



REPUBLIC OF ALBANIA

MINISTRY OF TOURISM & ENVIRONMENT

Joint Aarhus Convention & Convention on Biological Diversity

Global Round Table on Public Awareness,
Access to Information and Public Participation
regarding LMOs/GMOs

Enkelejda MALAJ
Ministry of Tourism & Environment
Geneva, 11-12 December 2023



REPUBLIC OF ALBANIA

MINISTRY OF TOURISM & ENVIRONMENT

Content:

- I. Country Profile
- II. Legal framework
- III. Institutional Structures and
Administrative Capacities
- IV. Future plans



REPUBLIC OF ALBANIA

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I. Country Profile

NO authorizations have been given for the release on the market of foods and food ingredients that contain or consist of GMO, in the Republic of Albania.



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II. Legal framework

LAW, No. 9863, of 28.1.2008, “**ON FOOD**” - (*amended by Law No. 74/2013, of 14.2.2013; No. 8/2019, of 26.2.2019; No. 16/2020, of 12.2.2020; No. 10/2022, of 27.1.2022, published in the Official Gazette number 33 on 28. 2. 2022.*)

Article 8: Principles of Transparency

1. The institution responsible for the official control of food and animal feed, directly or through authorized representatives of consumers and/or interest groups, during the preparation, evaluation and review of risk management measures, conducts public consultation, open and transparent, except if impossible, for ex. in emergency cases.

2. When there are justified doubts that the food or feed may present a risk to human or animal health, depending on the nature, seriousness and degree of this risk, the institution responsible for the official control of food and animal feed takes measures to inform the public about the nature of the risk.



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II. Legal framework: Law No. 9863/2008, “On Food” – last amended 2022

Introduced provisions:

- Chapter VII “New Novels”
- Chapter X “Food labelling and publication”
- Chapter XIV “Food for animals”

Chapter VII “New novels”

Article 27 “New novel categories”

- food and food ingredients, which contain or consist of organisms of genetically modified (hereinafter GMO);
- food and food ingredients, excluding additional foods (flavourings and enzymes) produced and not containing GMOs;



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II. Legal framework: Law No. 9863/2008, “On Food” – last amended 2022

Chapter VII “New novels”

Article 28 “Placing new novels on the market”

- To place new foods on the market in the Republic of Albania, the applicant must obtain a permit from the minister responsible for food, after providing the preliminary scientific opinion of the institution responsible for the official control of food and animal feed.

Article 29 “Register for the permits granted for the release of new novels on the market”

- The Ministry responsible for agriculture keeps the register for the permits granted for the release of new foods on the market.



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II. Legal framework: Law No. 9863/2008, “On Food” – last amended 2022

Chapter VII “New novels”

Article 30 “Prohibition of introducing new novels to the market”

1. If there is any scientific discrepancy about the harmful effect of new novels on human health, especially food and food ingredients, which contain or consist of genetically modified organisms, the minister responsible for food temporarily prohibits the release of such food on the market, to prevent or reduce the possibility of negative impacts on people's health.
2. The minister responsible for food prohibits the release of new novels on the market, especially food and food ingredients, which contain or consist of genetically modified organisms, if, based on a scientific risk assessment, they are assessed as harmful for people's health.



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II. Legal framework: Law No. 9863/2008, “On Food” – last amended 2022

Chapter X “Food Labelling and Publication”

Article 36 General food labelling requirements

1. The food, which is put on the market, is provided with the label, which states: the content or composition of GMOs, as well as the GMOs it contains.
2. The label must be written in the Albanian language, be distinct, legible and understandable.



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II. Legal framework: Law No. 9863/2008, “On Food” – last amended 2022

Chapter X “Food Labelling and Publication”

Article 37 “Presentation and advertising of food”

1. The presentation of food and feed includes their form, appearance or packaging, packaging materials used, the manner in which they are arranged and the environment in which they are presented, as well as relevant information about it by any means information.
2. Advertising of food or animal feed is done only after the institution responsible for the official control of food and animal feed grants the right to their production and marketing.



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II. Legal framework: Law No. 9863/2008, “On Food” – last amended 2022

Chapter XIV “Feed for animals”

Article 54 “Placing food on the market, which has GMOs in its composition or content”

1. The applicant, for the first time to place on the market the feed for animals and the ingredients of these foods, which have in their composition or contain GMOs, must be provided with a permit from the minister responsible for food, in support of the scientific opinion given previously by the institution responsible for the official control of food and feed.
2. The Ministry responsible for Agriculture keeps a register for permits granted for placing on the market feed for animals and their ingredients, which are composed of or contain GMOs.



