EC mandate on plants developed using type 1 and type 2 Site-Directed Nucleases and Oligonucleotide Directed Mutagenesis

Ad hoc meeting with industry representatives

23-24 October, Parma

Trusted science for safe food

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European Food Safety Authority

Mandate on SDN-1, SDN-2, and ODM

- Background 1:
  - EUCJ C-528/16
- Background 2:
  - EFSA GMO Panel 2010 (Guidance)
  - EFSA GMO Panel 2011 (Guidance)
- Background 3:
  - EFSA GMO Panel 2012 (Opinion on SDN-3)

Background 1 – EUCJ C-528/16

Press and Information

Court of Justice of the European Union

PRESS RELEASE No 111/18

Luxembourg, 25 July 2018

Judgment in Case C-528/16
Confédération paysanne and Others v Premier ministre and Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt

Organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive

Directive 2001/18/EC, that regulates the deliberate release of GMOs into the environment, **is applicable** to plants obtained by mutagenesis techniques that have emerged since its adoption

SDN-1, SDN-2, and ODM

Background 2 – EFSA Guidance

Two EFSA guidances outline the principles for

- the **environmental risk assessment** of genetically modified (GM) plants (GMO Panel 2010)
- the **risk assessment of food and feed** from GM plants (GMO Panel 2011)


European Food Safety Authority

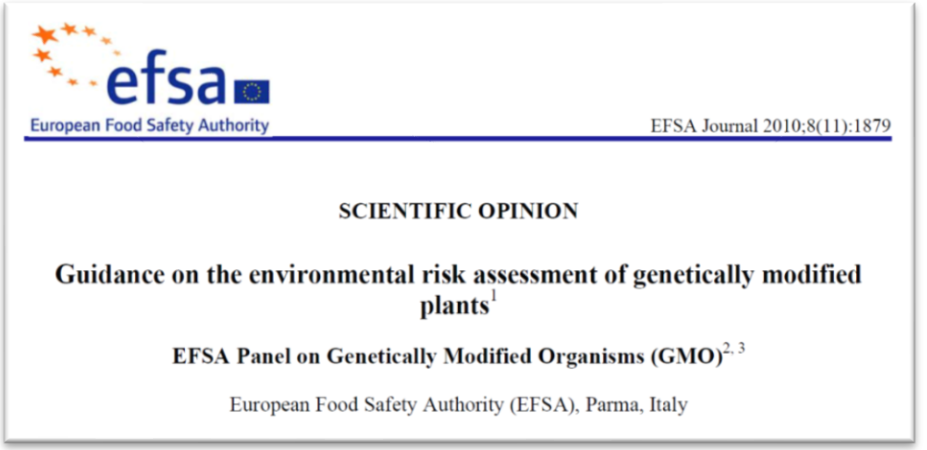
EFSA Journal 2011; 9(5):2150

SCIENTIFIC OPINION

Guidance for risk assessment of food and feed from genetically modified plants[1]

EFSA Panel on Genetically Modified Organisms (GMO)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy


European Food Safety Authority

EFSA Journal 2010;8(11):1879

SCIENTIFIC OPINION

Guidance on the environmental risk assessment of genetically modified plants[1]

EFSA Panel on Genetically Modified Organisms (GMO)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

Background 3 – Opinion on SDN-3

In 2011 EC requested EFSA to assess the adequacy of EFSA guidelines (2010 and 2011) to perform a risk assessment of plants developed through **Zinc Finger Nuclease 3 (ZFN-3)**.

In 2012 EFSA published a scientific opinion on ZFN-3/SDN-3:

