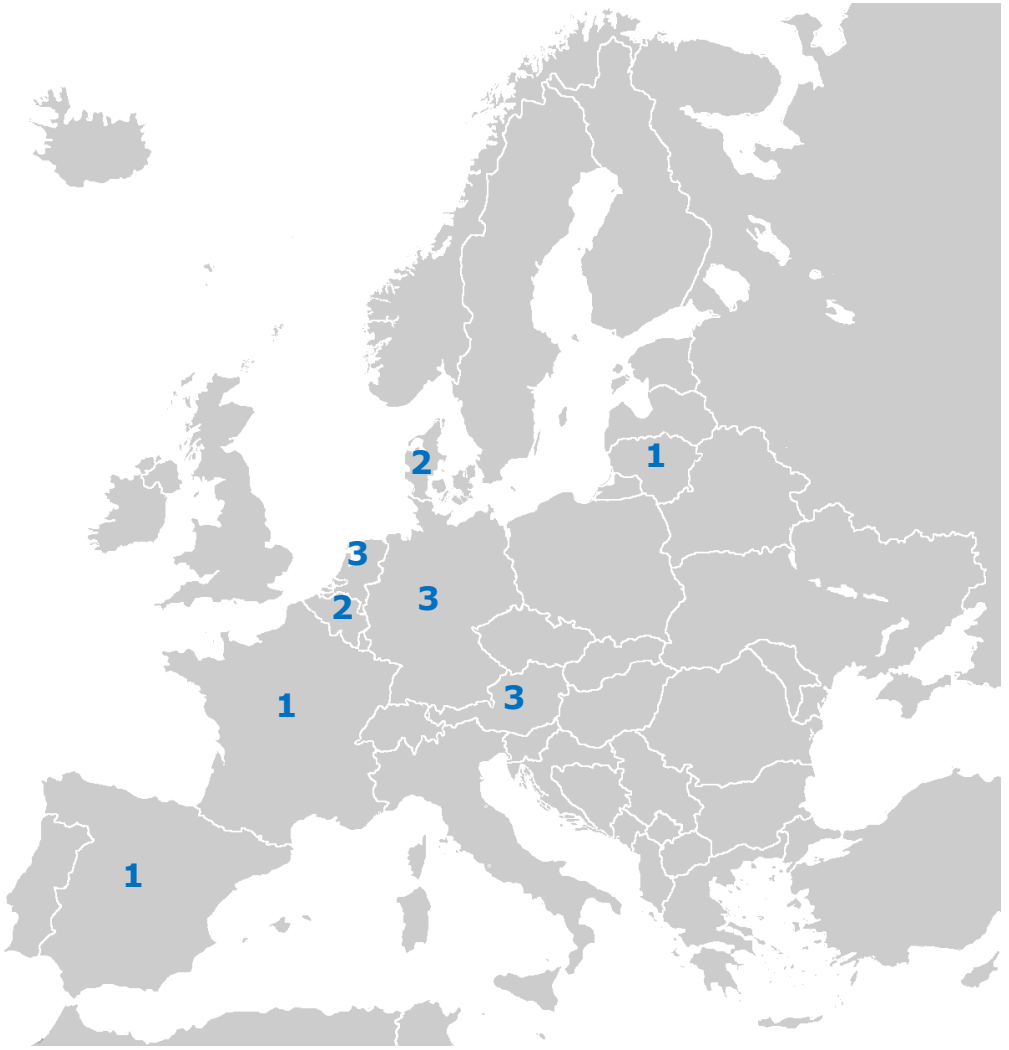
- 16 Member States (MS) scientific opinions on NGTs, from 2012 to 2020, following a request to all the MS via the Joint Working Group on new genomic techniques

  [AT (x 3), BE (x2), DE (x 3), DK (x 2), ES (x 1), FR (x1), LT (x 1), NL (x 3)]

- EFSA scientific opinion on plants developed through cisgenesis and intragenesis (EFSA GMO Panel, 2012)

- EFSA scientific opinion on plants developed using ZFN-3 and other SDNs with similar function (SDN-3) (EFSA GMO Panel, 2012)

- EFSA scientific opinion on plants developed through SDN-1, SDN-2 and ODM (EFSA GMO Panel, 2020)



Methodology

- Baseline set based on JRC document on new plant breeding techniques (JRC, 2011) and EC-SAM report on new techniques in Agricultural Biotechnology (EC-SAM, 2017)

- For opinions of broader content, inclusion/exclusion criteria applied:

Inclusion	Exclusion
Information on the **description of the NGTs** based on definition	techniques that **do not modify genetic material per se** (e.g. RNAi) or are applied **to organisms other than plants** (e.g. gene drive in insects)
RA aspects **of plants** developed through **one or a combination of NGTs**	elements **other than RA considerations** such as risk management/policy, detection methods and labeling

