Changes in the legislation on genetically modified organisms in order to speed up the registration of new vaccines against Covid-19 (Regulation (EC) 2020/1043)

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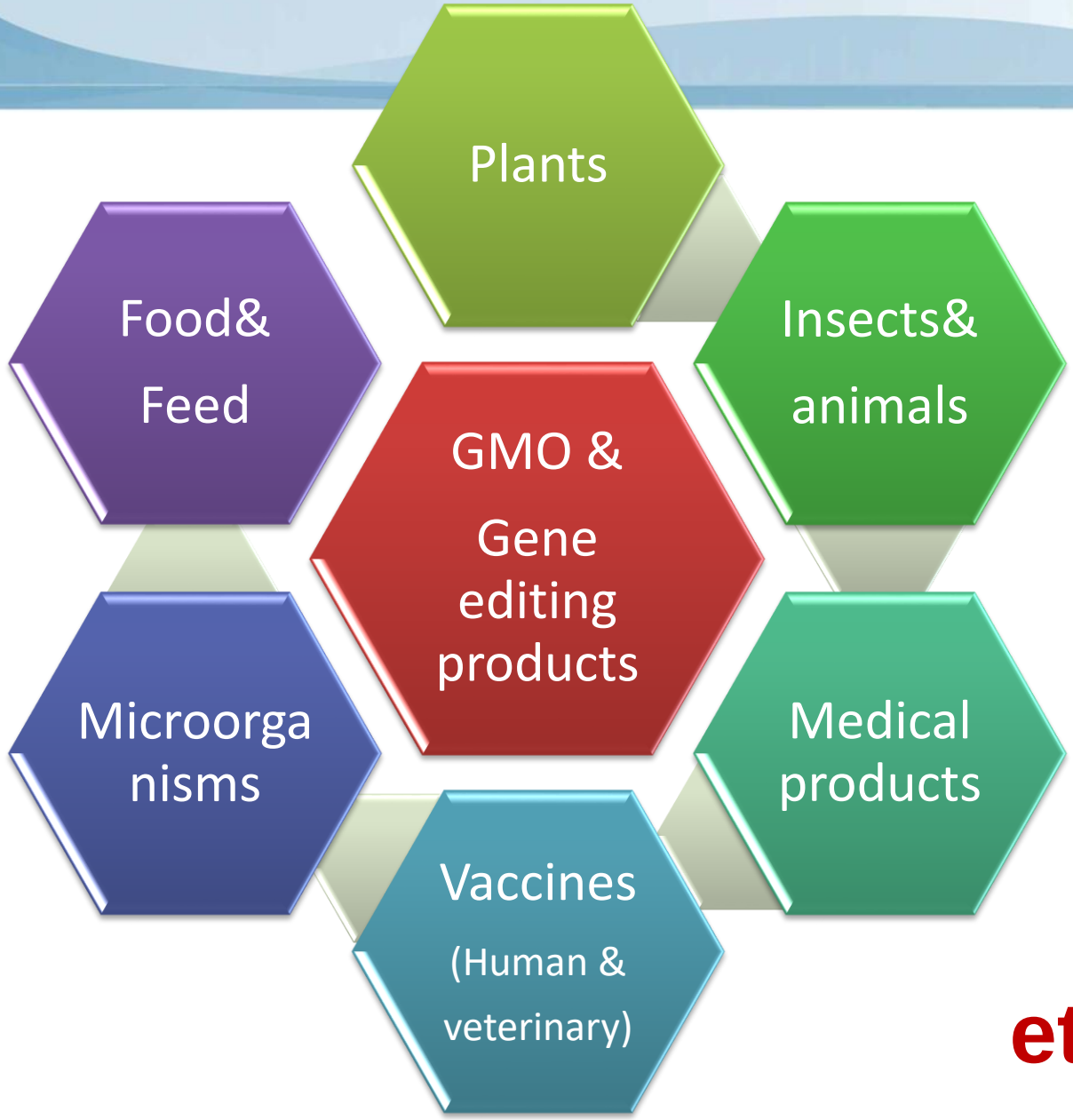

