

Field Trials with GMOs – Release into the Environment

Legislative Framework

Field trials are regulated in the EU through the Directive 2001/18/EC, Part B, on the Deliberate Release into the Environment of Genetically Modified Organisms. In the Czech Republic the Act No. 78/2004, on the Use of Genetically Modified Organisms and Genetic Products, as amended, applies. This Act covers the contained use, deliberate release of GMOs into the environment and placing on the market of GMOs as such or in products, including the export and import thereof, transposing the EU Directives 2001/18/EC, 90/219/EEC, 98/81/EC and complying with the Cartagena Protocol on Biosafety.

Formats of notifications for the use of GMOs, procedure of risk assessment and other specific requirements are laid down in the implementing Decree No. 209/2004, on Detailed Conditions for the Use of Genetically Modified Organisms and Genetic Products.

- Ministry of the Environment website on GMOs:
http://www.mzp.cz/cz/geneticky_modifikovane_organismy
- Czech Biosafety Clearing House - information in English on legislation, contacts, approvals in the Czech Republic:
<http://www.mzp.cz/biosafety>

State Administration on GMOs

The Competent Authority receiving the notifications and regulating the use of GMOs in the Czech Republic is the Ministry of the Environment (Competent Authority under the EU Directives 2001/18/EC and 90/219/EEC). It co-operates with the Ministry of Health regarding risks for human health and with the Ministry of Agriculture as to agricultural risk, animal health, crops and feeds. The Czech Commission for the Use of GMOs and Genetic Products serves as an expert advisory body to the Ministry of the Environment. Members of the Commission are representatives of administrative authorities, scientists and representatives of NGOs. The main task of the Commission is the environmental risk assessment of the notified GMOs. The Competent Authority on state supervision of the use of GMOs is the Czech Environmental Inspectorate that co-operates with other state supervision bodies in this respect.

Authorisation Procedure for the Use of GMOs

According to the Czech Act on GMOs, the process of authorisation for a release into environment for other purposes than placing on the market (Part B of directive 2001/18/EC, field trials) is as follows:

- (1) A notification is submitted by the applicant to the Ministry of the Environment of the Czech Republic (hereinafter “the MoE”).
- (2) The MoE assesses completeness of the notification. If the dossier meets all the requirements pursuant to the Act, the MoE forwards copies to the Ministry of Agriculture, Ministry of Health (hereinafter “the Ministries concerned”) and to the Regional Authority of the region where the deliberate release is planned. At the same time the MoE makes a

summary of the notification available to the public on the internet, on the official board of the Ministry and ensures its publication by the relevant municipality and regional authorities according to the intended release location. The notification, namely the risk assessment, is also circulated to the MoE's expert body, the Czech Commission for the Use of GMOs and genetic products (CzC GMO). The summary of the notification is made available to the European Commission and other Member States by entering the data into JRC WebSNIF database <http://gmoinfo.jrc.ec.europa.eu/>

(3) The Ministries and the region concerned as well as the CzC GMO provide to the MoE their opinions / comments regarding the notification, including the request for additional information, if appropriate, within 30 days of receiving the dossier. Consequently, the MoE may ask the notifier for additional information. The MoE forwards the received additional information to the Ministries concerned and to the CzC GMO. If the applicant fails to provide the requested information within the set time-period (30 days), the Ministry suspends the administrative procedure.

(4) Anybody may send to the MoE his/her opinion or make comments within 30 days of publication of the summary of the notification. If the MoE receives negative opinion/comments from the public, in which environmental risk assessment results are doubted or an objection to insufficient protection of the health and the environment is made, the MoE is obliged to arrange public hearing prior to making a decision.

(5) The MoE shall take a 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 the period during which public hearing is organised are not taken into account; however, the public consultation cannot prolong the period by more than 30 days.

(6) When making the decision, the MoE is obliged to consider the opinions of the Ministries concerned and CzC GMO and the results from the public consultation. The MoE also takes into account opinions and comments of the Competent Authorities of other Member States submitted through the WebSNIF database. The MoE can lay down in its decision special conditions for the release of genetically modified organisms.

(7) The final decision is made available to the public after its entry into force on the internet and in the municipality of the release. The information about the consent is provided to the WebSNIF database.

