|  |
| --- |
|  Dnr 4.6.18-14201/14201/17  |
|  |

2017-12-13

Excerpts of the Decision of the Swedish Board of Agriculture (translation from the Swedish)

**Field Trial with genetically modified aspen and hybrid aspen**

**Swedish Board of Agriculture’s decision**

The Board of Agriculture grants you permission for the continued field trial with genetically modified aspen and hybrid aspen with the protective measure identified in the application. Placing the plants out in the spring to adapt to outside conditions may be done in Umeå municipality, but no cultivation. This permit is valid until the 31 December 2022.

**Conditions for the decision**

You are to follow the conditions that you have taken upon yourself in the application. Above and beyond this, you are to follow the conditions given below.

1. You shall every year inform in writing the municipalities affected about the field trial. A copy of the information shall be sent to the Board of Agriculture by 15 March every year,
2. You shall give the people who carry out the field trial careful written instructions on how the trial shall be carried out and cared for. A copy of the written instructions shall have come to the Board of Agriculture by 15 March 2018. You shall even send a copy if you make any changes in the instructions.
3. From the third week in February until two months after the leaves have opened, inspections are to be made every other week to discover if flower buds and disposition for forming flower buds has developed.
4. If you should find flower buds on the hybrid aspens during the field trial, you shall immediately report this to the Board of Agriculture, If trees are removed because it has been observed that flower buds are developing, the trees’ root systems should be removed or killed.
5. Within a 10 meter broad zone around the trial, vegetation should be held back by cutting at least once during the growing season. Within this zone, the presence of root shoots should be held back (not permitted).
6. Within a surrounding zone of 50 meter from the trial, wild growing aspens should be removed and controlled. The control should be chemically or mechanically at least once per year. Trees or shoots, where control measure have been started but where the plant is still alive, shall be marked so that is is clear that control measures are being taken.
7. The experimental plants in the trial shall be killed when the trial is ended.
8. If the Board of Agriculture requests it, you shall make maps or something similar available, that show where hybrid aspens and aspens with the different constructions are planted.
9. During the years that the pace is monitored for root shoots, cultivations that may take place on the field must be composed of plants that allow monitoring.
10. Test material from the trial and plants that is taken away shall be taken care of in a way that spread does not occur.
11. The place for the trial, including the protective zone of 50 meters around the trial, shall after clearing be monitored annually for the presence of root shoots, for a minimum of 3 years. Root shoots, if found, should be destroyed. For every year that you find root shoots, the monitoring will be extended for two years.
12. By 31 December every year that the trial is ongoing, you are to turn in a report. The report format that you are to use, is on the website of the Board of Agriculture. The report for the last year shall be a final report using the same format.
13. Reports of the results of the monitoring shall even be sent in the year following the area inspections for the presence of root shoots. Reposts on root shoot do not need to be given on any special form.

**Description of the case file**

On 11 September 2017, you applied for permission to continue an existing field trial with genetically modified hybrid aspen during the period 1 January 2018 until 31 December 2022. The Board of Agriculture gave permission for the present trial on 17 April 2013 (SJV dnr 22-2655/12). The application has been complemented with additional information.

The application is about hybrid aspens and aspens that are modified with 28 different gene constructions with gene sequences from aspen or oats. The modifications result in down regulation or up regulation of the expression of the receiving aspen’s or hybrid aspen’s genes, and in one care expression of a gene from oats. Marker genes and genetic elements for gene expression are included in the constructions. The broader purpose of the research is to understand the function of all of the genes of the aspen. The purpose with this trial is to study the phenology of the aspen, that is to say, its seasonal related processes.

**Your proposed protective measures**

You have proposed a number of protective measures.

* The area is enclosed by a about 2 m high fence.
* The trees will not be allowed to flower. Control/inspection of the formation of flower buds will be made with inspections once a month from January until and including July. During the period from when the trees come into leaf and two months after, the inspections will be made every other week to discover if flowers could be formed in other places than normal. The Board of Agriculture has made this condition stricter so that the inspection should be made every other week from then middle of February. If a sign of swelling is noted on some plants the buds are to picked and opened to see if they are developing leaves or flowers. If it is development of flowers, all trees of that genotype are to be removed,
* The presence of root shoots is to be inspected during the vegetation period and held back. When the trial is ended, the hybrid aspens are to be cut down. The Board of Agriculture has defined this condition so that it is equivalent to the earlier approvals for permission.

