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Hellenic Foundation for Research & Innovation

Genetically Modified Organisms: Regulatory and socio-economic aspects

1st Call for H.F.R.I. Research Projects to Support Faculty Members & Researchers and Procure High-Value Research Equipment

Title of the research project:
Genetically Modified Organisms: Regulatory and socio-economic aspects

Principal Investigator:
Associate Professor Georgios Balias

Reader-friendly title:
GMOs

Scientific Area:
Social Sciences

Institution and Country:
Hellenic Foundation for Research and Innovation, Greece

Host Institution:
Harokopio University of Athens

Collaborating Institution(s):

Project webpage (if applicable):
www.gmosocialimpact.eu

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Budget: **117.000€**

Duration: **12/02/2020 - 12/08/2022**

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Research Project Synopsis

GMOs consist of a complex scientific, legal and socio-economic issue. The first refers to whether there are negative impacts on the environment and human health from the cultivation of the above organisms and this is one of the most vivid and controversial scientific topics. As for the second, the relative scientific debate is ongoing, and the relevant legislation is constantly developing. Finally, the third issue is of particular importance for Greece, where agriculture is based on small plots and quality products cultivations. Therefore, coexistence of genetically modified, conventional and organic cultivations may potentially become one of the major social and economic issues of the country.

The basic regulatory framework for GMOs in the European Union (Directive 2001/18/EC and Regulation 1829/2013) has been amended or is under consideration for amendment. The new Directive 2015/412/EU as regards the possibility for Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory is an important change of the regulatory framework of the EU for G.M.O.s.

The project shall create new knowledge (a) in relation to GMOs risk assessment, (b) in relation to the implementation problems of EU legislation on GMOs and in particular to those that are relevant with the new Directive 2015/412/EU and which constitute important challenges not only for our country, but also for all Member-States, and (c) in relation to the establishment of a new civil liability regime for damage to conventional or organic cultivations by genetically modified cultivations.

The whole conclusions of the project will be able to contribute considerably to dealing with GMOs in our country, where relevant legislation is rather deficient (approval procedure, no-existance of special civil liability regime or provisions on coexistence measures).

Project Originality

In recent decades the development of biotechnology is one of the important issues over which intense disagreements are expressed, in particular between USA and Europe. Those particular disagreements relate to the risk assessment of GMOs relating to the environment and human health and to the wider regulatory approach of biotechnology. Further, to the continuous scientific disagreements as regards the above risk, the discussion internationally is focused, equally, to the legal, financial, social and political aspects of the issue. In particular, in relation to the legal dimension of the GMOs issue, concerns of the international scientific community focus on critical elements of EU legislation that are related to the GMOs risk assessment relating to the environment and human health and the role of other factors (social, ethical, political etc.) in the decision making process. However, the risk assessment has important limitations because it is pervaded by key uncertainties surrounding the dose-response curve, applicability of results from animal and in vitro studies to humans or extrapolations from high level of exposure in controlled environment to lower levels encountered usually outside of the laboratory. Against this institutional background EFSA pays little attention on the uncertainties, assuming that risk assessment can capture risks with sufficient certainty and reasonable accuracy. Given the pervasive uncertainty about GMOs safety, EFSA and the European Commission need to acknowledge on the one hand the existence of limitations about scientific information and on the other hand the relevance of the precautionary principle during the risk assessment and risk management stages. It is important to note that the EU legislation explicitly calls upon the competent authorities to take into account, in the authorization process, not only the scientific evidence but also other legitimate reasons. So, the obligations to justify their decisions on scientific grounds and to take other factors into account are actually complementary. This study will combine qualitative doctrinal and socio-legal research using a synthesis of secondary and primary qualitative data.

Expected results & Research Project Impact

The basic aim of the project is to highlight the complex issue of GMO cultivation that is associated: (a) with scientific disagreements and scientific uncertainty in relation with environmental and human health impacts, (b) with the implementation problems of the GMO regulatory framework in the EU and Greece, (c) with important social and economic impacts caused by GMOs cultivation in every member State of the EU, and Greece in particular.
From scientific literature it emerges that the above issue appears particularly acute as far as social and economic impacts are concerned by the coexistence of conventional, organic and genetically modified cultivations in countries where agriculture is carried out on the basis of small-scale plots, as in Greece.
For this reason, the conclusions of the project shall be particularly useful for the adoption of protection measures of the cultivations and avoidance of social conflicts. Greece, in particular, does not have a complete legislation on GMOs as it has not transposed into national law all EU regulations, has not developed measures of coexistence of the above cultivations, has not established a special civil liability regime neither has regulated on the issue of GMO patents.
the implementation problems of GMOs risk assessment and in particular with the scientific methodology of substantial equivalence. New knowledge from the project will concerns, also, the problems of implementation of EU legislation on GMOs with particular emphasis on those related to the new Directive 2015/412. The project will streamline the relevant knowledge for the settlement of the issue: (i) of coexistence of conventional, organic and GMO cultivations and their socio-economic impacts in Greece, (ii) of liability for damage caused to the environment and human health by GMOs (establishment of a special civil liability regime by GMOs) and (iii) of GMOs patents. The conclusions of the project could be the basis for the elaboration of coexistence measures in Greece, bearing in mind the structure of Greek agriculture (small plots, different kinds of cultivation etc.).

The importance of this funding

The current research could not be carried out without the contribution of Hellenic Foundation for Research and Innovation, since its precondition is the thorough research of the literature and legislation, the familiarization of researchers with the latest technology, etc. actions that require time for optimal understanding, processing and finally, diffusion of knowledge. The recording, collection and processing of primary and secondary data from all over Greece through quality research is a costly and very time consuming process (travel, access to resources, specialized information, etc.). Therefore, without proper funding, the research could not be carried out.

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