Important: A separate notification has to be submitted by each institution that will participate in the field trials. Each subject (legal person) that will handle the GM seed, cultivate plants or analyse them after the harvest has to be authorised - including the company importing and distributing GMOs !

According to the Czech legislation, authorisation for the use of GMOs may only be granted to a legal person or a natural person authorised to run a business. This means that only a company (affiliate) registered in the Czech Republic is entitled to submit a notification.

The notifier has to pay **an administrative fee** for the authorisation for Part B release CZK 20 000 (approx. 800 EUR). The Ministry calls on the notifier to pay the fee shortly before issuing the consent. No fee is paid when the notification is rejected or withdrawn.

Applicants can discuss their notification prior to its submission with the staff of the Ministry of the Environment and also with the experts of the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products. To prepare the dossier in Czech language and for the communication with the Czech Authorities during the authorisation

process we recommend the notifier to hire a Czech expert as a **professional consultant**. (The professional consultant is required by the Act No. 78/2004.) The Ministry of the Environment cannot recommend any specific person, but it is advisable to contact the institutions, which are already authorised for the release of GM plants into environment. One person could be a professional consultant for all applicants conducting the field trials with a specific GMO.

The notification is assessed by different experts from various standpoints. That leads to wide spectrum of comments usually requiring **additional information** to be provided by the applicant. When the Ministry of the Environment asks the notifier for additional information, it “stops the clock” until the required documents are provided. 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.**

Risk Assessment

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. The risk assessment must be carried out or at least verified by the professional consultant (an expert) of the notifier and is submitted by the notifier to the Ministry of the Environment as a part of the notification dossier. After the authorisation the updated risk assessment is submitted by the consent holder every 5 years or in case of any new information concerning the risks of the use. The consent holder is obliged to keep records on the risk assessment for at least 10 years from the date of its submission, and provide it on request to the competent authorities referred to in the Act.

The risk assessment provided by the notifier / consent holder is reviewed by the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products. The assessment should be based on all available information, references, experience and comparison with relevant non-modified organisms.

Confidentiality and Information for Public

The notifier may indicate certain data in the notification as confidential business information, provided he/she is in the position to give verifiable justification that disclosure of such information might harm his/her competitive position.

Following information cannot be indicated as confidential business information:

- General description of the genetically modified organism
- Identity of the notifier
- Location of the site of field trials
- Risk assessment
- Emergency response plan.

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

- State Authorities referred in the Act
- Czech Commission for the Use of Genetically Modified Organisms and Genetic Products (as advisory body to the Ministry of the Environment)
- Laboratories carrying out the detection of GMOs for the Ministry and Czech Environmental Inspectorate under contract

- Relevant authorities of other EU Member States
- European Commission.

Public consultation is a part of the approval process (see above).

The summary of the notification which is provided to the public corresponds to the information required in summary notification information format according to the Council Decision 2002/813/EC. Only very technical information, confidential information, annexes and the personal data included in the dossier are not made public.

The exact location of field trials (the municipality and the land register number, cadastral number) is provided to the public, except the maps that are part of the dossier.

According to the administrative procedure any final decision on authorisation always contains detailed settlement of all received opinions and comments and also the results of the public hearing. The whole text of the decision is made public.

Samples

The applicant is obliged to provide control samples of the genetically modified organism to the Ministry of the Environment or to the laboratory carrying out the detection of GMOs for the Ministry and Czech Environmental Inspectorate under contract, at the time of submitting the notification or at the latest within 10 days after its submission. It is recommended to consult with the Ministry the specification of the sample material, its quantity and the designated laboratory in advance.

Prior to the authorisation for deliberate release, the sample must not consist of viable GMOs. Usually ground material is used. In such a case there are no special requirements as regards import and transport of such samples. After the consent is issued, in the course of the field trial, control samples of viable GMOs can be required by the authorities.

Methods of detection and identification of the GM material are required as a part of the notification dossier.

Accident and Emergency Plans

An emergency response plan is defined in the Czech Act on the Use of Genetically Modified Organisms and Genetic Products as a document describing activities and measures carried out in the event of an accident. The detailed requirements for an emergency response plan are laid down by the implementing Decree No. 209/2004.