Plants
Food&
Feed
Insects&
animals
GMO &
Gene
editing
products
Microorga
nisms
Medical
products
Vaccines
(Human &
veterinary)

etc. …

GMO and Medical Products

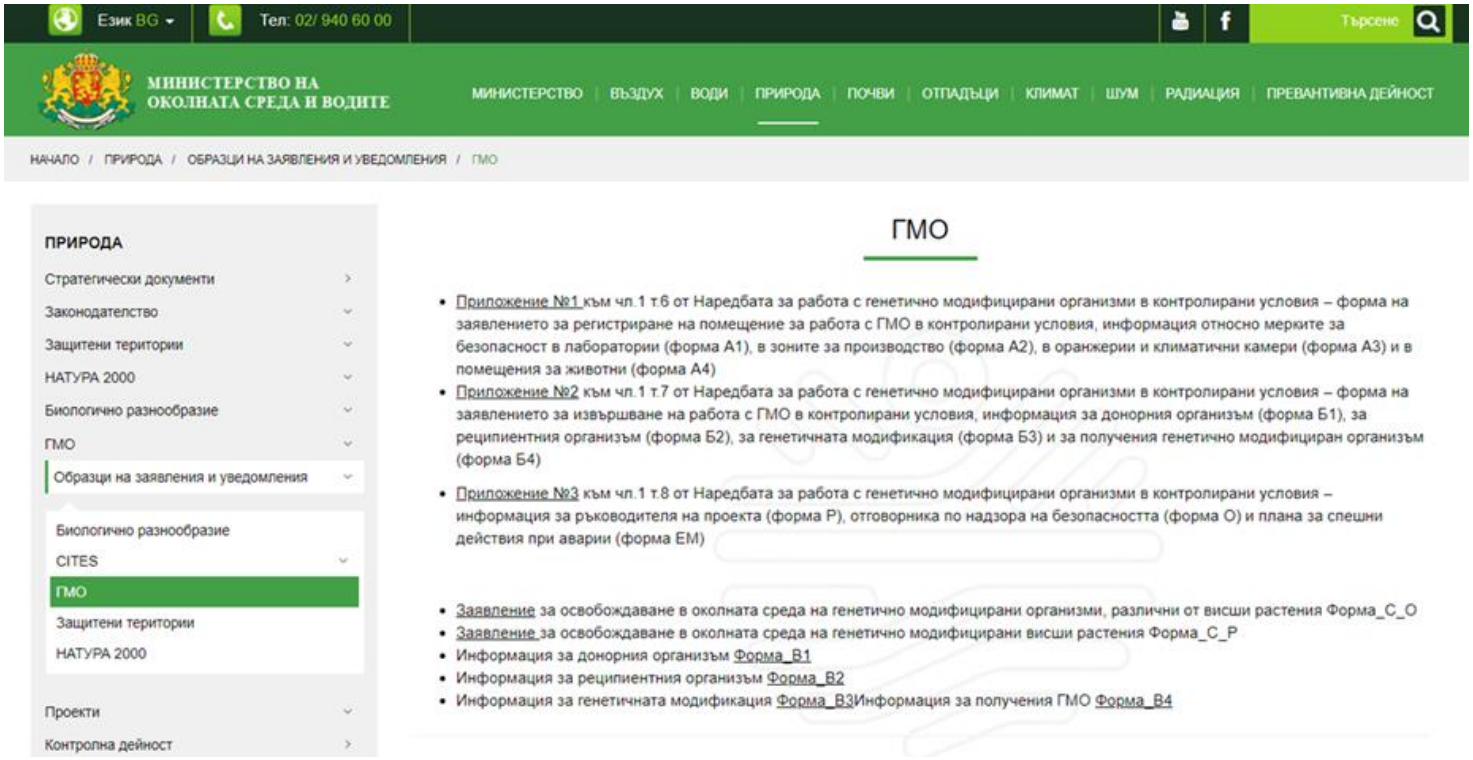
- The European Union-wide procedure for the authorisation of medicines, where there is a single application, a single evaluation and a single authorisation throughout the European Union. Only certain medicines are eligible for the centralised procedure.

- Each Member State shall have its own rules on the registration of clinical trials with medicinal products and vaccines when they are GMOs.

