Comment to the draft opinion on SDN-1&2 + ODM

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Quotes from the SDN-3 opinion (1)

"The main difference between the SDN-3 technique and transgenesis is that the insertion of DNA is targeted to a predefined region of the genome. Therefore, the **SDN-3** technique can **minimise hazards** associated with the **disruption of genes and/or regulatory elements** in the recipient genome.

Quotes from the SDN-3 opinion (2)

Whilst the **SDN-3** technique can induce **off-target changes** in the genome of the recipient plant these would be **fewer** than those occurring with most mutagenesis techniques. Furthermore, where such changes occur they would be of the **same types** as those produced by **conventional breeding** techniques."

Quotes from the SDN-3 opinion (3)

"on a case-by-case basis **lesser amounts of event-specific data** are needed for the risk assessment"

Quotes from the draft opinion

"The GMO panel considers that this conclusion applies also to plant generated via **SDN-1, SDN-2, and ODM** approaches. Indeed, in the absence of any transgene, the amount of **experimental data** needed for the risk assessment will mainly depend on the **modified trait introduced** and **even less amount of experimental data** would be needed for plants produced via SDN-1, SDN-2,and ODM **compared to plants generated via SDN-3**.

Conclusions from the opinions (SDN-3; SDN-1 + SDN-2 + ODM)

- Lesser likelihood of unintended effects
  - No disruption of host genes & regulatory elements
  - Off-target less or comparable to other forms of mutagenesis
- Focus on modified *trait*
  - No exogenous DNA introduced

Data currently supporting assessment of potential unintended effects

- Molecular characterization
- Comparative assessment
  - Composition
  - Agronomics/phenotypics
- Whole-food/feed feeding studies (mandatory in rodents)

Question: Can these steps be skipped (except for identifying effects linked to the target trait)?

Feedback welcomed on the following questions for SDN-1 + SDN-2 + ODM

- Will the EFSA GMO Panel develop more detailed guidance on specific requirements for these techniques?
- If not, should applicants themselves decide and justify if and which lesser experimental data they will provide for risk assessment?