Transformation of biosafety legislation in agriculture in the EU law and the laws of its selected trade partners, with respect to the scientific development

The goal of the study is to see if the laws governing research and use of products of modern biotechnology in agriculture and for food and feed purposes, were affected by new scientific developments at the time of their adoption and if they are up to date currently. The project will encompass research on European Union law in the last 20 years and on the laws of its biggest suppliers of staple, genetically modified agricultural products (Argentina, Brazil, Canada and USA).

Europe imports millions of tonnes of genetically modified (GMO) products per year (mostly maize and soybean) and its animal production is largely dependent on those products. In order to protect the human health and the environment, several laws (directives and regulations) were passed at the beginning of the XXI century. These laws, while serve to maintain a high level of protection are also rather restrictive and limit certain freedoms guaranteed in the EU law, such as a freedom of arts and sciences or the freedom to conduct a business. Such restrictions are justified as long as they are necessary to genuinely meet the objectives of the general interest. This in turn depends on available scientific information, which is being updated constantly. New information about risks is being gathered, new technologies are being developed, which means that that the assumptions on which the laws were based may not be correct anymore. Currently, mostly due to perceived risks connected with use or cultivation of products of modern biotechnology, the EU is rather an importer than a producer of such products.

The legislation in the countries selected for the comparison with the EU in the study changed significantly over the last 20 years. The most important changes encompassed de-regulation of products of certain techniques used for plant breeding that were developed in the XXI century already (e.g. CRISPR/Cas9). These products are still treated as restricted GMOs in the EU. Since the laws in all the compared jurisdictions have essentially the same goals and should be based on this same scientific information, several questions arise. Mainly: were the changes in law based on new scientific data? Or maybe the lack of changes still reflects the current state of knowledge, since new information still supports a restrictive approach to certain technologies? Maybe there are other reasons for the changes or lack of changes in the legislation?

The investigator plans to analyse the changes in the laws of compared countries over the last 20 years and see if according to scientific knowledge those changes were caused by new scientific developments as regards risks connected with the regulated technologies or invention of new technologies. For this purpose, the investigator plans to analyse scientific literature from the period, as well as patent information. Statistical analysis of patent data allows to determine trends and turning points in the development of technologies, which will also help to achieve the goals of the study.

The outcomes of the study are planned to be:

1. Identification of differences in approaches to biosafety of modern biotechnological agricultural products between the EU and its major suppliers of such products.
2. Identification of scientific reasons behind modification of laws designed to provide biological safety or behind lack of such modification.
3. Evaluation of the compared laws based on scientific developments over the last 20 years (2001 – 2021). Identification of areas, where:
    - the current approach seems to lack grounding in current scientific data and is potentially lacking, when it comes to providing a proper level of protection,
        - the current approach seems to lack grounding in current scientific data and potentially violates basic freedoms (i.a. the freedom of arts and sciences or freedom to conduct a business) through the introduction of restrictions, which are not necessary and do not genuinely meet objectives of general interest.
4. Identification of areas, where the differences between compared regulatory systems may hamper the flow of goods between third countries and the EU.
5. Formulation of proposals for changing the laws to address identified issues.

The results will be published in academic articles and in a book, as well as presented at conferences.