GM vaccine/medial products Clinical Trials Regulation – Bulgaria

- Advisory Commission to the Minister of Environment and Water - brings together representatives of scientific institutes in various fields related to GMOs proposed by the Ministry of Environment and Water, Ministry of Health, Ministry of Agriculture, Food and Forestry, Ministry of Education, Ministry of Economy and quota for non-governmental organizations with interests in the field
- Gives opinions on the environmental risk assessment in and work with GMOs in controlled conditions, according to Directive 2001/18, the Bulgarian GMO Act and its Regulations
- In the case of vector gene therapies and vaccines for human and veterinary use, and in particular in the conduct of clinical trials, the applicant shall be required to carry out a detailed environmental risk assessment as well as compactness and biosafety and waste management procedures.

GM vaccine/medial products
Clinical trials regulation – Bulgaria



GMOs Used in Medicine and What are the Benefits?

- The benefits of GMOs in medicine are widespread and extremely important, especially as the demand for new treatments and vaccines increases globally. Currently, most pharmaceutical medications are manufactured using natural (non-synthetic) ingredients.
- GMOs assist in this process via the process of genetic engineering (GE). Organisms with therapeutic potential used in the genetic engineering process include bacteria, which are the easiest to grow at a large scale of production. Yeasts and mammalian cells are also used to produce certain GMO medicines.

GMOs' Role in Vaccines and Medical Research

- GMOs have played a major role in the development of several vaccines that are either in use or in development, including:
  - *Zika virus*
  - *Ebola virus*
  - *Flu virus*
  - *Hepatitis B*
- Many GMO vaccines contain specific proteins as their main ingredients. Using GE and other GMO techniques, researchers can coax living cells into producing specific proteins that can be utilized to manufacture vaccines.

Gene Editing Differ in Agricultural and Medicinal Use

- May be farmers benefit from GE crops because they're designed to be resistant to herbicides and insects, protecting their profits and livelihoods while not damaging the crops themselves. GE organisms targeted for medicinal use and GMO medical research, on the other hand, are intended to exhibit changes in their actual biochemistry to make them more suitable for usage in medications.
- Researchers tasked with changing crops and organisms via GE, whether it's for agricultural or medicinal purposes, use extensive and careful screening processes to find specific molecules and proteins.
- For potential drugs, those proteins and molecules must show promise in treating specific diseases or conditions. For crops, those proteins and molecules must provide useful traits to plants without harming consumers or the environment. Once selected, the desired genes are inserted into host organisms and plants, eventually creating ideal conditions for real-world usage.

- Medicinal products for human use may contain or consist of genetically modified organisms ("GMOs").
- In the EU, the marketing of such medicinal products is authorised by the European Commission and the environmental aspects thereof are addressed in the context of the marketing authorisation procedure.

Covid crises

- In the summer of 2020, as a result of the Covid crisis, a discussion began on easing the authorization procedures and clinical trials for drugs and vaccines for Covid in the European Union, with a view to speed up registration.

Regulation (EC) 2020/1043

- Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July 2020 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19)
- Directive 2001/18/EC provides that a deliberate release into the environment of genetically modified organisms ('GMOs') for any purpose other than for placing on the market is subject to a notification to and to written consent by the competent authority of the Member State within whose territory the release is to take place. **The notification is to include an environmental risk assessment performed in accordance with Annex II to Directive 2001/18/EC and a technical dossier supplying the information specified in Annex III to that Directive**.
- Directive 2009/41/EC provides that the **risks to human health and the environment associated with the contained use of genetically modified micro-organisms are to be assessed on a case-by-case basis**. To that end, that Directive provides that the user is to assess the risks to human health and the environment that the specific type of contained use may pose, using as a minimum the elements of assessment and the procedure set out in Annex III to that Directive.

- In order to protect public health as a result of the COVID-19 pandemic, the Commission is preparing a proposal for a Regulation which provides for a temporary derogation from the application of part of the provisions of Directive 2001/18 / EC and Directive 2009/4 / EC, namely the requirement to submit an environmental risk assessment
- The derogation will allow for the timely development and entry into the market of medicinal products, some of which may fall within the scope of GMOs or genetically modified products.

to date

- Projects in progress
- A number of candidate COVID-19 medicinal products, up to now only vaccines, are genetically modified organisms (GMOs)
- Eexpectations

take-home message in the light “One Health”

- at present, GMOs fall within the scope of the competent authorities for food safety and the environment
- as a result of the entry of GMO products and those of genetic editing in medicine (human and veterinary), it is necessary to expand the scope of competence
- need an interdisciplinary approach
- legislation on GMOs needs to be adapted

Thank you for your attention!

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