Italy—GMOs and Synthetic Biology Rules/ Regulations and Biodiversity: The Legal Perspective of Italy

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Abstract The Italian regulatory framework on genetically modified organisms (GMOs) follows the cardinal principles of the European Union legal order. The incomplete implementation of the Italian legislation has led to a de facto moratorium of the deliberate releases of GMOs into the environment, also for experimental purposes, thus slowing down the Italian research in this field. The most recent techno-

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logical developments opened new perspectives for research and applications, posing new challenges for the regulatory system. Synthetic biology is one of these new challenges: even if in Italy there is still a growing debate on whether the application of the existing legislation on GMOs to some of the organisms resulting from the applications of synthetic biology is possible, training and research activities are already under way. We would like to emphasize that, although the present GMOs regulatory framework is effective to preserve biodiversity, further improvements could be needed and should be focused on simplifying the authorization procedure for certain products. It is also necessary to promote and guarantee research and experimentation, in order to provide policy makers with science-based decision support system, and not to keep Italy out of the opportunities offered by technological advances.

Keywords Italy · Genetically modified organisms · Biodiversity · Regulatory framework · Precautionary approach · Risk assessment and risk management · Biosafety · Synthetic biology · Modern biotechnology · Research

GMOs: Existing Regulations and How They Are Addressing Biodiversity Issues

In Italy the regulatory framework for the authorization of genetically modified organisms (GMOs) follows the European Union (EU) legal order, which is composed of two main instruments: (1) Directive 2001/18/EC on the deliberate release into the environment of GMOs, for experimental purposes and placing on the market, including cultivation (transposed into national law with Legislative Decree n° 224 dated 8 July 2003), and (2) Regulation (EC) 1829/2003 on genetically modified food and feed, including cultivation of plants for food and feed uses.[1] A further legislative instrument made compulsory the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs (Regulation (EC) 1830/2003).

The National Competent Authority (NCA), responsible for complying with the requirements of Directive 2001/18/EC on the deliberate release into the environment of GMOs, is the Italian Ministry of the Environment, Land and Sea; the NCA responsible for implementing Regulation (EC) 1829/2003 at national level is the Italian Ministry of Health, which also carries out management and coordination activities of the official controls on the presence of GMOs in food and feed, envisaged by the Italian local authorities. The NCAs can be supported by Advisory Committees: for the deliberate release, the Italian Institute for Environmental Protection and Research (ISPRA) has taken on this role from September 2018.

[1] Within the European Union, regulations are binding legislative acts that must be applied in their entirety across the EU, while directives are legislative acts that set out goals that all EU Member States must achieve, but it is up to the individual States to devise their own laws on how to reach these goals. For this reason, directives have to be transposed into national law.