The Decision came into force on19 December 2017.

Prague, January 28, 2019

Reference Number: MZP/2018/750/2786

DECISION

The Ministry of the Environment of the Czech Republic as the administrative body competent according to § 5 of the Act No.78/2004 Coll., on the use of genetically modified organisms and genetic products, as amended (hereinafter the „Act“) and § 10 of the Act No. 500/2004 Coll., the Administration Code, as later amended,

has decided

on the basis of notification of the Usovsko joint-stock company , located in Klopina 33, 789 73 Usov, for granting consent for the deliberate release into the environment of three transgenic lines of spring barley producing the LL-37 peptide, carried out on the plot No. 2502/4 owned by Mohelnice farm, Usovsko joint-stock company, pursuant to § 5 par. 8 of the Act:

USOVSKO joint-stock company,

Klopina 33

789 73 Usov

i s g r a n t e d c o n s e n t

for

the deliberate release into the environment of three lines of genetically modified spring barley producing the LL-37 peptide, carried out on the plot owned by the Mohelnice farm (plot No. 2502/4) Usovsko joint-stock company.

Requirements of the consent according to § 18 par. 6 of the Act:

Authorised person

Name: USOVSKO joint-stock company

Address: Klopina 33, 789 73 Usov

Identification Number: 607 93 015

Specification of the genetically modified organism

Notification was submitted in accordance to § 18 par. 3 of the Act for three modification types of transgenic barley producing the LL-37 peptide: LL-37 – UBI:LL-37, bHOR:LL-37 and bHOR:MBP_LL-37 that differ from each other by regulatory and signal sequencies and the presence of proteins facilitating a purification process.

Peptide LL-37– only one gene coding the Cathelicidine protein was recorded in human, i.e. the *CAMP* gene (Cathelicidine AntiMicrobial Peptide). The CAMP gene is located on a chromosome 3, its size is ca 2 kb and contains 4 exons. The gene expresses the hCAP-18 antimicrobial protein, and LL-37 antimicrobial peptide is produced by a proteolytical cleavage its C-terminal. Primary structure of LL-37 is built from 37 amino acid residues.

Immature zygotic embryos of barley cv. Golden Promise were transformed with *Agrobacterium tumefaciens* under the contained use regime at the Palacký University in Olomouc.

Specification of the genetic modification

UBI:LL-37 modification: no phenotypic manifestation; *hpt* selectable marker gene coding for hygromycin phosphotransferase and confering resistance to Hygromycine B antibiotics is a part of inserted DNA, except of LL-37 peptide. Expression of *hpt* gene is driven by CaMV 35S promoter and NOS terminator. These regulation sequences are widely used for plant transgenosis and considered safe. *Hpt* gene has been used in the long term for the selection of transformed cells, monocotyledonous and dicotyledonous plant tissues, and does not pose any risk for the environment, human or animal health or non-target organisms.

Expression of LL-37 gene is driven by the maize ubiquitin promoter (UBI) and NOS terminator. Promoter sequence originates in maize (*Zea mays* L.), the nopaline synthase terminator sequence originates in *Agrobacterium tumefaciens*. except of LL-37 peptide. Expression of *hpt* gene is driven by CaMV 35S promotor and NOS terminator. These regulation sequences are widely used for plant transgenosis and considered safe. Inserted DNA contains also C-terminal sequence for the retention of peptide on endoplasmatic reticulum – KDEL.

In addition, cytokinine oxidase/degydrogenase 1 N-terminal signal peptide that occurs naturally in maize is inserted.

bHOR:LL-37 modification: Free of phenotypic expressions; similarly as abovementioned modification it contains LL-37, *hpt,* KDEL, ZmCKX1sp and NOS. In this case, B1 hordein promotor (bHOR) and NOS terminator are regulatory sequences. Bhor is an endosperm specific barley promoter (GenBank: X87232.1). Bhor modification: Mbp _ LL-37: Free of phenotypic expressions, contains, as in previous modifications, LL-37, HPT, KDEL, ZmCKX1sp, Bhor and NOS. In addition, a sequence encoding maltose binding protein (MBP) and histidine anchor (6xHis) was introduced. These peptides are commonly and long-term used to facilitate purification of the target protein and are considered safe.

