Field Trials with GMOs – Deliberate Release of GMOs into the Environment in the Czech Republic

Legislative Framework

Czech Act No. 78/2004 Coll., on the Use of Genetically Modified Organisms and Genetic Products, as amended, covers contained use of GMOs, deliberate release into the environment (Part B of EU Directive 2001/18/EC) and placing on the market of GMOs as such or in products, including their export and import. The Act transposes EU Directives 2001/18/EC and 2009/41/EC and complies with the Cartagena Protocol on Biosafety.
Formats of notifications, procedures of risk assessment and other specific requirements are laid down by the implementing Decree No. 209/2004, on Detailed Conditions for the Use of Genetically Modified Organisms and Genetic Products, as amended.

- Website of the Ministry of the Environment on GMOs:
http://www.mzp.cz/cz/geneticky_modifikovane_organismy

- Czech Biosafety Clearing House - information in English on legislation, national contacts and GMO authorisations in the Czech Republic:
http://www.mzp.cz/biosafety

State Administration on GMOs

The Competent Authority receiving notifications and regulating the use of GMOs (Competent Authority under EU Directives 2001/18/EC and 2009/41/EC) in the Czech Republic is the Ministry of the Environment (MoE). It co-operates with the Ministry of Health as regards risks for human health and with the Ministry of Agriculture as food and feed, seeds and cultivation of GM crops are concerned. The Czech Commission for the Use of GMOs and Genetic Products (CzC GMO) as an expert advisory body to MoE deals with the environmental risk assessment. Members of the CzC GMO are representatives of administrative authorities, scientists and representatives of NGOs. The Competent Authority on state supervision of the use of GMOs is the Czech Environmental Inspectorate (CEI) that co-operates with other state supervision bodies in as well.

Authorisation for field trials with GM plants

General requirements set by the Czech Act on GMOs:

- **The notifier has to be a person established in the European Union.** Only a subject which has been granted an authorisation for deliberate release of GMO into the environment can conduct a field trial, within the scope and according to the conditions laid down in the authorisation decision issued by MoE.
- **The GMO which is released into the environment or any material derived from it must not be placed on the market** unless it is authorised for placing on the market in EU. That means even a chemical substance produced from the tested plants must not be placed on the market.
- Prior to submitting a notification, the notifier has to appoint a **biosafety officer** – a person responsible for risk assessment of the use of the GMO and a contact person for the Czech authorities. The biosafety officer has to meet the requirements set by the Act on GMOs as regards his/her education and experience with GMOs and has to be available in case consultations are needed. Whether he/she is an employee of the notifier does not matter for the MoE.

- A separate notification has to be submitted by each institution that will participate in the field trial. Each subject (a legal person or a natural person authorised to operate business) that will handle the GM seed, cultivate the plants or analyse them after the harvest has to be authorised - including the company importing and distributing the GMOs. However, one person can be empowered to submit all the notifications and one biosafety officer can deal with the whole project. The individual notifiers can refer to data included in any notification of the same project.
- The notifier can discuss his notification prior to its submission with the staff of MoE (see contacts below).

Authorisation procedure:

