GenØk - Centre for Biosafety

Vår ref:2011/h89
Deres ref: 2011/3958 ART-BI-BRH

Direktoratet for naturforvaltning
Tungasletta 2
7485 Trondheim

Dato: 13.05.2011

Vedlagt er inspill fra GenØk – Senter for Biosikkerhet om høringer EFSA/GMO/NL/2010/89 for genmodifisert mais **DAS-40278-9 fra Dow AgroSciences LLC** for import, prosessering, og bruk i mat.

Hvis du har noe spørsmål, vennligst ta kontakt.

Med vennlig hilsen,

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GenØk - Centre for Biosafety

Vår ref:2011/h89
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Assessment of the technical dossier submitted under EFSA/GMO/NL/2010/89 for approval of transgenic maize event DAS-40278-9 by Dow AgroSciences LLC

Submitted to

Direktoratet for Naturforvaltning

by

David Quist
Centre for Biosafety – GenØk
May 2011

Konklusjon på norsk

Vi trekker frem noe informatoriske mangler i dossieret som ikke gir grunnlag for en konklusjon om sikker bruk, samfunnsnytten og bidrag til bærekraftighet av **DAS-40278-9**. Søker har ikke inkludert noe av den informasjonen omkring samfunnsnytten og bærekraftighet til **DAS-40278-9** som kreves i den norske genteknologiloven (Appendix 4) for godkjenning i Norge.

Basert på våre funn foreslår vi en rekke konkrete anbefalinger som vi adresserer i vårt høringssvar, og som vi har oppsummert her

Direktoratet for Naturforvaltning bes vurdere følgende

1. Søker må fremskaffe den nødvendige informasjon om samfunnsnytten av **DAS-40278-9** samt bidraget til bærekraftig utvikling (inklusive data om sprøtemiddelbruk og utbredelsen av skadedyrinsekter som er i målgruppen for denne GMOen).

Hovedkonklusjon og anbefalinger

Søker har ikke fremskaffet noe av den informasjonen som er nødvendig for å kunne vurdere samfunnsnytte og bærekraftighet, noe som er påkrevd i den norske genteknologiloven for godkjenning i Norge. Disse manglene gjør at vi mener at denne søknaden er ufullstendig i sin nåværende form. Vi anbefaler derfor å avslå søknaden samt at en ny søknad bare bør vurderes om søker har adressert de mangler vi har belyst.

Summary of the assessment of the technical dossier related to EFSA/GMO/NL/2010/89

As a designated National Competence Center for Biosafety, our mission at GenØk in advice giving is to provide independent, holistic and useful analysis of technical and scientific information/reasoning in order to assist authorities in the safety evaluation of biotechnologies proposed for use in the public sphere.

The following information is respectfully submitted for consideration in the evaluation of product safety and corresponding impact assessment of event **DAS-40278-9**, setting out the risk of adverse effects on the environment and health, including other consequences of proposed release under the pertinent Norwegian regulations.

This submission is structured to address specific provisions for an impact assessment required under the Norwegian Gene Technology Act of April 1993, focusing on the requirements in Appendix 4 - Evaluation of ethical considerations, sustainability and benefit to society, cf section 17 of the "Regulations relating to impact assessment pursuant to the Gene Technology Act" of December 2005, pursuant to section 11 cf section 8. Lack of commentary on our part towards any information under consideration should not be interpreted as specific endorsement of that information.

Key findings

- The applicant has not submitted the necessary information to be compliant with provisions under the Act, specifically those related to Appendix 4 - Evaluation of ethical considerations, sustainability and benefit to society, cf section 17 of the "Regulations relating to impact assessment pursuant to the Gene Technology Act" of December 2005, pursuant to section 11 cf section 8.

- The use of the acceptance of **DAS-40278-9,** in which the intended use includes the use of a banned product (2,4-D), would violate basic ethical and social utility criteria as laid out in the Act.

Recommendations

The Direktoratet for naturforvaltning is encouraged to request:

The Applicant should submit required information on the social utility of **DAS-40278-9** and its contribution to sustainable development, including information for an ethical assessment, in accordance with the Norwegian Gene Technology Act.

