

18 June 2019



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

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

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

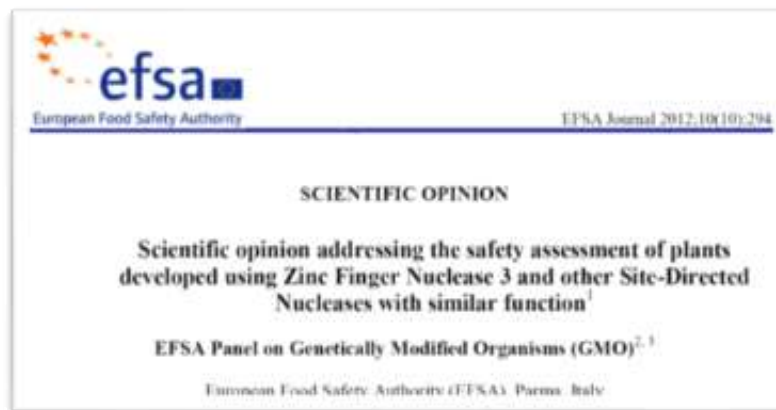
2. the **environmental risk assessment** of genetically modified (GM) plants (GMO Panel 2010) and
3. the **risk assessment of food and feed** from GM plants (GMO Panel 2011)



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).**

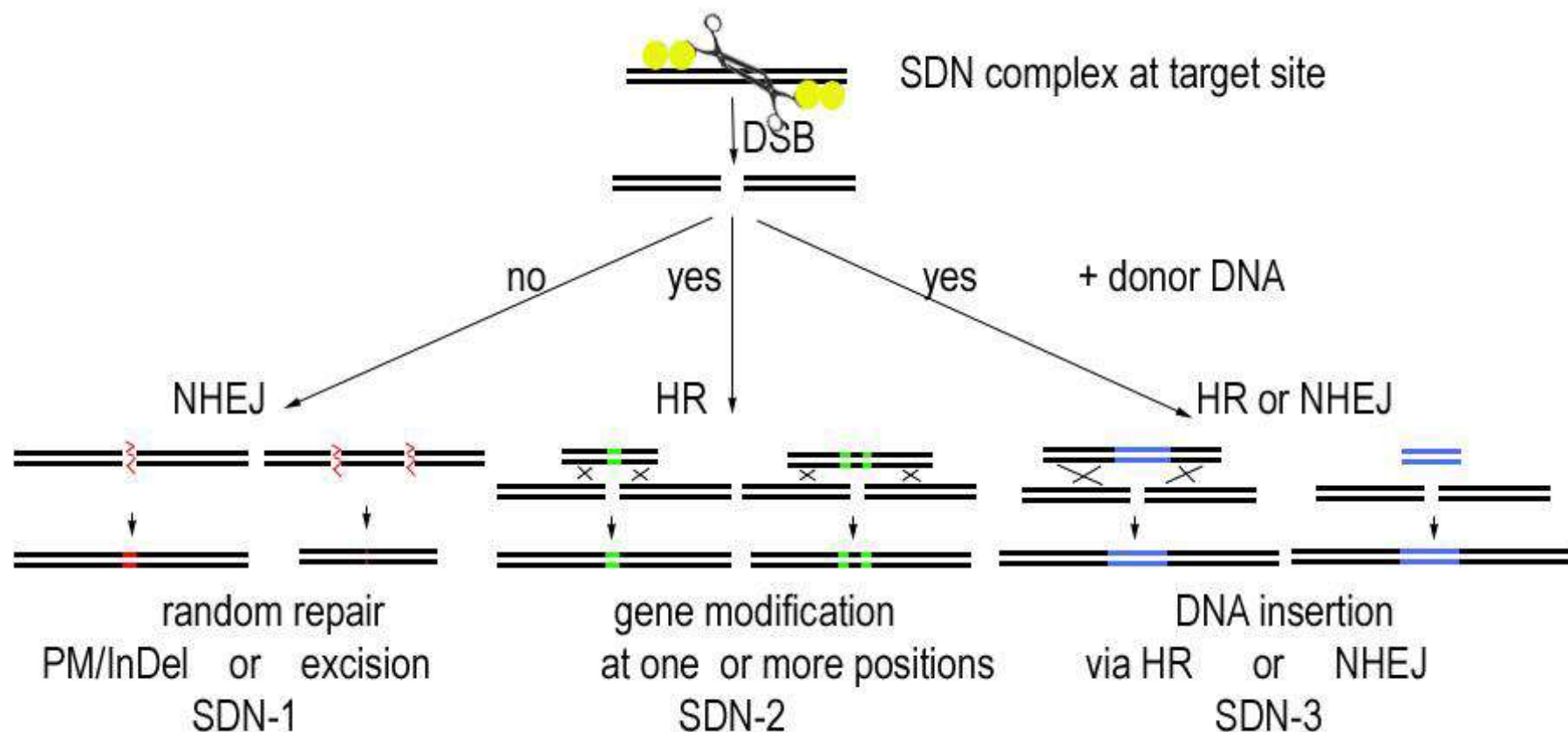
In case the advice in 1. is affirmative



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

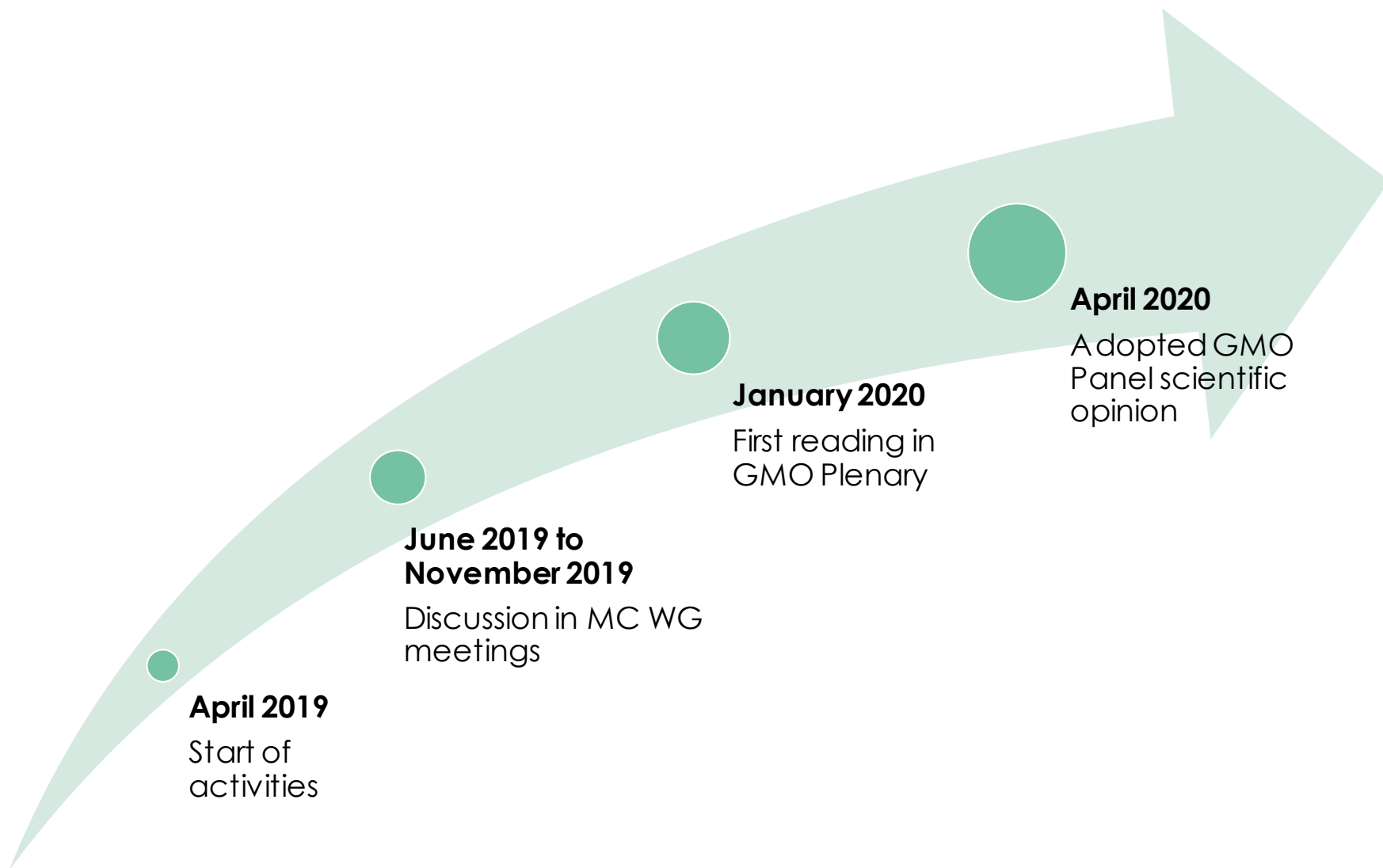


This mandate on SDN1&2

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



- 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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