1. The notification, signed by an official representative of the notifier, is submitted to MoE. The risk assessment has to be verified (signed) by the biosafety officer. If the notification is submitted in a printed format it has to be provided also electronically (eg. on CD, by email). The dossier has to be in the Czech language, except literature annexes.
2. Having received the notification, MoE checks its completeness. If the dossier meets all the requirements pursuant to the Act on GMOs, it is circulated to the MoE´s expert body (CzC GMO), to the Ministry of Agriculture, Ministry of Health and to the Regional Authority of the region where the deliberate release is planned to be carried out. At the same time, MoE makes a summary of the notification available to the public on its website and ensures its publication by the relevant municipality and regional authorities, according to the intended release location. The summary of the notification according to Council Decision 2002/813/EC (SNIF) is also made available to the European Commission and other EU Member States through the JRC WebSNIF database http://gmoinfo.jrc.ec.europa.eu/. Therefore MoE asks the notifier to provide the SNIF in English.
3. The Ministries and the regional authority as well as CzC GMO provide to MoE their opinions / comments on the notification within 30 days of receiving the dossier. Consequently, MoE may ask the notifier for additional information. In case the notifier fails to provide the requested information within the set time-period (30 days), MoE terminates the administrative procedure. The additional information is forwarded to the Ministries, Region and to CzC GMO, if appropriate.
4. The summary of the notification which is provided to the public in the Czech language corresponds to the information required in SNIF. **The exact location of field trials** (the municipality and the land register number, cadastral number) **is provided to the public, with exception of the maps** that are part of the dossier.
5. Anybody can send his/her opinion to MoE or make comments within 30 days of publication of the summary of the notification. If MoE receives a negative opinion / comments from the public, by which any doubt is cast on the results of the environmental risk assessment or an objection to insufficient protection of health or the environment is made, MoE is obliged to arrange a public hearing prior to making a decision on the authorisation.
6. MoE should make the final decision on the notification within 90 days of receiving the dossier. For the purpose of calculating this time-period, any period of time for completing the notification by the notifier upon request for additional information and/or the period during which the public hearing is organised are not taken into account - the clock stops. It has to be noted that the notification is assessed by different experts from various points. That leads to wide spectrum of comments usually requiring additional information to be provided by the notifier. Consequently the time for issuing

the decision is longer than the above mentioned 90 days. The notifier has to take this possible delay into account and submit the dossier well in advance before the growing season.

7. When making the decision, MoE is obliged to consider the opinions of the Ministries, regional authorities, CzC GMO and the results from the public consultation, if organised. MoE also takes into account opinions and comments of the Competent Authorities of other Member States submitted through the WebSNIF database., MoE can lay down special conditions for the deliberately release of GMOs in the decision.
8. The notifier has to pay an administrative fee for the authorisation CZK 20 000 (approx. 750 EUR). MoE calls on the notifier to pay the fee shortly before issuing the consent. No fee is paid when the notification is rejected or withdrawn.
9. The whole text of the final decision is made available to the public after the decision has entered into force, on the MoE website and in the municipality of the release. The information about the consent is provided to the WebSNIF database as well.

Risk Assessment

The requirements and procedure of the environmental risk assessment are set in the implementation Decree No. 209/2004, on Detailed Conditions for the Use of Genetically Modified Organisms and Genetic Products, as amended. The risk assessment, carried out or at least verified by the biosafety officer, must be submitted by the notifier to MoE as a part of the notification dossier. It is reviewed by the CzC GMO within the authorisation process.

Confidentiality and Information for the Public

The notifier may indicate certain data in the notification as confidential business information, provided he is able to justify that disclosure of such information might be detrimental to his competitive position.
Following information cannot be indicated as confidential business information:

- General description of the GMO;
- Identity of the notifier;
- Location of the field trial;
- Risk assessment of the GMO;
- Emergency response plan.

The information indicated as confidential business information is only accessible to:

- State Authorities referred in the Act on GMOs;
- CzC GMO;
- Laboratories carrying out the detection of GMOs for MoE and CEI;
- Relevant authorities of other EU Member States;
- European Commission.

Samples

The notifier is obliged to provide control samples of the GMO (processed material, not seeds) **on request** to MoE or to the laboratory carrying out the detection of GMOs for MoE under contract. Description of detection and identification methods for the specific GMO is required in the notification dossier.

Emergency response plans

An emergency response plan is a document describing activities and measures applied in the event of an accident. Detailed requirements for the emergency response plan are laid down by the implementing Decree No. 209/2004.

The notifier is obliged to submit the emergency response plan prior to commencement of the use of GMOs to MoE as a part of the notification and then separately to the municipalities where the release is to take place, to the local Fire Rescue Brigade, to the regional authority and upon request also to any persons that may be directly affected by an accident. The consent holder updates and submits the plan every 5 years or in a case any new information on potential risks emerges.

MoE makes information on the emergency response plan available to the public. The scope of such information is laid down by the implementing Decree.