Risk assessment results

Barley is a self-pollinating, non-invasive plant in nature. Sexual compatibility with the wild wall barley (*Hordeum murinum* L.), which freely occurs in our territory, is difficult; they neither cross nor create

hybrids. There are no other sexually compatible wild barley species in the European Union, and the genetic modification of spring barley LL-37 brings no selection benefits to the modified plants of spring barley. It is highly unlikely that the modified spring barley producing LL-37 peptide will become more resistant or invasive in the environment and will get wild.

The horizontal transmission of genes in higher organisms is considered rare, but the following steps will be taken to prevent it: Herbicide field treatment prior to barley sowing, an isolation zone of 3 m and an isolation distance of 100 m from all non-trial spring barley plants on adjacent land.

The genetic modification of spring barley with the production of LL-37 peptide does not introduce any new substances which are expected to produce immediate or delayed effects on animal health and do not present any risks to the environment or to human or animal health. Moreover, spring barley resulting from the deliberate release into the environment shall not enter the food or feed chain.

Spring barley LL-37 is highly unlikely to cause immediate or delayed effects on biogeochemical processes.

The very limited deliberate release into the environment of modified spring barley with the production of LL-37 peptide (maximum area of sowing up to 5000 m^2 with a sowing of 300 plants / m^2) will result in negligible immediate or delayed environmental effects due to direct or indirect interactions between spring barley and non-target organisms.

Barley growing in the isolation zone will be treated as GMOs. Access of humans, wild animals, birds and rodents to the trial with transgenic barley will be prevented by fencing, marking, restricted access to the premises and warehouse, fencing, and deterring devices.

All staff coming into contact with GM material will be properly trained. Since the introduced LL-37 and *hpt* genes are commonly found in the environment (human, *E. coli*), we can assess that the presence of barley transgenic lines does not further increase the risk of horizontal transmission of these genes to other living organisms.

Transgenic plants producing LL-37 peptide (T1-T3 generations) were grown under the contained use regime in the phytotron and the greenhouse of the Center for Biotechnology and Agricultural Research (CRH), the Faculty of Science of the Palacký University in Olomouc.

During this contained use no selection advantages or disadvantages were observed for the modifications. No interaction with control plants or other plants or other target organisms was observed.

Peptide LL-37 inhibits bacterial biofilm production and also prevents infections of viral or fungal origin.

In addition to the antimicrobial effect, peptide inhibits tumour growth, induces mastocyte chemotaxis, cellular apoptosis or positively affects the wound healing process by stimulating angiogenesis and epithelial recovery.

Based on the results published so far, the LL-37 gene for catelicidine or its variant has been introduced into three different plants, namely chinese cabbage (*Brassica rapa* var. *chinensis)*, tomato (*Solanum lycopersicum*) and rice (*Oryza sativa* L. var. *Japonica* cv. Dongjinbyeo). No negative effect on the growth and development of target plant organisms has been demonstrated.

No negative effects on the environment are expected since:

- They are not substances alien to the environment (produced by humans and other vertebrates).
- Mammalian antimicrobial peptides are commonly found, for example, in rodent excretes in fields (therefore transgenic lines do not increase the risk of horizontal transmission).
- LL-37 peptide is in the UBI:LL-37 barley line stored in a cell in an endoplasmic reticulum, in membrane wrapped bodies, is not excreted in other parts of the cell or plant, or out of the plant. For the other two lines, it occurs only in grains.
- LL-37 peptide and the *hpt* gene have not been found to be toxic or allergenic to animals or to plants,
- In the case of release of peptide from a cell, e.g. in case of severe plant injury, the LL-37 peptide is rapidly degraded (before its self-degradation (which runs into minutes) the LL-37 peptide is substantially diluted with both cellular and extracellular content and degradation) and its effect on micro-organisms is therefore considered insignificant or negligible.
- The European Food Safety Authority has concluded that the use of the *hpt* gene (part of DNA integrated into GM barley) as a selection marker in genetically modified plants (and derived food or feed) does not pose a risk to human or animal health or the environment (EFSA, 2004, 2009).
- No interaction with control plants or other plants or other target organisms was observed during the use of this GM barley at the Faculty of Science of the Palacký University workplace.