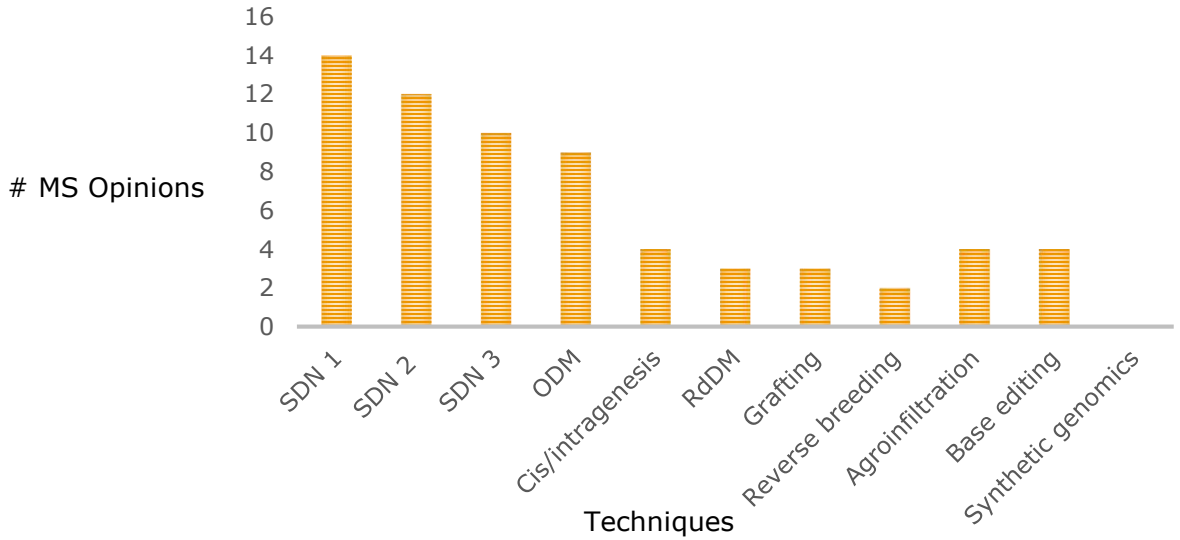
- EFSA tasked RIVM in the frame of a procurement to prepare an overview of the scientific opinions produced by the MS

- Content was evaluated and relevant information was extracted and summarized

4. Results

MS Scientific Opinions

- Information on: Site-directed nucleases (SDN) technology (SDN-1, SDN-2, SDN-3), oligonucleotide-directed mutagenesis (ODM), cis/intra-genesis, RNA-dependent DNA methylation (RdDM), grafting, reverse breeding, agro-infiltration (**no info on synthetic genomics**)
- Information extracted on SDN technology, including newly developed genome editing methods (e.g. **CRISPR-Cas**), from 14 MS opinions
- Information extracted on **base-editing** from 4 MS opinions
- Two scientific opinions discussed how multiple NGTs can be used in various combinations (e.g. cis/intra-genesis with SDN and ODM methods)



4. Results

EFSA Scientific Opinions

- All three SDN approaches discussed, including newly developed methods such as CRISPR-Cas
- ODM and cisgenesis/intragenesis
- Prime/base editing briefly discussed and considered comparable to SDN-2 (EFSA GMO Panel, 2020)
- All EFSA scientific opinions on NGTs followed a comparative approach with respect to safety considerations on conventional breeding and transgenesis
- All EFSA scientific opinions discussed the applicability of current EFSA Guidance documents (F&F and ERA) for the discussed NGTs

4. Results

Conclusions from EFSA Scientific Opinions

- EFSA scientific opinion on plants developed through cisgenesis and intragenesis (EFSA GMO Panel, 2012)
- EFSA scientific opinion on plants developed using ZFN-3 and other SDNs with similar function (SDN-3) (EFSA GMO Panel, 2012)
- EFSA scientific opinion on plants developed through SDN-1, SDN-2 and ODM (EFSA GMO Panel, 2020)

- No new hazards associated with plants produced by cis/intra-genesis and SDN-1,-2, -3, ODM techniques were identified compared to transgenic and conventionally bred plants
- The current EFSA Guidance documents are applicable in case of plants produced by cis/intra-genesis and SDN-3, and partially applicable in case of plants produced by SDN-1, -2, ODM techniques
- There is a need for flexibility in the data requirements for the risk assessment, as on a case-by-case lesser amounts of data might be needed

5. Acknowledgements

EFSA GMO Panel

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