COMMITTEE PAPER FOR DISCUSSION **ACNFP/145/03**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

DEFRA CONSULTATION ON THE REGULATION OF GENETIC TECHNOLOGIES

Issue

Members are invited to consider and provide feedback on the Department for Environment Food and Rural Affairs consultation on the regulation of genetic technologies.

Background

1. At the end of the transition period, EU legislation on the deliberate release of genetically modified organisms (GMO) was retained. Current UK legislation requires organisms obtained by mutagenesis* including genome edited (GE) organisms to be classified as genetically modified, irrespective of whether the organism could have been produced via conventional breeding methods. *excluding exempt mutagenesis techniques, namely those which have conventionally been used in several applications and have a long safety record.

2. Defra have started a public consultation period of three months from the 7th January 2021 to the 17th March 2021. The consultation focuses on organisms produced through genome editing or other genetic technologies that are equivalent to those that could have been produced through conventional breeding methods.

3. Defra's view is that organisms produced by GE or by other genetic technologies should not be regulated as GMOs if they could have been produced by conventional breeding methods. Leaving the EU provides an opportunity to consult on the implications of addressing this issue.

4. The genetic technologies which may produce organisms that could have been produced by conventional breeding include: random mutagenesis, site directed nuclease 1 (SDN1), some SDN2 genome editing and cisgenesis.

The consultation

1. The consultation comprises of two parts, and can be found at https://consult.defra.gov.uk/agri-food-chain-directorate/the-regulation-of-genetic-technologies/

2. Part 1 focuses on the regulation of genome edited organisms possessing genetic changes which could have been introduced by conventional breeding. The results of which may influence amendments to the definition of a genetically modified organism in England. This could mean that organisms produced by genome editing and other genetic technologies where the resultant organism is equivalent

to those which could have been produced through conventional breeding are not considered GM in future.

3. Part 2 focuses on gathering views on the wider regulatory framework governing genetically modified organisms. The responses from part 2 will be used to inform Defra policy development and stakeholder engagement plans on any potential wider GMO reform.

Committee Action Required

- Members are asked whether the Committee would provide a response to the public consultation process.
- If the Committee wish to respond to the consultation, members are asked to discuss and formulate a Committee response to the consultation questions (Annex A).
- Members are asked to consider if all products that could occur naturally regardless of the genetic technology applied are considered non-GM, what would the Committee want to see to ensure safety of the products? Would a review of data or risk assessment be needed?
- What are the key differences in safety risk between genome editing SDN1, 2 and 3 changes or cisgenesis and which would trigger the need for a risk assessment?
- Members are asked to discuss if a risk assessment is needed in response to the questions above, what would an appropriate risk assessment comprise of?

Secretariat
January 2021

Annex A. Defra gene editing consultation questions.