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II. Legal framework: Law No. 9863/2008, “On Food” – last amended 2022

Chapter XIV “Feed for animals”

Article 55 “Elimination of animal feed containing GMOs”

Animal feed and its components, which are in the composition or contain GMOs, which do not comply with the safety requirements, defined by this law, must be destroyed, according to the legislation for the protection of the environment.



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II. Legal framework

LAW No. 10 416, of 7.4.2011, ON PLANT & PROPAGATION MATERIAL

(Amended by Law No. 67/2013, dated 14.2.2013, No. 105/2015, dated 1.10.2015, No. 12/2019, dated 5.3.2019)

Some provisions introduced by this Law:

1. Chap. I - General Provisions;
2. Chap. II - Requirements for the trade of plant and plant propagation material;
3. Chap. VI - Registration procedures of varieties in the national catalogue.



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II. Legal framework: Law No. 10416/2011, “On Plant and Propagation Material” – last amended 2019

Article 3 “Definitions” for GMO

Article 4 “Requirements for trading”

When the planting and propagating plant material is or contains GMOs, it must also meet the requirements of the legislation in force on GMOs, as well as be marked as GMO.

On the label of the planting and propagating material, it is noted whether it has genetically modified even just one of the components.



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II. Legal framework: Law No. 10416/2011, “On Plant and Propagation Material” – last amended 2019

Article 30 “Request for registration of a variety in the National Catalogue”

The procedure for registering a variety in **National Catalogue** begins with the submission by the applicant of a request, in writing, to **State Entity for Seeds & Seedlings**.

If the request is made for the registration of a variety designated for use only as a genetic component for the production of planting and propagating plant material or of a variety that is a GMO, the applicant must clearly state this in the request.



REPUBLIC OF ALBANIA

MINISTRY OF TOURISM & ENVIRONMENT

II. Legal framework: Law No. 10416/2011, “On Plant and Propagation Material” – last amended 2019

Article 31 “Conditions for registration of the variety in the National Catalogue”

State Entity for Seeds & Seedlings, approves the registration of a variety that contains GMO in the National Catalogue only if:

- it is certified that it has been approved as a new variety and the person responsible for its preservation has been appointed;
- the right to use this variety is proven;
- meets the acceptable standards for cultivation and use, approved by decision of the **Evaluation Committee of Varieties & National Catalogue Registration.**

2. If the acceptance or keeping of such a variety does not conflict with the relevant legislation on GMOs.



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II. Legal framework

Law no. 10 431, dated 9.6.2011 “For the Protection of the Environment”

Article 36 "Genetically Modified Organisms"

Prohibits the intentional discharge into the environment or the release on the market of Genetically Modified Organisms, which may **cause harmful effects on the environment and human health**, except in cases where it is provided otherwise by the legislation in force, in accordance with the principle of prevention and preliminary measures.



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II. Legal framework

Regulation (EC) N° 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

partially harmonized through

Decision of Council of Ministers, No. 406, dated 20.5.2020 “On approval of the rules on labelling of feed for animals used for food, including those consisting or containing GMOs”, published in the Official Gazette number: 95, dated 27 May 2020.

Chapter I “Objective and definitions” - Article 2, Definitions, point 7,9,10.

Chapter III “Genetically Modified Feed” - Article 15 “Scope”.