European Food Safety Authority

EFSA Journal 2012;10(10):2943

SCIENTIFIC OPINION

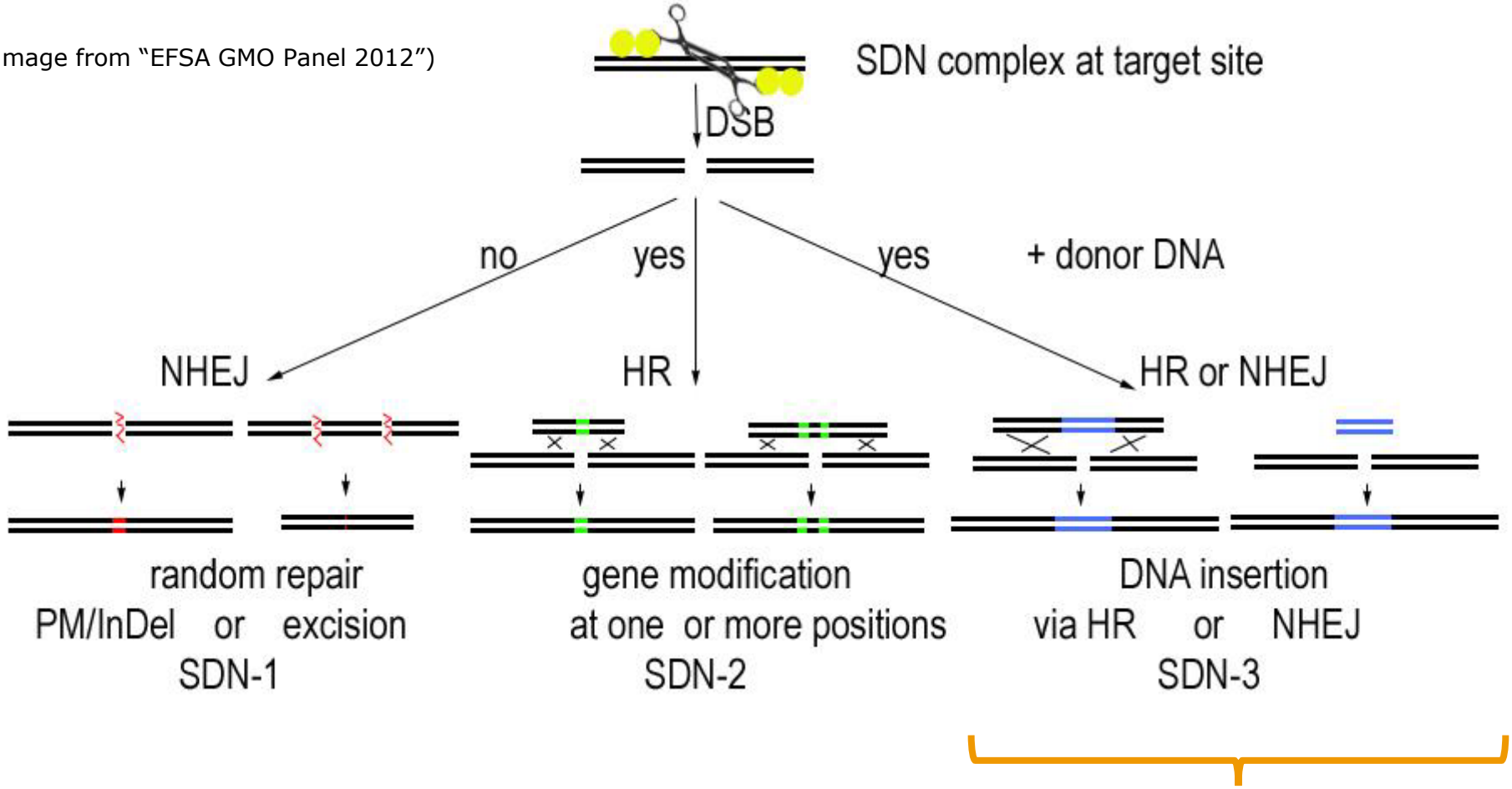
Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function[1]

EFSA Panel on Genetically Modified Organisms (GMO)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SDN1, SDN2, and SDN3: COMPARISON

(image from "EFSA GMO Panel 2012")



