



18 June 2019

# Scientific opinion on plants developed using SDN-1&2 and ODM

**Tommaso Raffaello**

Scientific Officer



- Requestor:
  - European Commission (EC)
- Date:
  - April 2019
- Output type:
  - GMO Panel Scientific Opinion
- Timeline:
  - Final opinion adopted by 30 April 2020

# Background

The CJEU in Case C-528/16, has clarified that

**1. 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

Two EFSA guidances outline the principles for

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



**efsa**  
European Food Safety Authority

EFSA Journal 2011;9(9):2150

**SCIENTIFIC OPINION**

**Guidance for risk assessment of food and feed from genetically modified plants<sup>1</sup>**

**EFSA Panel on Genetically Modified Organisms (GMO)<sup>2,3</sup>**

European Food Safety Authority (EFSA), Parma, Italy



**efsa**  
European Food Safety Authority

EFSA Journal 2010;8(11):1879

**SCIENTIFIC OPINION**

**Guidance on the environmental risk assessment of genetically modified plants<sup>1</sup>**

**EFSA Panel on Genetically Modified Organisms (GMO)<sup>2,3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

# Background

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.



**In 2012 EFSA published a scientific opinion on Site-Directed Nuclease type 3 (SDN-3):**



In this scientific opinion, the assessment methodology applied by the EFSA GMO Panel was **to compare the hazards associated with plants produced by the SDN-3 technique with those obtained by conventional plant breeding techniques** and by traditional transgenesis.

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)**.

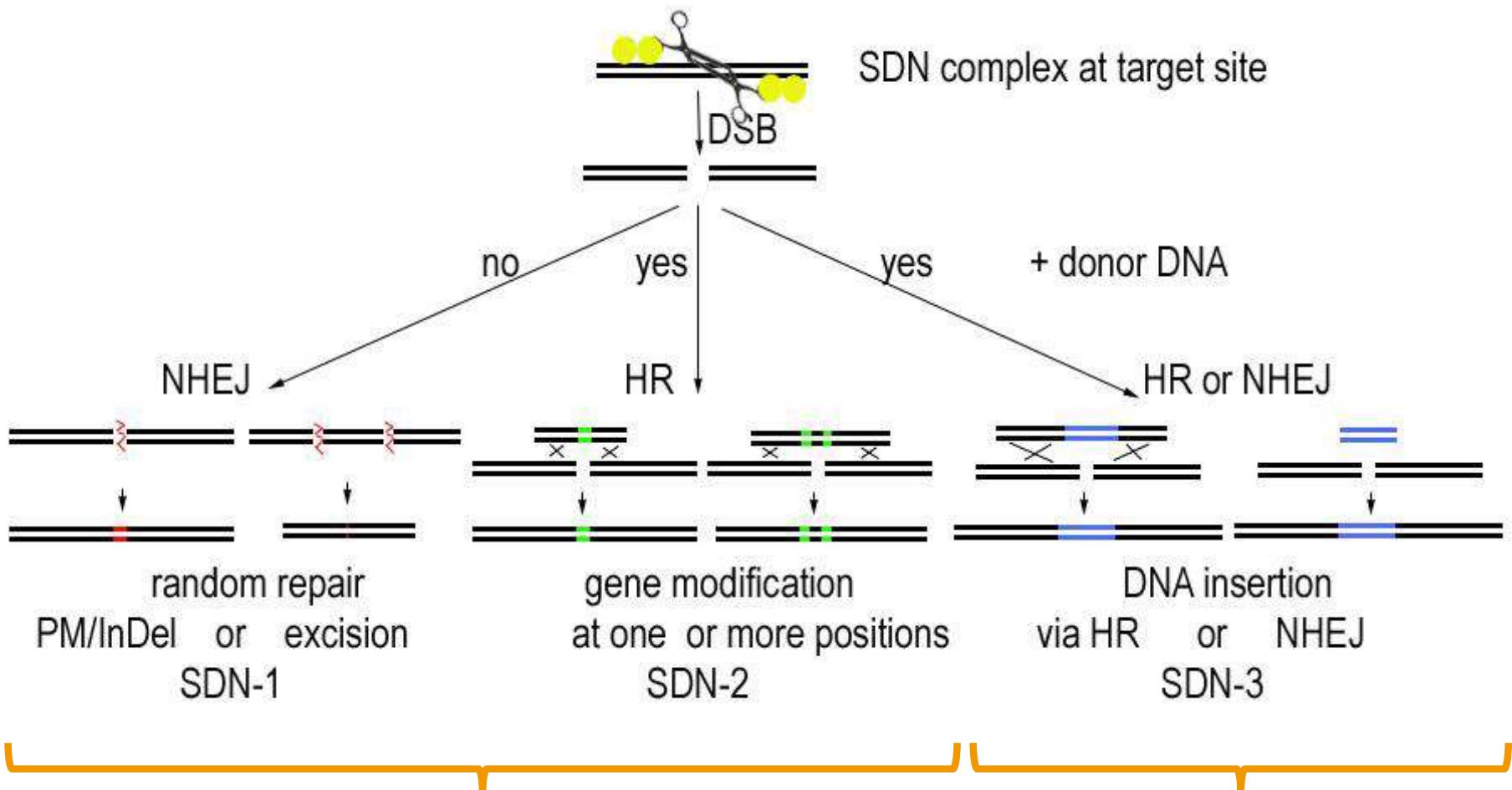
In case the advice in 1. is affirmative



Yes?

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.

# SDN1, SDN2, and SDN3: COMPARISON



**This mandate on SDN1&2**

**EFSA GMO Panel 2012**

- Discussion in **the standing MC working group**
- ***Ad-hoc discussion in FF and ERA WGs if needed***
- **GMO Panel Scientific Opinion** on the applicability of section 4 of GMO Panel 2012 (SDN3) and the overall adequacy of the its conclusions for GM plants produced by SDN1-2 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  
opinion

- Project coordinator

- Tommaso Raffaello

- Project contributors

- Molecular characterisation (MC)

- Konstantinos Paraskevopoulos

- Environmental risk assessment (ERA)

- Andrea Gennaro

- EC observers

- Ilaria Ciabatti

- Alexandre Huchelmann

- Luis Vivas-Alegre

# Thanks!



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