Clinical trials on products containing genetically modified organisms

(instructions for applicants concerning requirements of the Czech Ministry of the Environment)

1) Applicants for authorisation to conduct a clinical trial (hereinafter "CT") involving products containing genetically modified organisms ("GMOs") are required to obtain an permission for the use of GMOs as specified by Act No. 78/2004 Coll. on the Use of Genetically Modified Organisms and Genetic Products. Such permission, issued by the Czech Ministry of the Environment, should either be enclosed to the documentation on making application to the State Institute for Drug Control ("SÚKL") for a CT authorisation, or submitted subsequently, however, no later than three days prior to the final outcome of the assessment process. Should the applicant fail to submit this permission by the end of assessment process, the application for CT authorisation shall be refused.

2) The major sponsor's responsibilities laid down by Act No. 78/2004 Coll. are as follows:
   - In case of „contained use" of the first and second risk categories: to ensure submission of a notification to the Ministry of the Environment; in other cases: to apply for permission from the Ministry of the Environment to use GMOs. A separate notification/ application form should be submitted for each site where the CT is to be conducted. Generally, the notification/ application form should be submitted by the legal person who will be using the GMOs. However, a single notification/application made by an authorized person e.g. the sponsor or the contact research organization (CRO) on behalf of all trial sites involved would also be accepted; in such cases only one documentation and relevant authorisations may be submitted. .
   - To provide the risk assessment by a professional consultant who should comply with the requirements of impeccability, professional qualification and practice. Documents proving compliance with the above requirements are to be submitted together with the notification/ application form.
   - To provide a detailed description of all sites /all premises/ and to sufficiently document the measures taken to ensure the „contained use".
   - To provide the emergency plan. The emergency plan shall be subsequently kept also at the local municipal authority.

The professional consultant:
   - may be from abroad; however, the documentation submitted to the Ministry of the Environment should be in Czech i.e. the applicant should submit both the original version and its certified (sworn) translation,
   - is considered a contact person and in case of any deficiencies or comments the Ministry of the Environment contacts him/her.

3) Prior to submitting an application, the applicant may also make a direct contact with the Ministry of the Environment (section of environmental risks, Ing. Doubková, tel.: 267 122 922, e-mail: doubkova@env.cz or Ing. Routa, tel.: 267 122 554, e-mail: routa@env.cz) and clarify the requirements applicable to his/her request with respect to the particular clinical trial.

4) After obtaining the clinical trial authorisation the sponsor is obliged to:
   - train the staff in handling of GMOs,
   - inform the Ministry of the Environment about the GMOs import at least five days in advance /This applies to imports from a third country and the authorization for import is included in the permission for GMO use/ The sponsor should proceed in accordance with Act No. 78/2004 Coll. /requirements for labelling, documentation etc./,
   - inform (in writing) the Ministry of the Environment about the conduct of the clinical trial once a year (using a provided form),
   - inform the Ministry of the Environment about the completion of the clinical trial and submit a final report (within 60 days of study completion). This report should focus on potential environmental risks and must contain information on handling the unused medication.

References:

Act. No. 78/2004 Coll., on the use of genetically modified organisms and genetic products
Decree No. 209/2004 Coll., on detailed conditions for the use of genetically modified organisms and genetic products