**Explanation**

**The total assessment**

With a total assessment of the environmental risk assessment and the other assessment and with the conditions that are made, the Board of Agriculture regards that the field trial is safe for human health and the environment and is ethically sound as well as fills other demands.

The Board of Agriculture is of the opinion that you have made a risk assessment that is sufficient. We are of the opinion that permission for the activity can be given.

**The Board of Agriculture’s environmental risk assessment.**

The Board of Agriculture carried out and reported an environmental risk assessment for intentional release of hybrid aspen lines in the decision from 17 April 2013 (dnr 22-2655/12). The Board of Agriculture has studied the environmental risk assessment and application on extension that was complemented with certain experiences from the trials so far. No new information has come forth from your reports or other research that changes the earlier environment risk assessment that the Board of Agriculture has carried out.

However, mature flower buds were observed in another of your field trials with the same clone, T89, in 2017. Those hybrid aspens that were planted outside in 2010, for which permission was granted in 2014. You observed this at the end of February and immediately informed the Board of Agriculture. You destroyed the tress in a safe manner. To ensure that possible disposition for developing flowers are observed in good time before flowering, even in this trial, which is already an extension, we propose that your inspections should begin in January, instead of February as earlier.

Why the clone T89 developed flower buds is difficult to say. You have indicated that the dry summer and autumn at the place can have been a contributing reason. The Board of Agriculture is of the opinion that if flower buds developed on the somewhat older trees, this is not a reason to not extend permission for the hybrid aspens. One reason is that your monitoring worked, and the trees could be destroyed in a safe manner in good time before flowering began. Another reason is to study if the climate at the place, the age of the trees, the inserted characteristics, a combination of these or some entirely unknown factor affected the development of flower buds. This can only be determined if more long-term experiments are carried out.

The probability for initial spread as a result of the flowering or root shoots increases with the age of the trees. To see if there is a sufficient margin of time between the inspection of flower buds, and possible flowering, we regard that the frequency of the inspections should increase. The Board of Agriculture therefore, makes the condition that the inspection of flower buds should occur at intervals of every other week from and with the third week in February. We place the same conditions for treatment of root shoots as in the former decision.

The Board of Agriculture regards that field trial is safe for the environment with the commitments and conditions that are given for the trial.

*The inserted genes effects on aspens*

The intentional release to the environment concerns aspen and hybrid aspen that have been genetically modified with some of the 28 described gene constructions. Certain of the gene constructions overexpress, that is to say increase the amount of the product from the character gene. Other gene constructions down regulate, that is to say reduce the amount of product of the character gene. The character genes come in 27 constructions from aspen or hybrid aspen. In one of the constructions, the character gene comes from oats.

The constructions contain even the marker genes *nptII, hpt, bla* eller chloramphenicol acetyltransferase that catalyze the breakdown of different antibiotics. The genes and their functions are described in the decision from 17 April 2013, dnr 22-2655/12. We have not changed the assumption about the function of the genes or the effect of the assessed molecules since the previous decision.

You have only planted hybrid aspens in the field trial, not aspens. You have studied several phenological parameters about hybrid aspens during the trial. From the data on among other things, growth, date for bud development and bud opening, it is difficult to see an increased risk with either of the lines.

**Effects on human health**

No new information has come forth from the reporting of the trials that have been carried out or from other research that changes the Board of Agriculture’s earlier assessment that the field trial is safe for health.

*Conclusion of other assessment*

We assess that the Environmental Code’s rules for consideration are fulfilled. The Board of agriculture has identified value for society with the field trial and has not been able to identify any special ethical aspects that are against the approval of the application.

*The Environmental Code’s consideration rules*

You have many years of experience with genetically modified plants and experience of experimental activity with genetically modified plants. In the application is information that shows that your knowledge of genetically modified plants sufficient and the application shows an insight in the potential types of environmental effects that can occur with this activity. We consider that you fulfill the knowledge requirement.

We consider that the design of the trial and the proposed risk management measures, together with the conditions in this decision, mean that the best possible technique is used with the trial. The field trial in Laholm is cultivated on already intensively cultivated land, that is not situated in the direct vicinity of any officially known biotopes or protected areas. We make the assessment that the choice of place for the field trial will not mean that the activity brings any problem for human health or the environment.

The application covers even release to the environment in Umeå municipality, but you have not described any place or conditions of a place. We can therefore, not give you permission to a field trial in Umeå municipality. However, you may

Have plants outside for conditioning in the proximity of the university because this place has been sufficiently described for the purpose.