Conclusion

The risk assessment of three spring barley lines producing LL-37 peptide for the environment does not present any risks to human health, animal health or the environment caused by the proposed deliberate release into the environment of modified spring barley producing LL-37C peptide.

Conditions for the use

The above mentioned genetically modified organisms shall be used only in the way described in the application Ref. No. MZP/2018/750/2786 submitted to the Ministry of the Environment on October 12, 2018, and supplemented with the submission to the Ministry of the Environment on December 19, 2018, provided that all given conditions have been met, particularly as follows:

- The workplace of ÚSOVSKO joint-stock company. fully complies with current company standards for quality assurance of field experiments. Suitable conditions are created for working with transgenic materials.
- Legal liability for infringements of the law in the context of deliberate release of GM barley into the environment lies with the applicant - ÚSOVSKO joint-stock company, which is 100% owned by ÚSOVSKO AGRO Ltd., located in Kopina 33, 78973, Kopina. ÚSOVSKO AGRO Ltd., is engaged exclusively in agricultural production. The employees of this subsidiary company will for the applicant ÚSOVSKO joint-stock company provide and carry out part of the work operations under the project“ Optimisation of purification of LL-37 peptide produced by transgenic barley by the method indicated in the publication Holásková et al., 2018 ”.
- All handling with the genetically modified material will be carried out under conditions minimising the possibility of transgene leakage into the environment.
- The principles of good agricultural practice and good experimental practice (GEP) will be respected. When carrying out a field experiment with genetically modified barley producing LL-37 peptide, all statutory measures on the use of genetically modified organisms and genetic products, as laid down by law, shall be observed.

- The safe handling of seeds and plant material (harvesting, storage, transport and disposal) shall be ensured in such a way that no environmental risk arises.
- The plot with GM barley will be safely fenced with a mesh. The entire area behind which the plot is located is protected against the access of unauthorised persons (card entry). The experimental plot can only be accessed from this secured area.
- GM warehouse is located in this secure area on the parcel number 2477, K.U. Mohelnice (a built-up area and a courtyard). The facility shall be intended exclusively for storage of GM seeds. The grain of GM barley will be stored in two rooms with a total storage area of 39 m^2, the entrance to the storage is directly from the outdoor area of the courtyard through a metal two-wing door secured by a security hanging lock. The grain shall not be cleaned or washed in the warehouse.
- Only three persons holding a valid licence shall enter the warehouse. These persons shall be responsible for recording the entries and activities in the GM warehouse. Access to the storage shall be registered and restricted (locked), the warehouse shall be duly marked and its windows shall be fitted with a net.
- Personnel who ensure the transport of plant material and who will carry out sowing and handling of seed shall be regularly trained by a professional consultant on the principles of handling GM material. They will be equipped with mandatory protective work equipment - working clothes (long trousers, blouse or cloak), protective gloves for handling with GM seed (latex examination gloves) and suitable footwear (boots or boots with a rigid sole). All activities that do not comply with the experiment methodology are prohibited on the plot. Workers will be notified of the prohibition on the consumption and feeding of the product, and will be familiar with the obligation to report any health problem related to the deliberate release into the environment. They shall comply with the trial methodology, the standard operating procedures for field experiments according to the EPPO methodology and the methodology for testing the use-value of field crops issued by the Central Institute for Supervising and Testing in Agriculture (CISTA).
- Persons qualified to conduct field experiments and persons trained by CISTA to become competent for the use of plant protection products shall be in the workplace. The application of plant protection products will be carried out by a professionally qualified person for handling plant protection products on the basic level. The selection of plant protection products, their accurate application, the term of application based on forecasting, signalling and immediate need are ensured by a professionally qualified person holding a valid certificate of professional competence of persons for the handling plant protection products on the second level.
- Persons working with plant protection products under field conditions shall follow generally applicable principles for pesticide application and the recommendations of the manufacturer and a valid label for the product used. If plant protection products are applied to GM barley, only the products with a valid authorisation stated in the CISTA register shall be used.
- Authorised staff shall carry out (i) preparation of the plot prior to the setting of the experiment, (ii) agro technical procedures relating to the standard treatment of spring barley and (iii) harvesting and post-harvest work.
- The experimental plots will be prepared according to the current standard technological agro-technical practices for growing spring barley in the given area (pesticides, fertilisers). Before sowing, spraying with total herbicide will be performed, shallow processing of the soil into the depth of the sowing bed together with the application of basic fertilisers (N, P, K), settling the land and crushing the lumps. GM crop will be secured by pest-strippers, which generate a