EFSA GMO Panel 2012

New Mandate on SDN-1, SDN-2, and ODM

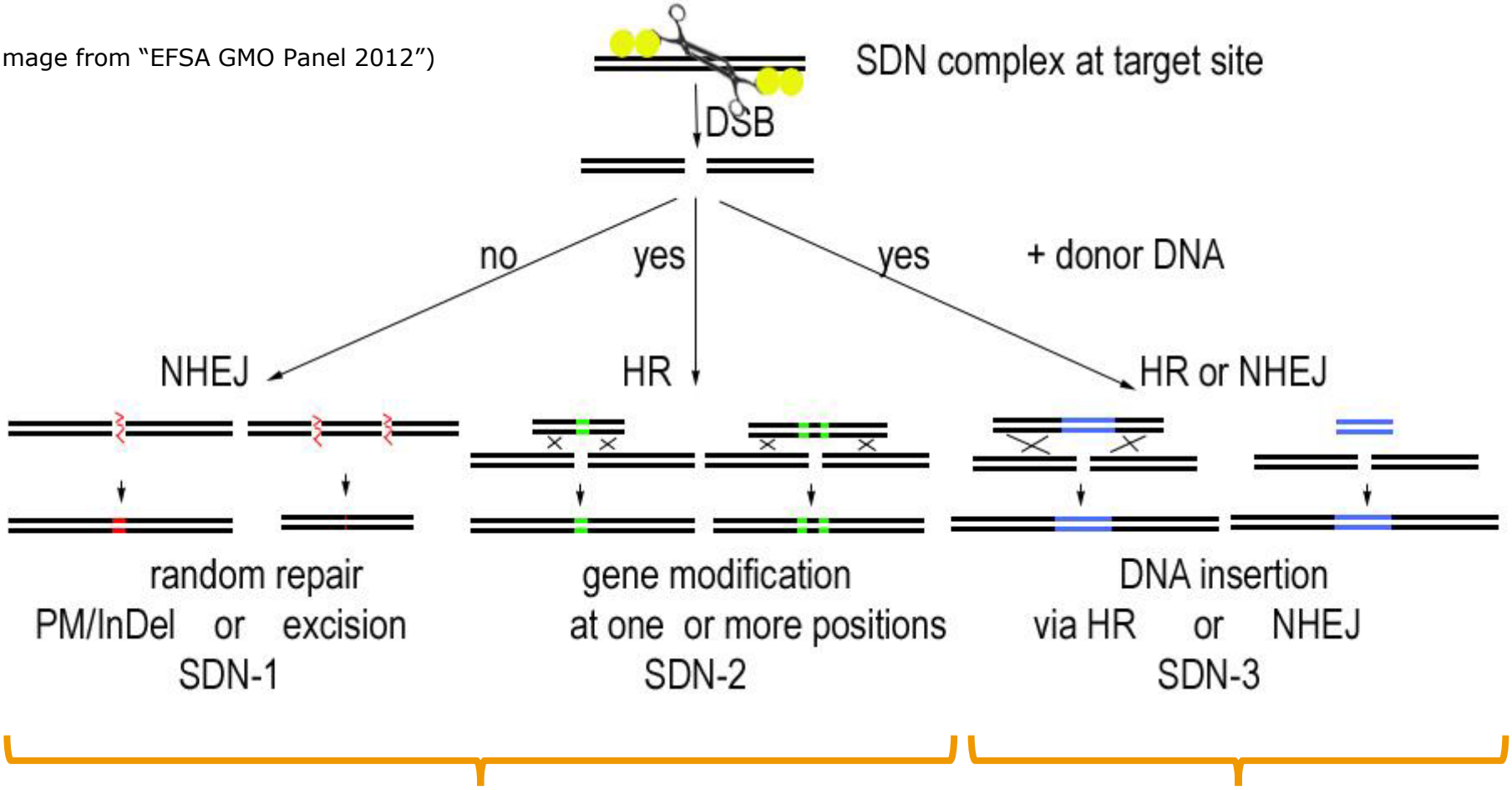
Scientific opinion on plants developed using type 1 and type 2 Site-Directed Nucleases and Oligonucleotide Directed Mutagenesis

- Requestor:
  - European Commission (EC)
- Date:
  - April 2019

- Output type:
  - **GMO Panel Scientific Opinion**
- Timeline:
  - Final opinion adopted by 30 April 2020

SDN1, SDN2, and SDN3: COMPARISON

(image from "EFSA GMO Panel 2012")



This mandate on SDN1&2 + ODM (Ongoing!)

EFSA GMO Panel 2012 (Published!)

Terms of reference (Mandate)

1. To advice whether the assessment methodology described in **section 4 of the 2012 EFSA** scientific opinion addressing the safety assessment of plants developed using SDN-3, **may be applicable, in whole or in part, to plants developed with type 1 and type 2 Site-Directed Nucleases (SDN-1, SDN-2) and with oligonucleotide directed mutagenesis (ODM)**.

In case the advice in 1. is affirmative

2. To advice whether the **conclusions of the EFSA 2012 scientific opinion** addressing the safety assessment of plants developed using SDN-3 **are valid**, in whole or in part, to plants developed with SDN-1, SDN-2 and ODM.

EFSA GMO Panel 2012 – **Section 4**

HAZARD IDENTIFICATION ADDRESSING QUESTION TWO OF THE MANDATE: IDENTIFICATION OF CHARACTERISTICS WITH THE POTENTIAL TO CAUSE ADVERSE EFFECTS