The emergency response plan has to be submitted to the Ministry of the Environment as a part of the notification and consequently by the consent holder every 5 years or in a case of any new information concerning the risks of the GMOs use. The notifier is obliged to submit the emergency response plan prior to commencement of the use of genetically modified organisms and in the above mentioned cases also to the municipalities where the deliberate release is to take place, to the fire rescue brigade, to the regional authority and on request also to any persons that may be directly affected by an accident.

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

Other Requirements

The **isolation distance** for field trials is not set by any general regulation, every case is assessed individually and the distance is crop-specific. The location of the field trial has to be described in detail in the notification. In the previous approvals of field trials issued by the Ministry of the Environment the isolation distance was 200 m for GM maize as minimum from the nearest maize grown conventionally, for GM potatoes the isolation distance was 10 m . The distance from organic maize should be minimally 600 m.

Every year a short **report** on the trial is requested according to the Act 78/2004. Final report is required after the end of the trial and than after the period of required monitoring of the site. The formats for this reports (in Czech) are available on the GMO website of the Ministry of the Environment (see above). The format for the final report is identical with the relevant EU Commission Decision 2003/701/EC. This report is required both in Czech and in English, because it should be sent to the EU database of field trials.

The authorisation holder is obliged to carry out monitoring (defined as identification of the presence of a genetic modification in an organism and observation of the impacts of the genetically modified organism or genetic product on the health of human beings and animals, the environmental components and biological diversity) in accordance with the monitoring plan provided as a part of the notification and with any additional requirements set in the consent. The duration of the monitoring is crop-specific, e.g. usually one year for maize, two years for potatoes.

The authorisation holder (notifier) is obliged to ensure that no material derived from GMOs is placed on the market unless the GMO has been approved for placing on the market. Usually the GM plants are destroyed on the trial site, except for the samples that are taken for later analyses and has to be destroyed afterwards. Handling with the GM material and the waste management has to be described in detail in the notification.

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

The authorisation holder is obliged to ensure proper **labelling**: Packaging of the genetically modified organism must have a visible label clearly stating “genetically modified organism”, in Czech “geneticky modifikovaný organismus” or “this product contains a genetically modified organism” or “this product contains genetically modified organisms”, in Czech “tento výrobek obsahuje geneticky modifikovaný organismus” or “tento výrobek obsahuje geneticky modifikované organismy”. This text has to appear also 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 “genetically modified organism” or “GMO”.

Import and Export

Only genetically modified organisms or genetic products authorised for **placing on the market** in the EU may be imported or exported to and from the Czech Republic. (*Applies for third countries outside the EU.*)

Furthermore, the **person authorised for contained use** may import or export GMO to which this authorisation applies, provided that they are exclusively intended for contained use.

The **person authorised for deliberate release** under part B of Directive 2001/18/EC may import or export genetically modified organisms to which the authorisation applies, provided that they are exclusively intended for the authorised deliberate release.

The authorised person that intends to import or to export genetically modified organisms for contained use or deliberate release (see above) is obliged to inform the Ministry of the Environment on the species and number / volume of genetically modified organisms 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 before the import or export.

The authorisation holder is obliged to ensure proper **labelling**: Packaging of the genetically modified organism or genetic product must have a visible label clearly stating “genetically modified organism”, in Czech “geneticky modifikovaný organismus” or “this product contains a genetically modified organism”, in Czech “tento výrobek obsahuje geneticky modifikovaný organismus” or “tento výrobek obsahuje geneticky modifikované organismy”. This text has to appear also in the accompanying documents during the transport. Any further requirements for the labelling laid down in the authorisation decision must be observed.

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

Transboundary movements within the EU (e.g. from France to the Czech Republic) are not considered as export or import. However, such transport has to be described in the notification (packaging, way of transport, emergency measures etc.)

The **Cartagena Protocol on Biosafety** is focusing specifically on transboundary movements of living modified organisms (viable GMOs). The Czech Republic as well as the European Union are Parties to the Protocol.

National Biosafety Clearing House of the Czech Republic has been established as an information-exchange system under the Cartagena Protocol where the following information are available:

- Final decisions regarding import to the Czech Republic or 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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