

Central and Eastern European Training Course
on Risk Assessment of Living Modified Organisms (LMOs)

Minsk, 24-28 September 2018

Biosafety Framework in Serbia

LEGAL FRAMEWORK

- **Law on Genetically Modified Organisms (OG RS No 41/09)**
- **Food Safety Law (OG RS No 41/09)**

Bylaws (rulebooks):

- Rulebook on deliberate release of GMO and products derived from GMO into the environment (OG FRY No 62/02),
- Rulebook on the content and data of the register of GMO and products derived from the GMO (OG FRY No 66/02),
- Rulebook on the content and application form for use in closed systems GMOs, manner of protection of confidential information in the application, as well as the content of the application for renewal of approval for use in closed systems (OG RS No 69/12).

LEGAL FRAMEWORK

✓ the experimental work with GMOs

Law on Genetically Modified Organisms (scope)

✓ covers GMOs, as well as LMOs to be used:

➤ in closed systems,

➤ for the deliberate release of GMOs into the environment,

LEGAL FRAMEWORK

Law on Genetically Modified Organisms (exemptions):

- product containing GMOs which is not a LMOs and is not used as food, feed, medicine or auxiliary medicine
- GMMs and product containing GMOs which is not a LMOs, if they are intended for medical use and if their use is governed entirely by other regulations

LEGAL FRAMEWORK

Law on Genetically Modified Organisms (Ban on trade):

„ No genetically modified organisms or product containing genetically modified organisms can be traded or grown for commercial use at the territory of the Republic of Serbia.“