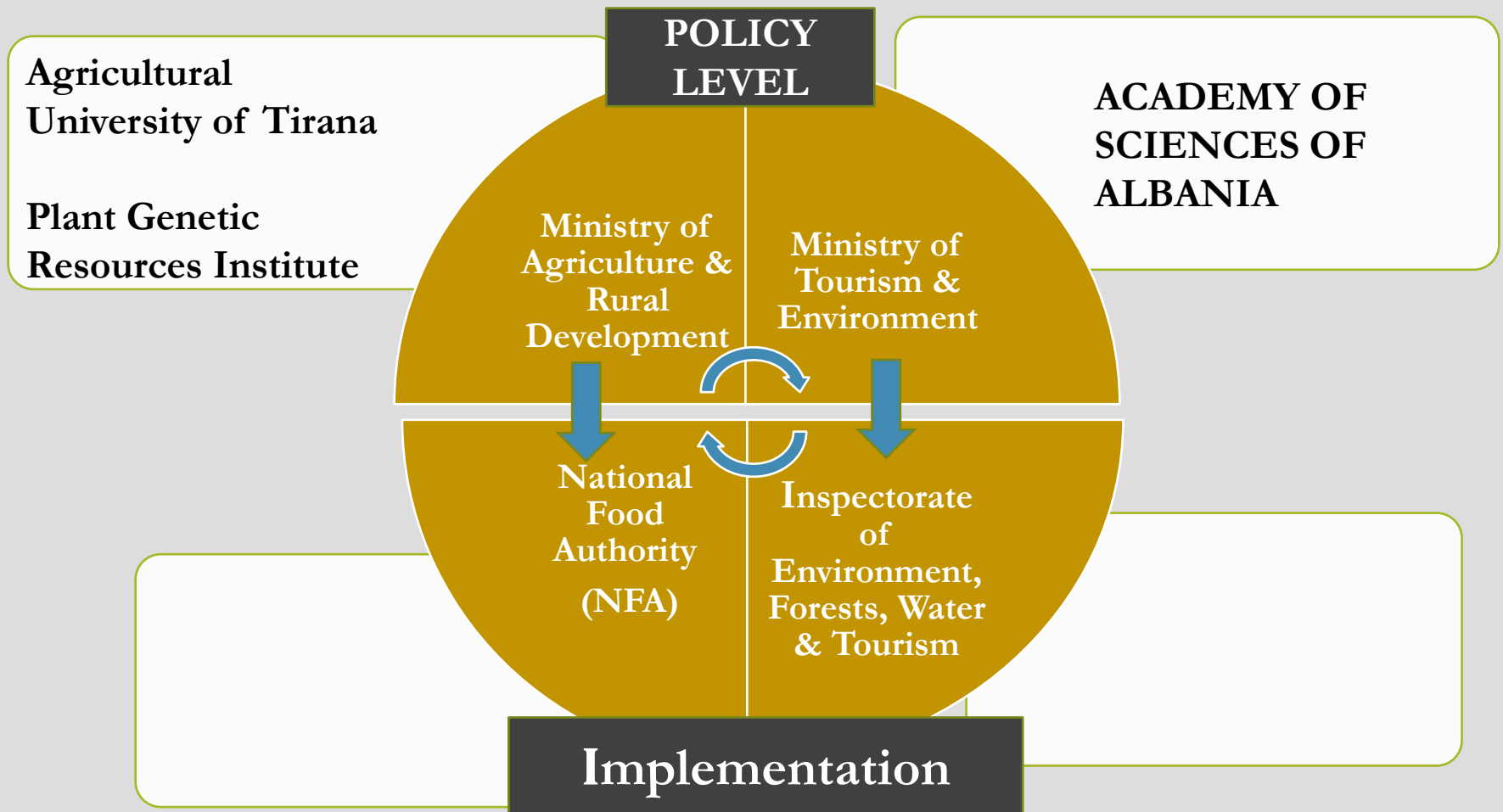
Section 2 “Labelling” - Article 25 “Requirement”.



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III. Institutional Structures and Administrative Capacities





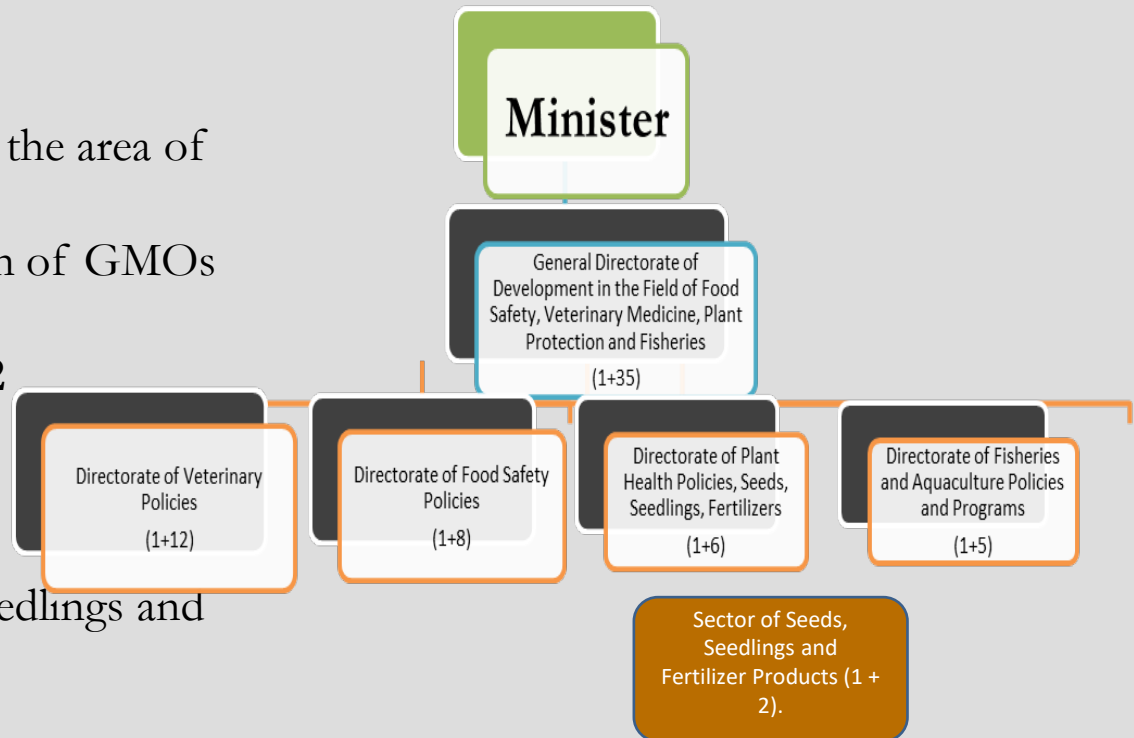
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III. Institutional Structures and Administrative Capacities

