# Contained use of genetically modified organisms

# 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 all 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.

According to the Act on GMOs, the contained use of GMOs means any activity inside a closed area, in course of which organisms are genetically modified and/or GMOs are cultivated, stored, transported, destroyed, disposed of or used in any other way, unless the GMOs have been authorised for placing on the market in EU. Genetically modified cells in culture are regarded as GMOs as well (by legal definition they are GM microorganisms).

- 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 contained use of GMOs

**General requirements set by the Czech Act on GMOs:**

- The notifier has to be a person established in the European Union. Only a legal person or a natural person authorised to operate business may be authorised for contained use of GMOs.
- Prior to submitting a notification, the notifier has to appoint a **biosafety officer** – a person responsible for the 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.

- The risk assessment of the contained use should result in the assignment of the activity to one of the **four risk classes** specified in Annex 3 to the Act on GMOs (= **biosafety levels**).
- The contained area must comply with the requirements on containment and protective measures laid down for the pertinent or higher risk classes of the contained use in Decree 209/2004.
- Description of **waste management** for each facility using GMOs is required in the notification. The key step in the disposal of waste from contained use of GMOs is the inactivation of any viable organisms in the waste.
- The notifier can discuss his notification prior to its submission with the staff of MoE (see contacts below).

**Authorisation procedure:**

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.

**Risk classes 1 and 2**

For the contained use in classes 1 and 2, the notification does not lead to an administrative procedure; no written decision from MoE is needed to start the activity.

Contained use classified as **class 1 may commence immediately** after the submission of the notification.

For the subsequent contained use classified as class1 in the same premises, only the risk assessment of the new GMOs is required, with a reference to the previous notification.

Contained use classified as **class 2 may commence 45 days** after the submission of the notification, provided MoE has not raised any objections during this period.

MoE checks the completeness of the notification and acknowledges its receipt within 5 days after the submission. If the notification meets all the requirements pursuant to the Act on GMOs, MoE circulates it to the expert body, the Czech Commission for the Use of GMOs and genetic products (CzC GMO), and to the Ministry of Health and Ministry of Agriculture, if appropriate. The Ministries and CzC GMO can make comments and express their opinion on the notification.

Considering all comments and opinions, MoE may ask the notifier for additional information or require changes in the intended activity or in the assignment of the risk category within 30 days after the submission of the notification.

No administrative fee is required.

MoE makes available to the public only the basic data on the authorized contained use: the name and address of the authorized user, GMO(s) used, class of the contained use, date of the authorization and, in case of the second class (BSL 2), the information on emergency response plan are recorded in the List of GMO Users at the MoE website (see above).

The notification formats are set in **Annex 1 to Decree No. 209/2004 Coll.**, as amended.
Annex 1 Part A1: Notification format for the first class 1 contained use
Annex 1 Part A2: Risk assessment format for the subsequent class 1 contained use
Annex 1 Part A3: Notification format for the first class 2 contained use

Annex 1 Part A4: Notification format for the subsequent class 2 contained use

**Risk classes 3 and 4**

Contained use in the third or fourth classes may only commence on the basis of written consent issued by MoE, and only within the scope and under conditions laid down in this consent.

Having received a notification, MoE checks its completeness. If the dossier meets all the requirements pursuant to the Act on GMOs, MoE circulates it to the expert body, the Czech Commission for the Use of GMOs and genetic products (CzC GMO), to the Ministry of Health and Ministry of Agriculture and to the Regional Authority of the region where the contained use is planned.

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 any 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.

MoE shall issue 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 is 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. Therefore the time for issuing the decision is longer than 90 days.

The notifier has to pay an administrative fee for the authorisation CZK 2 000 (approx. 75 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.

Contained use of GMOs is not consulted with the public during the authorisation procedure. The text of the final decision is published at the MoE website and by the municipality of the release after the decision has entered into force.

## Risk Assessment

Requirements and procedures 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 (signed) by the biosafety officer, must be submitted to MoE as a part of the notification dossier or separately in case of a subsequent class 1 contained use. The environmental risk assessment is reviewed by the CzC GMO within the authorisation process.

## Confidentiality

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 genetically modified organism;
- Identity of the notifier;
- Location of the premises;
- Risk assessment;

- Information on the emergency response plan if the plan is required.

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.

## Emergency response plans

An emergency response plan is required for contained use in the classes 2 and higher (**not** in the class 1). It is a document describing activities and measures applied in the event of an accident. Detailed requirements for the emergency response plan are laid down in the implementing Decree No. 209/2004.

The notifier is obliged to submit the emergency response plan to MoE as a part of the notification and separately, prior to commencement of the use of GMOs, to the municipalities where the contained use is to take place, to the local Fire Rescue Brigade, to the regional authority and upon request also to any person that may be directly affected by an accident. The authorised user 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 plans available to the public. The scope of such information is laid down by the implementing Decree.

## Other Requirements

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

- Check the **measures for containment** regularly.
- Send to MoE a short **report** on the contained use every year. The format for the report (in Czech) is available on the GMO website of the MoE (see above). A final report is required after termination of the contained use of GMOs in the premises.
- Ensure proper **labelling and packaging in case the GMO is transported**. 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.
- Keep the documentation on the contained use during the activities and for another 5 years after the end of contained use in the premises.
- Meet any further requirements laid down in the authorisation decision for classes 3 and 4.

## 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** may import or export the GMOs to which the authorisation applies, provided that they are exclusively intended for the authorised contained use. 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 is obliged to inform MoE on the species and number / volume of GMOs that will be imported

or exported and on the intended place of entry to or exit from the territory of the Czech Republic, at the latest **5 days prior to** the import or export. This information can be sent by email (see contacts below).

The notifier is obliged to ensure proper **labelling**: Packaging of the exported / imported GMO 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.

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

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## Contacts

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