



REGULATORY SYSTEM

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REPUBLIKA SLOVENIJA

MINISTRSTVO ZA OKOLJE, PROSTOR IN ENERGIJO



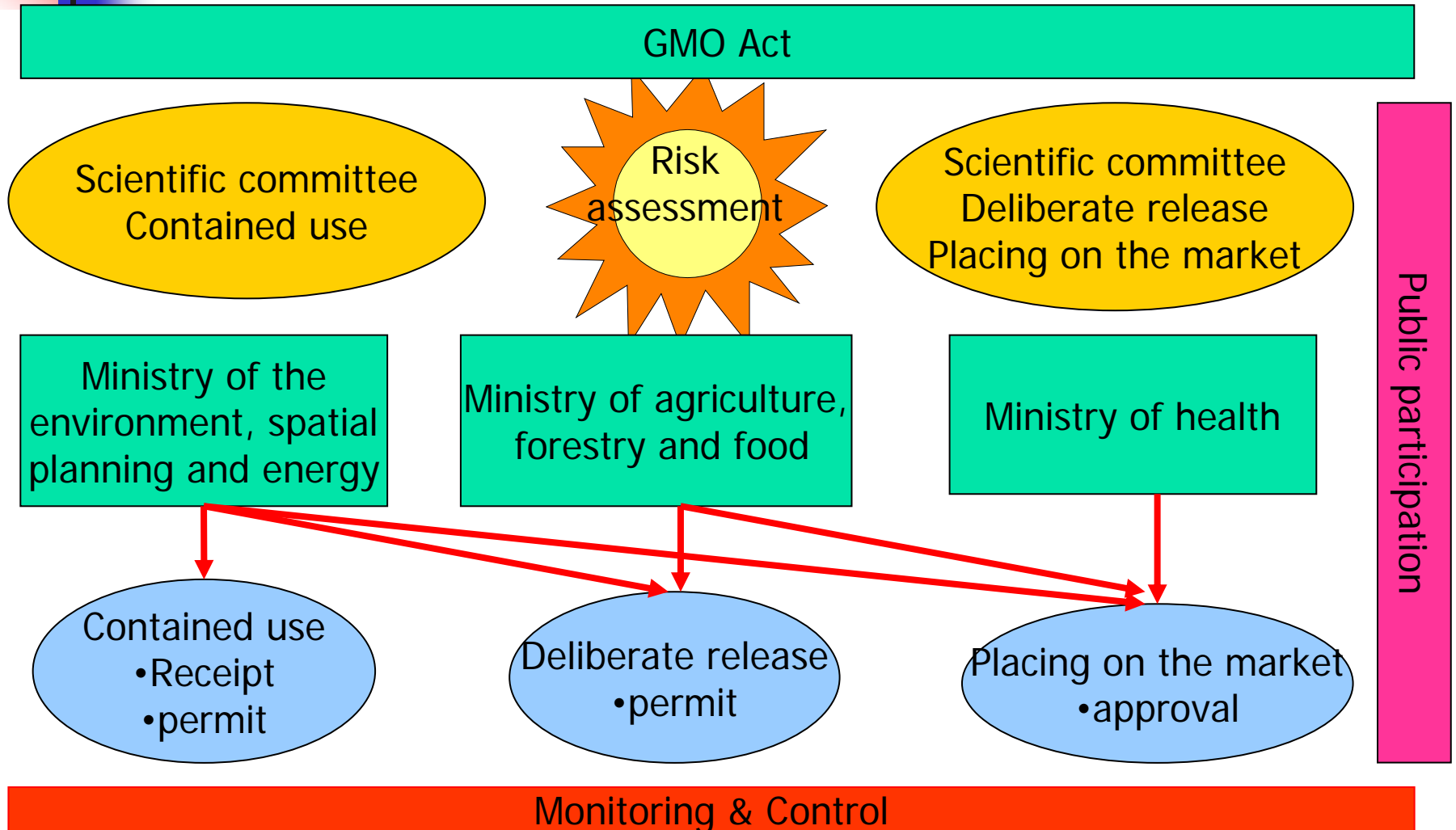
Scope of GMO Act

- Contained use, deliberate release, placing on the market
- Export, transit

Exclusion:

- Feed
- Food
- Transport

Administrative system





Regulatory framework

GMO act second level legislation

- General

In force:

- The government shall provide the **method of operation of the two committees**, the manner and form of providing expert opinions in procedures according to this Act, the manner and form of reporting of the committees and procedures for ensuring the exclusion of interest and protection of data which are confidential in accordance with this Act, in the work of the committees.