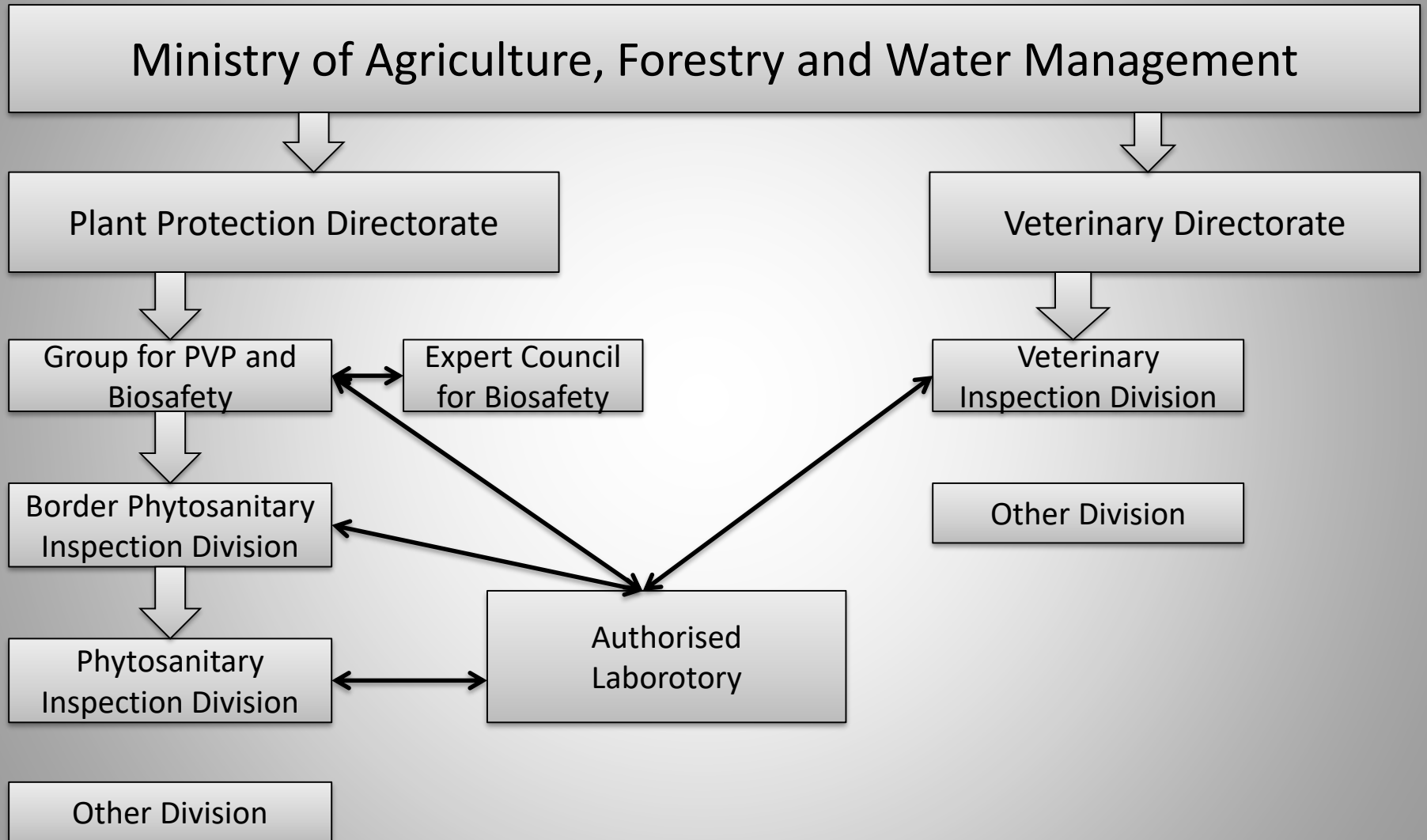
LEGAL FRAMEWORK

Food Safety Law (scope):

- ✓ GMOs for food/feed use,
- ✓ food/feed containing or consisting of GMOs,
- ✓ food/feed produced from or containing ingredients produced from GMOs.

➤ first placing on the market of GM food and GM feed

INSTITUTIONAL FRAMEWORK



INSTITUTIONAL FRAMEWORK

Ministry of Agriculture, Forestry and Water Management is NCA

Risk assessment – **Expert Council for Biosafety(ECB)**

Inspection supervision is conducted by the **Plant Protection Directorate** and **Veterinary Directorate**, through the:

- ✓ Border phytosanitary inspection Division,
- ✓ Phytosanitary inspection Division, and
- ✓ Veterinary Inspection Division;

INSTITUTIONAL FRAMEWORK

Group for Plant Variety Protection and Biosafety (4 officers)

- drafting legislation
- cooperation with international organisations - UPOV, CPVO, Cartagena Protocol on Biosafety
- keeping of required registers – PVP & Biosafety
- coordinating the work of the Expert Council for Plant Breeders' Rights and the Expert Council for Biosafety (ECB)
- check of completeness of submitted applications with Law on GMO & Rulebooks
- preparation of documentation for the final decision in accordance with the opinion of the ECB

PROCEDURE (1) - Law on GMO

GMO MUST be approved for:

- use in closed systems,
- the deliberate release of GMOs into the envir.
(experimental releases)

Application by the user:

- information in accordance with Law and Rulebooks,
- plan and methods of supervision of GMOs,
- plan of measures in case of an incident,
- risk assessment,
- propose classification for use in closed system:
class 1 to 4,
- propose of location where GMO will be released
into the environment.

Check of completeness – 30 days

Public discussion – 30 days

PROCEDURE (2) – **Law on GMO**

Risk assessment – **Expert Council for Biosafety(ECB)**

Final decision – **by the Minister**, based on the opinion of Expert Council,
and relevant public comments

Register of GMOs and products of GMOs – approved for deliberate release
into the environment

Duration of authorisation procedure – **90 days + additional time**
(additional information, if are asked)

Informing the Public - opinion of ECB & final decision

PROCEDURE (3) – **Food Safety Law**

The first placing on the market of GM food & feed - HAVE to be approved

Records keeping of issued approval

Requirements for traceability & obligatory labelling

CONTROL

Division of Phytosanitary Inspection control:

Law on GMO { - closed system
- deliberate release into the environment

Food Safety Law { all stages of food production, processing and
transport

Veterinary Inspection controls the feed at all stages of production, processing and placing on the market

Border Inspections – controls the presence of GMOs in certain import consignments of plants and plant products (and take samples)

AUTHORISED LABORATORIES

- Authorised by the Ministry – 4 laboratories
- GMOs and GMO products – detection, identification & quantification
- Analytical methods for detection, identification and quantification of GMOs - polymerase chain reaction (real-time PCR)
- Accredited SRPS ISO/IEC 17025 standard by Accreditation Body of Serbia.
- NO national reference laboratory for GM food and GM feed

FUTURE PLANS

In accordance with NPAA (National Programme for Adoption of the EU Acquis) it is planned to adopt the new law on GMO in line with relevant EU legislation

THANK YOU

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And Water Management

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