strong, usually ultrasound signal (inaudible to humans) that protects outdoor areas from pests such as mice, rats, moles, crows or birds.

- All handling of GM material shall be recorded and will also be part of the field diary. Records on operation and sanitation of equipment used for working with transgenic materials (sewing machine, harvester) shall be kept in the workplace diary. The date and time of the operation carried out and the method of sanitation shall always be stated.
- Seed of transgenic barley will be obtained from the Faculty of Science, University of Palacky (UP), Olomouc, Slechtitelu 27 (Department of molecular biology, building H, 2nd floor, and laboratory No. 2.40). Legal liability for the violation of the law in the context of the contained use is borne by the Faculty of Science, UP in Olomouc, which is authorised to use GMOs under the contained use regime (notification No. 4498/ENV/13). The use of transgenic lines LL-37 to the department of molecular biology is authorised on the basis of the notification of 20 June 2016, Ref. No. 66915/ENV/16.
- GM material will be transported by trained personnel of ÚSOVSKO joint stock company, and ÚSOVSKO AGRO Ltd. The grain of three transgenic lines of spring barley with the production of LL-37 peptide intended for sowing shall be transported from UP Olomouc to the farm Mohelnice (ÚSOVSKO joint stock company, and ÚSOVSKO AGRO Ltd. before sowing in early April 2019), by a car (trained driver) to a designated GM grains warehouse near the experimental field in closing, clearly marked double plastic boxes, which will be marked in a way to avoid confusion.
- She seed shall be transported from the warehouse to the experimental field (plot No. 2502/4) on the day of sowing. The transport shall also include an emergency plan, an autoclavable Biohazard bag (for temporary storage and subsequent autoclaving of the grains collected in the event of accident), as well as an emergency plan, a broom, a shovel and an extra plastic container in case of damage to the original transport boxes. Once delivered to the plot, the packaging shall be checked for the completeness according to the list before sowing.
- As regards good experimental practice, a three-year crop sequence of experimental land is proposed. The exact area of the GM crop will be designed each year according to the technological and organisational needs of the research project to optimise the purification of LL-37 peptide produced by transgenic barley,
- The seeds will be sown separately one by one, in rows, using a one-line precision sowing machine. The machine works as a stainless plant and shall be carefully cleaned before leaving the place of sowing in order to avoid the uncontrolled spread of GM seeds outside this place. The experiment shall be designed in such a way that no seeds are left during sowing and the whole monitored population transmitted to the site is always planted. However, if any genetically modified seeds remain at the field trial site, they shall be returned to the GMO warehouse without delay.
- Trained staff of the Usovsko Joint-stock company and Usovsko Ltd. shall ensure the sowing of the GM barley. A record shall be made on the transmission of seed for sowing and on the process of sowing in the field. Once sowing has been carried out, the Ministry will be supplied with a plan with the final shape of trial, accompanied by GPS coordinates of its location.
- In the first year, the transgenic barley will be sown to about 400 m^2. The area of cultivated transgenic barley with LL-37 peptide in 2019: UBI line: LL-37 shall not exceed 100 m^2, Bhor line: LL-37 shall not exceed 260 m^2 and Bhor line: Mbp _ LL-37 shall not exceed 30 m^2, - approximately 120 000 GM plants shall be planted: 30,000 plants line UBI: LL-37, 80,000 plants line Bhor: LL-37 and 10,000 plants line Bhor: Mbp _ LL-37. The plant density in each year shall not exceed 300 plants / m^2.