MARD

1. Proposes policies/strategies in the area of GMOs.
2. Planning for the harmonization of GMOs regulations.
3. **EU Negotiations Chapter 12**



2022 - GMO covered by Seeds, Seedlings and Fertilizer Products Unit, MARD



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III. Institutional Structures and Administrative Capacities

National Food Authority - Responsibilities/Functions

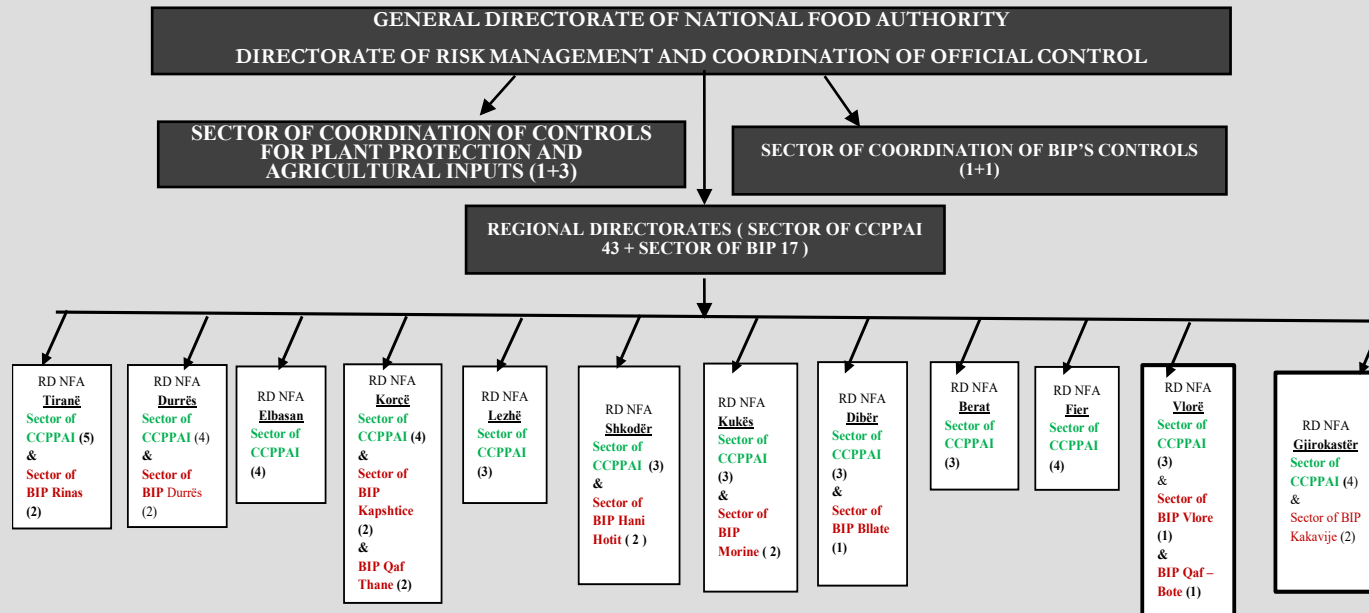
- Responsibilities and functions set forth in **Law no. 9863, dated 28.01.2008 "On food", amended and DCM no. 708, dated 9.9.2020 "On the organization and operation of NFA"**;
- The NFA performs documentary control, identity control (verifying the compatibility of the documentation with the declaration on the label) and physical control at border inspection points (BIP).
- Principles of inspection, inspection procedures, inspection standard forms provided in the law 10433/2011 "*On inspection in the Republic of Albania*", as amended, and other regulations issued by the Central Inspectorate for inspections for business operators operating in the territory of Albania.