4.1. Source of genes and safety of gene products

4.2. Alterations to the genome

4.2.1. Alteration at the insertion site

4.2.2. Alteration elsewhere in the genome

4.3. Conclusion

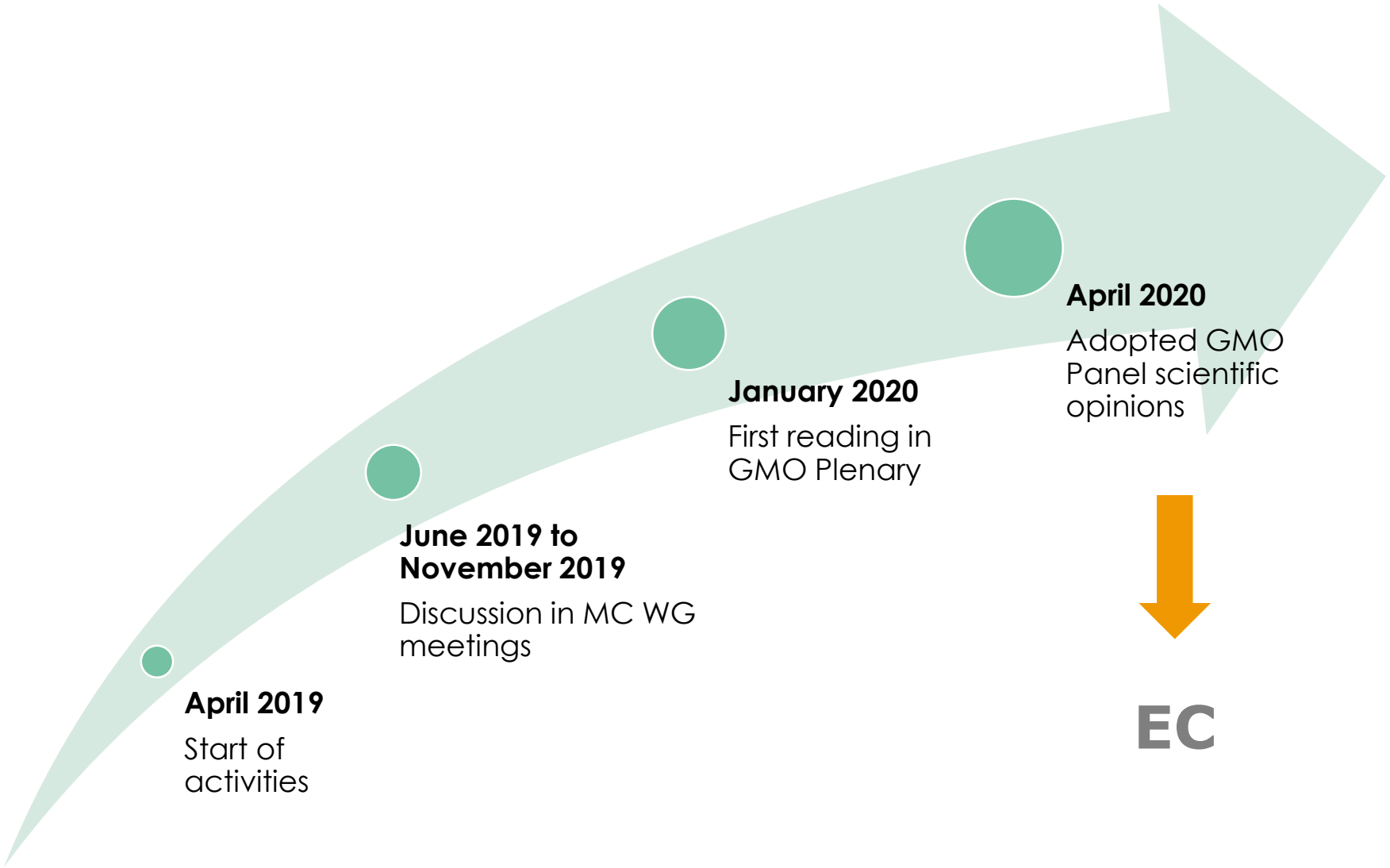
EFSA GMO Panel 2012 – **Conclusions**

1. For SDN-3 technique, the **insertion of DNA is targeted** to a predefined region of the genome.
2. The SDN-3 technique can induce **off-target changes but these would be fewer** than those occurring with most mutagenesis techniques.
3. With respect to the genes introduced, SDN-3 technique **does not differ** from the other genetic modification techniques currently used
4. **The Guidance (EFSA GMO Panel 2011) and (EFSA GMO Panel 2010) are applicable** for the evaluation of food and feed products derived from plants developed using the SDN-3 technique and for performing an environmental risk assessment.
   - ✓"on a case-by-case basis lesser amounts of event-specific data may be needed for the risk assessment"

Mandate work and outcome

- Discussion in the standing **molecular characterization (MC) working group (EFSA GMO Panel)**
- ***Ad-hoc* discussion in FF and ERA WGs if needed**
- **GMO Panel Scientific Opinion** on the applicability of section 4 of GMO Panel 2012 (SDN-3) and the overall adequacy of the its conclusions for GM plants produced by SDN-1, SDN-2 and ODM techniques

Timeline


April 2019
Start of activities
June 2019 to November 2019
Discussion in MC WG meetings
January 2020
First reading in GMO Plenary
April 2020
Adopted GMO Panel scientific opinions
EC

Thanks!

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