- Maximum number of plants deliberately released into the environment will be 1.5 million per year. The number of plant progeny released into the environment may vary from year to year depending on the results of the experiments so that sufficient grains are obtained to optimise the purification of LL-37 peptide.
- Total area required for experiments with GMO barley (experimental field, including buffer zones) and the edges of the plot where no other commercial barley can be grown shall not exceed 5000 m^2 during the experiment.
- Trials will be finished by harvesting in the period of reaching physiological maturity of barley grain. Part of the ears will be taken in milky wax maturity.
- Harvest will be carried out by qualified and trained workers of ÚSOVSKO joint-stock company and ÚSOVSKO AGRO Ltd. by hand and mechanically using Harvester Combine Hege 160. This harvester, owned by the Faculty of Science, UP in Olomouc, is specially designed for experimental purposes and meets all the necessary parameters for an accurate, seamless harvest. Harvesting bags of 10-25 kg will be used for harvesting purposes. The grains will be stored in partially sealed pallets, ca 1 palette of 300 kg or the possibility of storing freely on the storeroom floor. Production will reach tonnes in a period of 3 years or more.
- The harvester shall be properly cleaned after harvesting on the plot so that no grains or other plant material remain. Possible GM waste (grains), will be put to properly marked autoclavable bags and transferred to the UP Olomouc workplace for disposal by autoclaving in the GMO laboratory, the Faculty of Science, the University of Palacky, Olomouc, Slechtitelu 27, building H, level II, the laboratory No. 2.39.
- The seeds will be harvested and transported in sealed, clearly marked harvesting bags in a double transport box. A properly marked transport box shall consist of an external and internal sealed plastic container in order to prevent leakage of the transported GM material.
- Transport from the field to the warehouse intended for storage of GM seed shall be ensured by a four-wheeler.
- After the trial is completed, the unripe ears and harvested grains used to optimise the purification of LL-37 peptide will be transferred:
    - all to Olomouc, Slechtitelu 27 (Department of molecular biology, H-building, 2nd floor, the laboratory No. 2.40);
    - in the event of more remaining grains, they will be further stored in the GM grain warehouse of USOVSKO joint-stock company, and processed gradually (in this case, the MoE shall be notified about the amount of grains stored each year);
    - if the experiment is completely finished, the grains shall be transferred to the Palacky University in Olomouc, Slechtitelu 27 (Department of Molecular Biology, Building H, 2nd floor, Laboratory No. 2.39), where the grains and all samples will be disposed of by autoclaving.
- The use of GM material under the contained use regime (production and storage of barley seed and analysis of samples) will be carried out at the workplace of Palace University in Olomouc, Faculty of Science, Department of Molecular Biology, Breeders 27, Building H, 2nd floor, Laboratory No. 2.40., and Building F, 2nd floor, Laboratory No. 2.22. This institution is authorised to use GM barley according to the notification Ref. No. 91997/ENV/10, 4498/ENV/13 and 66915/ENV/16, submitted to the MoE.
- Purification of peptide LL-37 (using a method by Holaskova et al., 2018) will be carried out at the Faculty of Science, the Palacky University in Olomouc.