Other Requirements

The location of the field trial has to be described in detail in the notification. An **isolation distance** (that is the minimum distance between the tested GM plant and the same commercially cultivated non-modified plant) is not set by any general regulation, every case is assessed individually and the distance should be crop-specific. In the authorisations decisions issued so far by MoE, the isolation distance has been set at 200 m for GM maize as the minimum distance from the nearest maize grown conventionally and 600 m from organic maize. For GM potatoes the isolation distance has been 10 m.

The requirements for a **storage** facility are the same as for contained use class 1 (the lowest, BSL1) as described in the Act and the Decree. The storage place and the ways of **transport** have to be described in the notification.

According to the Act 78/2004 on GMOs, **the authorisation holder is obliged to:**

- Ensure proper **labelling and packaging.** The text "Genetically modified organism" and/or in Czech "Geneticky modifikovaný organismus" has to appear on the label and in the accompanying documents during the transport. Any further requirements for the labelling laid down in the authorisation decision must be observed. Also the area of the field trial has to be marked with signs clearly bearing the text "Geneticky modifikovaný organismus" or "GMO".

  Send to MoE a short **report** on the trial every year. A final report is required after the end of the trial and then another report after the set period of monitoring of the site. The formats for these reports (in Czech) are available on the GMO website of the MoE https://www.mzp.cz/cz/formulare_metodicke_pokyny_gmo. The format for the final report is identical with the relevant EU Commission Decision 2003/701/EC https://www.mzp.cz/Biosafety/acts_regulations_guidelines.html. This report is required both in Czech and in English, because it is sent by MoE to the JRC WebSNIF database.
- Carry out **monitoring** (observation of the impacts of the GMO on human and animal health, on the environment and biological diversity) in accordance with the monitoring plan provided as a part of the notification and according to any additional requirements set in the consent. The duration of the monitoring is crop-specific and it is set in the authorisation decision.
- Ensure a proper **treatment of the site**. Usually after the harvest, the GM plants are destroyed on the trial site, except for the samples taken for analyses that have to be destroyed afterwards. Handling with the GM material and the waste management has to be described in detail in the notification.
- **Keep the documentation** for 10 years after the end of the trial.
- Meet any further requirements laid down in the authorisation decision.

Import and Export

"Import and export" means transboundary movements **into and out of EU**. Transboundary

movements within the EU (e.g. from France to the Czech Republic) are not considered as export or import.

A **person authorised for contained use or for deliberate release of GMOs** may import or export only the GMOs covered by the authorisation, provided that they are exclusively intended for the authorised contained use or deliberate release. Means of transport, country of origin / export etc. have to be described in the pertinent notification.

The authorised person that **intends to import or export** GMOs for contained use or deliberate release (see above) is obliged to inform MoE on the species and number / volume of GMOs that will be imported or exported and on the supposed place of entry to or exit from the territory of the Czech Republic, at the latest **5 days prior to** the import or export. The information can be sent by email (see contacts below).

The authorised person is obliged to ensure proper **labelling**: Packaging of the exported / imported GMO or genetic product must have a visible label clearly stating "Genetically modified organism", in Czech "Geneticky modifikovaný organismus". This text has to appear also in the accompanying documents during the transport. Any further requirements for the labelling as laid down in the authorisation decision must be observed.

Detailed requirements for import and export documentation are defined in § 25 of the Act 78/2004.

The Czech Republic as well as the European Union are Parties to the **Cartagena Protocol on Biosafety** to the Convention on Biological Diversity**.** The Protocol focuses specifically on transboundary movements of living modified organisms (viable GMOs) for intentional release into the environment.
The National Biosafety Clearing House of the Czech Republic has been established as an information-exchange system under the Protocol where the following information is available:

- Final decisions regarding release of living modified organisms,
- Existing laws, regulations and guidelines,
- Summaries of risk assessment or environmental assessment of genetically modified organisms generated by regulatory process, including relevant information on genetic products where appropriate,
- Other documents in English.

Contacts

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