AS DELIVERED

REGULAR DSB MEETING-18 DECEMBER 2018

<u>AGENDA POINT 1</u>: SURVEILLANCE OF IMPLEMENTATION OF RECOMMENDATIONS ADOPTED BY THE DSB

C. EUROPEAN COMMUNITIES – MEASURES AFFECTING THE APPROVAL AND MARKETING OF BIOTECH PRODUCTS: STATUS REPORT BY THE EUROPEAN UNION (WT/DS291/37/ADD.128)

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- In July, the Court of Justice of the European Union provided important clarification on the scope of application of the GMO legislation in relation to organisms obtained by mutagenesis techniques.
- The CJEU ruled that organisms obtained by means of new techniques/methods of mutagenesis, which have appeared or have been mostly developed since the adoption of Directive 2001/18, fall within the scope of the Directive.
- The ruling has <u>not</u> extended the scope of the legislation but has clarified how it should be read.
- The Commission is now working to ensure proper implementation of the ruling together with the Member States. Member States are responsible at national level for the relevant control activities regarding the placing on the market of both products produced in the EU and imported ones. To this effect, the Joint Research Centre (JRC) is helping national laboratories to develop relevant detections methods.
- The Group of Chief Scientific Advisors of Scientific Advice Mechanism (SAM) provides independent scientific advice to the Commission.
- The recent statement on gene editing initiated by the Group of Chief Scientific Advisors provides a scientific perspective on the latest developments on the use of directed mutagenesis, in particular on their regulatory status, which feeds into discussions with all stakeholders.