- All packaging intended to handle GM plants shall be properly marked with: “Contains genetically modified spring barley material LL-37. Not for food and feed! Do not hand it over to unauthorized persons!
- After the work has been completed, each worker shall clean his or her work clothing or protective equipment. Workers who handle GM material shall carefully carry out maintenance of all machinery and techniques.
- After harvesting, any post-harvest plant remains, including conventional spring barley cultivated in buffer zones, shall be crushed immediately and cut up (crushing the straw with a crusher, spraying it with total herbicide, and planting the crushed straw in the soil by ploughing - heavy disk gates). The plant scrub shall be evenly dispersed across the experimental plot and after application of nitrogen fertilisation to accelerate decomposition ploughed under the soil.
- Ploughing is also an effective protection against sprouting from released mature seeds. If spring barley plants occur in a subsequent crop (other than spring barley), they shall be destroyed mechanically or by herbicide.
- For the next two years, no commercial spring barley or other cereals shall be grown on the experimental area, and only such crops that allow monitoring of volunteers and its effective chemical disposal, if occur, shall be planted (e.g. winter rape).
- Maize grown for silage, rapeseed, winter wheat and sugar beet will be planted on surrounded plots in 2019.
- In subsequent years, the applicant shall submit a written information to the MoE on what crops will be planted on the areas and plots surrounding with planned GM barley trials, no later than 30 days from sowing.
- The GM barley detection method will be added to the Emergency plan (point 9 - GMO detection).
- Written records shall be kept on all waste management, including disposal of GM barley material. Official written records on handling the harvested material shall be also kept.
- In case of the use of an unauthorised plant protection product or unauthorised use of a plant protection product the request for granting consent to carry out experiments for research or development purposes according to the Regulation (EC) No. 1107/2009, Article 54, para 2 shall be submitted in advance, and the testing of the product shall be realised only after granting consent for the application by the Central Institute for Supervising and Testing in Agriculture, Hroznová 2, 656 Brno. Where appropriate, Regulation (EC) 1107/2009, Article 54, para 4, and the Act No. 326/2004 Coll., on phytosanitary care, as amended, shall be followed.
- Usovsko joint-stock company shall in accordance with § 19 letter c) of the Act submit to the MoE data on the amount of barley and on handling with it in written and electronic form annually, always by February, 15 in the calendar year, and pursuant to § 19 letter d) of the Act submit within 60 days from termination of the use of genetically modified organisms a final report on the course and consequences of this activity, particularly with regard to risk for human health and the environment. The final report shall be submitted in English as well pursuant to the Annex to the Decision of the European Commission 2003/701/EC.

Other conditions stipulated under § 5 par. 10 of the Act

- All possible measures shall be taken to ensure cultivation on experimental plots: Possibly released pollen from GM barley plants with peptide production LL-37 will be regulated with a 100 metre isolation distance from all non-testing spring barley plants to avoid any sexual species compatibility.

- The experiment site shall be protected by a 3 m wide buffer zone of conventional spring barley of similar earliness (commonly grown 'Francin' variety). The buffer zone shall be treated as GM plants.
- Plots No. 7908 and 8001/3, where USOVSKO joint-stock company operates its agricultural activities, are located in the 100 m isolation distance from the field trial.
- The trial with GM barley shall be safely fenced with a mesh fence. The entire area in which the trial plot is located is secure against trespassing (card entry). Access to the trial is only possible from this secure area. The GM warehouse is located on parcel number 2477 in the above mentioned secure area (built-up area and courtyard). The warehouse is lockable with the key that is being placed in the locked office of a authorised and trained person.
- Plot on which the field trial will be carried out shall be labelled at all corners with visible warning signs as follows: "Attention! GMO! No Entry! Not for Feed! Not For Food! Chemically Treated! Delivery to non-authorised persons prohibited!" in order to prevent the access to non-authorized persons. If necessary, regarding the organisation of the field trial, more warning boards shall be used so that notices can be seen from one to another.
- Usovsko, joint-company, is required to conclude a contract on crop rotation and keeping isolation distances from the trial plot with the director of Palomo joint-stock company that has been managing a plot No. 7001/8.
- Every year, after sowing the trial, the company shall notify to the MoE no later than 30 days after sowing, information on setting the trial, its area with buffer zone and provides a map of the parcels with an accurate indication of its location, including GPS coordinates, as well as an up-to-date trial scheme.
- Usovsko, joint-company must, upon request of the MoE or a laboratory, if appropriate, as referred to in § 28(1f) of the Act, provide at any time during the field trial duration samples of the 3 GM barley lines or their genetic material.
- In accordance with § 19 (h) of the Act, Usovsko joint-stock company must provide administrative authorities (Ministry of Environment, Czech Environmental Inspectorate, Central Institute for Supervising and Testing in Agriculture) according to the § 28 and 31 to 33 with synergies in controlling plots, premises and equipment intended to use genetically modified organisms or plots, premises and facilities in which such handling occurs or may occur, including the provision of documents at any time during duration of the field trial. For control purposes, free sampling of the above GMOs or their genetic material must be allowed.