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III. Institutional Structures and Administrative Capacities



NATIONAL FOOD AUTHORITY



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III. Institutional Structures and Administrative Capacities

Ministry of Tourism & Environment

- No GMO specific structure at Ministry of Tourism & Environment;
- National Environmental Agency – Inspection functions in cooperation with other state structures;
- All policy and legislative initiatives belong to Ministry of Agriculture as Leader of Chapter 12.
- Prime Minister’s Order no. 135, of 28.6.2010 “On the establishment and functioning of the inter-ministerial Working Group for the preparation of the Action Plan on alignment of national legislation with the *acquis communautaire* on GMOs”.



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Legislative amendments

- Law no. 84/2020, On approval of Decision II/1 of the parties, amending “Aarhus Convention” ratification law no. 8672, of 26.10.2000.
- *Article 6/1 added:* Public Participation in Decisions on the Voluntary Release into the Environment and Placement on the Market of GMOs.
- 1. The Party (Albania) will ensure that the **public is informed at an early stage** and will ensure **effective public participation** in decisions to be made regarding genetically modified organisms.
- 2. To ensure implementation of item 1, actions undertaken must be in line with national framework Law on Biosafety and the Cartagena Protocol, to which Albania is a party.



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Legislative amendments

- **Law no. 84/2020, On approval of Decision II/1 of the parties, amending “Aarhus Convention” ratification law no. 8672, of 26.10.2000.**
- *Added, Annex 1/1, after Annex 1.*
- In this Annex, under Modalities as referred to Article 6/1, 8 detailed points are added to ensure that public participation obligations are met regarding decisions on voluntary release into the environment placing genetically modified organisms on the market.



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Legislative amendments

Added, Annex 1 / 1, after Annex 1.

- 1. Party it is required to determine measures & reasonable time limits to inform the public, effective time limits to ensure public consultation on proposed decisions regarding GMOs.
- 2. Specific cases when public participation in decision-making on GMOs is not carried out.
- 3. Determines what is not confidential information and must be made available to the public, in line with national legislation and biosafety legal framework.



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Legislative amendments

Added, Annex 1/1, after Annex 1.

4. List of Documents which do not contain confidential data, which are to be made public.
5. GMO decision-making institutions make GMO decision-making procedures transparent to the public.
6. Ensures decision makers receive public opinion in all forms, comments, information, analysis and opinions.
7. Encourages decision-makers to take public opinion into account during the decision-making process.
8. Decision is made public in ways that are accessible by the public.



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V. Future Steps

- ❑ Instrument for Pre-Accession Assistance (IPA III) Programming Framework for the period 2021-2027, support is provided to draft the Law "On Genetically Modified Organisms (GMOs)".
- ❑ Full transposition of GMOs regulations is expected to be done within 2027, while implementation will require a longer time after adoption of the new law.
- ❑ Albania will evaluate the existing system and if necessary adapt it according to the needs for the implementation of the new law.
- ❑ IPA II "The Food Safety Project" implemented in January 2020
 - ❑ Assisting MoARD in the assessment and identification of potential issues regarding implementation of GMO legislation in Albania.
 - ❑ Assisting MoARD staff at policy level tasked with drafting national legislation on GMOs for Albania; etc.



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CHALLENGES

- ❑ GMO – new field, inadequate expertise and capacities;
 - ❑ Policy level;
 - ❑ Regional Inspection & Monitoring level;

- ❑ Still not a Law "On Genetically Modified Organisms (GMOs)"; expected within 2027;

- ❑ Inter-institutional coordination & cooperation;
 - ❑ MoARD, MTE, NFA, Inspectorates, NEA, MoI, State Police, Border Authorities, Customs, etc.
 - ❑ Prime Minister's Order no. 135, of 28.6.2010 "On the establishment and functioning of the inter-ministerial Working Group for the preparation of the Action Plan on alignment of national legislation with the *acquis communautaire* on GMOs".
 - ❑ Overlapping of responsibilities: MoARD & MTE.

Thank you for your attention!