

**Submission by the European Union to Notification 2019-031: Socio-economic considerations (Article 26 of the Cartagena Protocol on Biosafety)**

The EU is pleased to share views and information on issues related to this notification. Individual EU Member States will provide additional and more specific information in their submissions.

*a) Preliminary experiences using the voluntary Guidance, as well as examples of methodologies and applications of socio-economic considerations, in the light of the elements of the voluntary Guidance, preferably in the form of case studies.*

The EU has no experiences using the voluntary Guidance on the Assessment of Socio-Economic Considerations in the context of Article 26 of the Cartagena Protocol on Biosafety.

The EU has a science-based regulatory framework for the release and placing on the market of Genetically Modified Organisms (GMOs), including import and processing. This framework aims at ensuring a high level of protection of human and animal health and of the environment as well as the good functioning of the EU's internal market.

The deliberate releases (including experimental releases), the placing on the market and the food and feed uses of GMOs are subject to specific authorisation procedures and a risk assessment carried out by an independent risk assessment authority. At EU level, the assessment of risk is the responsibility of the European Food Safety Authority (EFSA). A GMO authorisation can only be granted where, based on the outcome of such risk assessment and under specified conditions of use, this GMO is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment.

Cultivation is an issue with strong national, regional and local dimensions, given its link to land use, to local agricultural structures and to the protection or maintenance of local habitats, ecosystems and landscapes. In this respect, a Member State may decide to restrict the cultivation of an authorised GMO, based on grounds related to environmental or agricultural policy objectives, or other compelling grounds including socioeconomic impacts, which might arise from the cultivation of the GMO on the territory of the Member State concerned.

In 2011, the European Commission published a Report to the European Parliament and the Council on socio-economic implications of GMO cultivation on the basis of Member States contributions (COM(2011) 214 final)<sup>1</sup>. These contributions were compilations of public bodies and stakeholders' views, including inputs from ministries, regional authorities, professional federations, companies, Non Governmental Organisation (NGOs), research centres and individuals. Data collected originated from a wide range of sources, including peer review studies, opinion polls, field trials, outcome of national controls, scenario building and analysis, stakeholders and individuals' assumptions. In parallel, the Commission reviewed knowledge of the socio-economic dimensions of cultivation of GMOs in Europe and worldwide, through different channels, including European and international

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<sup>1</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011DC0214&qid=1558625435939&from=EN>

research programs and scientific publications. Based on the above information, the Commission suggested that a methodological framework should be built-up to define appropriate socio-economic indicators and rules for data collection. Following this report, in 2013, the European GMO Socio-Economics Bureau (ESEB) was established in order to organise and facilitate the exchange of technical and scientific information regarding the socio-economic implications of genetically modified (GM) crops between Member States and the European Commission. In particular, its mission was to develop Reference Documents that enable a science-based assessment of these socio-economic impacts in Member States across the EU. The ESEB was composed of representatives of Member States with assistance from the European Commission's Joint Research Centre.

The ESEB published:

- In 2015, a report on the “Framework for the socio-economic analysis of the cultivation of genetically modified (GM) crops”<sup>2</sup>.
- In 2016, a report on the “Framework for assessing the socioeconomic impacts of Bt maize cultivation”<sup>3</sup>.

In these documents, the ESEB compiled topics relevant for impact assessment, indicators, methodological guidelines and potential data sources to carry out analyses of the socioeconomic consequences of the cultivation of GM crops for farmers, upstream and downstream industries, as well as consumers. The reports showed evidence of impacts in the EU for some topics, but for most topics this evidence proved to be limited. It concluded that while methodologies are available for many of the topics and indicators, the main constraint is a lack of data.

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<sup>2</sup> <http://publications.jrc.ec.europa.eu/repository/bitstream/JRC95572/ipts%20jrc95572%20%28online%29.pdf>

<sup>3</sup> <http://publications.jrc.ec.europa.eu/repository/bitstream/JRC103197/lbna28129enn.pdf>