Purpose of the release

The purpose of deliberate release of three lines of transgenic spring barley with the production of peptide LL-37 into the environment at the workplace of Usovsko joint-stock company is (i) to study the stable production of peptide LL-37 in field conditions, (ii) to grow enough barley to optimize the purification of peptide LL-37 from mature grains of transgenic barley plants as well as grains in milky phase.

Other requirements for labelling

For the deliberate release of GMOs into the environment, the general requirements for labelling of genetically modified organism, which are given by law, apply. In addition, packaging containing grains or parts of GM barley plants will be marked with the words "Not for food or feed! No hand over to unauthorized persons!

The unique identifier pursuant to Commission Regulation (EC) No. 65/2004 for genetically modified spring barley producing LL37 peptide has not been defined yet.

Place of the deliberate release into the environment

Deliberate release of GM spring barley producing LL-37 peptide into the environment will be conducted on the plots owned by the Mohelnice farm that belongs to the Usovsko joint-stock company. In subsequent years, concrete plots (incl. the plot numbers) shall be notified to the MoE Environment 30 days after sowing at latest. Land block number shall be notified to the MoE before sowing.

Region: Olomoucky
Municipality: Mohelnice
Name of cadastral territory and parcel No.: Mohelnice, 2502/4 (field), 2477 (warehouse)
Land type – arable land
Total area of the plot: 14,919 m^2
Total area of the parcel where GM higher plants will be cultivated: 12,800 m^2
Total area of all cultivated GM spring barley plants, incl. buffer zone will not exceed 5000 m^2

Requirements for monitoring and reporting of monitoring results

- The monitoring plan has been based on the results of risk assessment, and its objective is to early observe and identify both expected and unexpected effects of GM barley plants on the environment after their deliberate release into the environment.
- Under the monitoring plan, general observations will be made once a month and the environmental impact caused by interactions with non-target organisms will be monitored once every two weeks. Furthermore, any harmful effects on human health related to the field trial will be reported between planting and harvesting. After harvesting, the presence of volunteers (at least 1x per month for two years) and any harmful effects on the environment (at least 1x for two months for two years) will be monitored.
- Monitoring will be carried out on the experimental land on which GM barley cultivation takes place or has taken place and in its vicinity, including the edges of this area and the edges of the adjacent surrounding plots.
- Monitoring under the monitoring plan will be carried out by trained personnel of USOVSKO joint-stock company, and USOVSKO AGRO ltd. Notifiers submitting the application for the field trial with GM barley are legally responsible for monitoring and implementation of the monitoring plan.
- Phenological observations are part of the monitoring. The workplace keeps a separate field trial diary on GM plants cultivation, where all necessary data are recorded, the copy will be kept in electronic form. Accurate records on all controls being carried out shall always be kept.
- If any volunteers are found, they shall be removed even before the heading stage, and this shall be done manually or using appropriate herbicide.
- No cereals shall be cultivated commercially on the experimental area for the next two years and winter rape is planned to be grown in the following year, which has significant competitiveness and allows the spring barley to be chemically disposed of effectively.

- If the event of accident, monitoring shall be carried out also at the accident site and its closest vicinity. The monitoring in such place and its vicinity shall be carried out in the same extent as on the experimental site.
- All manifestations of any adverse effects resulting from the deliberate release of GM barley into the environment shall be immediately reported to the MoE and the relevant authorities.
- A monitoring report will be submitted annually to the relevant competent authorities, summarising the results of observations during the field trial.
- After the end of monitoring, the written report on its course and results shall be submitted to the Ministry of the Environment according to the law and the European Commission Decision 2003/701/EC.

Validity

The consent shall apply to December 31, 2028.