Draft:

- Procedure for **selection of representatives of NGOs** for the GMO commission responsible for environmental protection
- Regulation on **GMO register**

Regulatory framework

GMO act second level legislation

Contained use

In force:

- Regulation on the **criteria to classify each contained use of GMO into a specific class**, containment and other safety measures, rules of management and other conditions for individual class shall be specified in a separate regulation.
- Regulation on the detailed **contents of the notification**
- Regulation on the elements and the extent of the **risk assessment** for contained use and the methodology for its production

Draft:

- Detailed contents and the extent of the **emergency plan** in relation to the class of the work, the methodology of its preparation, examining and supplementing and the manner and extent of informing and warning competent bodies, services and the general population in the event of an accident



Regulatory framework

GMO act second level legislation

Deliberate release:

Draft:

- Regulation on methodology, the elements, and extent of the **assessment of risk** of the deliberate release of the GMO into the environment
- Regulation on **contents of the notification**
- Regulation on **report on the results** of the deliberate release of the GMO into the environment



Regulatory framework

GMO act second level legislation

Placing on the market:

Not yet drafted:

- Regulation on elements and the extent of the **assessment of the risk** of placing a product on the market and the methodology of its production.
- Regulation on the **contents of the notification**
- Regulation on the extent and elements of the **assessment report**
- Regulation on the contents and extent of the **programme of monitoring** and the manner and extent of reporting

Lessons learned

Contained use

SI is in the process of testing the notification system with four real notifiers.

Guidelines for notification procedure for administrators and notifiers are drafted.

Simulations of CU inspection and joined inspections (AT, NL) were already organized. Guidelines and check lists are already prepared.

Information system for handling notification for CU is running. Guidelines for administrators and notifiers are drafted.

In 2005 we expect all notification for CU.

Information system for handling notification - CU

PODATKI O DELU Z GSO IZ PRVEGA VARNOSTNEGA RAZREDA

STRAN 1 STRAN 2 STRAN 3 STRAN 4 STRAN 5 STRAN 6

Prijava uporabe zaprtega sistema za delo z GSO

Reg. št. Klasif. ozn.

Lokacija zap.sist.

Status prij. Datum vl.

Status MOPE Datum od do

Reg. št.

1. Prijavitelj

Prijavitelj je Firma

Ident. št. Naslov

Poštna št. Kraj

Država

Telefon Telefaks e-pošta

2. Odgovorna oseba

Zaupno?

ID Priimek Ime

Položaj v firmi

Strokovni naziv Stopnja izobrazbe

Naslov

Poštna št. Kraj

Telefon Telefaks e-pošta



Lessons learned

Deliberate release

There were no deliberate releases of GMO
in SI yet.

Lessons learned

Placing on the market

SI is involved in EU procedure since 1.5. 2004.

SI has not yet been lead CA.

System as set up in GMO Act is workable!

Learning by doing!

Lessons learned

Placing on the market

Most difficult point = intersectoral coordination

- Rules for reaching decisions should be determined.
- Arguments should be scientifically based.

- RA (limited resources)
 - SC gives opinion to the M. of Env.
 - Nominated by gov. through expert system, signed opinions, publicly available, focused on env.
 - M. of Agri. And M. for Health ask internal or external people for expert opinions.
 - Chosen case by case, anonimous, focused on feed and food.



Additional information

Slovenian biosafety clearing house

www.bch.bf.uni-lj.si

Ministry for the Environment, Spatial
Planning and Energy

http://www.gov.si/mop/podrocja/uradzaokolje_biotehnologija.htm



Thanks!