Overall recommendation

Based on our detailed assessment, we find that the informational deficiencies identified in the dossier do not support ethically defensible acceptance of **DAS-40278-9**. **Critically, the Applicant has not included any of the required information to assess social utility and sustainability as required in Appendix 4 of the revised reguations (2005) under the Norwegian Gene Technology Act, which would be necessary for consideration of approval in Norway.** Hence at minimum, the dossier is deficient in information required under Norwegian law.

Assessment of the technical dossier related to EFSA/GMO/NL/2011/69

About the event

The transgenic maize **DAS-40278-9**, developed by Dow AgroSciences LLC, has been genetically engineered to confer tolerance to 2,4-D and AOPP ("fop") herbicides.

1. Missing information in relation to requirements under the Norwegian Gene Technology Act

1.1. Social utility and sustainability aspects

In addition to the EU regulatory framework for GMO assessment, an impact assessment in Norway follows the Norwegian Gene Technology Act. In accordance with the aim of the Norwegian Gene Technology Act, production and use of the GMO shall take place in an ethically and socially justifiable way, under the principle of sustainable development. This is further elaborated in section 10 of the Act (approval), where it is stated that "significant emphasis shall also be placed on whether the deliberate release represent a benefit to the community and a contribution to sustainable development".

These issues are further detailed in the regulation on consequence assessment section 17 and its annex 4. The Applicant has not provided relevant information that allows an evaluation of the issues laid down in the aim of the Act, regarding ethical values, social justification of the GMO within a sustainable development. Given this lack of necessary information for such an evaluation, the Applicant has not demonstrated a benefit to the community and a contribution to sustainable development from the use of **DAS-40278-9** . The Applicant should thereby provide the necessary data in order to conduct a thorough assessment on these issues, or the application should be refused.

It is also important to evaluate whether alternative options, (e.g. the parental non-GM version of this **DAS-40278-9** has achieved the same outcomes in a safer and ethically justified way.

Further, the Norwegian Gene Technology Act, with its clauses on societal utility and sustainable development, comes into play with a view also to health and environmental effects in other countries, such as where GMOs are grown.

Recommendation: The Applicant should submit required information on the social utility of **DAS-40278-9** and its contribution to sustainable development, in accordance with the Norwegian Gene Technology Act.

1.2 Ethical considerations

DAS-40278-9 has been genetically altered to permit to tolerance to 2,4-D and AOPP ("fop") herbicides. The evaluation of co-products, that is, secondary products that are specifically designed and intended to be used in conjunction with the GMO, is considered important in the risk assessment of a GMO (Dolezel et al, 2009). Therefore, considerations of the co-products also warrant an evaluation of safet use, particularly when there is precedence in policy concerning its use.

The chemical 2,4-D is banned for use in Norway. While it is understood that the Applicant has not applied for deliberate release of **DAS-40278-9** in Norway, the acceptance of a product in which the intended use includes the use of a product banned in Norway would violate basic ethical and social utility criteria, as laid out in the Act. That is, we find that it would be ethically incongruous to support a double standard of safety for Norway on one hand, and safety for countries from which Norway may import its food on the other. This is consistent with the provisions under the Act to assess ethical, social utility and sustainable development criteria not only for Norway, but for countries from which Norway imports food.

Therefore, we find it difficult to arrive at justified use of the product **DAS-40278-9** without engaging in such an ethical double standard. Specifically, this issue is relevent particularly in revised regulations of 2005 Section 17 "Other consequences of the production and use of genetically modified organisms" points 2 and 3 "ethical considerations that may arise in connection with the use of the genetically modified organism(s), and "any favourable or unfavourable social consequences that may arise from the use of the genetically modified organism(s)", respectively.

DAS-40278-9 as a stand-alone product may prove to be perfectly as safe as its conventional counterpart. However, given this considerable justification for the non-acceptance of **DAS-40278-9** on other grounds that are considered in the impact assesment, we have not undertaken the investment of considerable time necessary to perform a technical evaluation of this GMO, particularly when other considerations loom equally as large, or larger in the final assessment leading to decisionmaking.

Conclusion

In our brief assessment of **DAS-40278-9**, we conclude that the acceptance of any product, though perhaps produced elsewhere, for which a necessary co-product is banned in Norway, violates ethical principles of promoting safe and sustainable production. Further, the applicant has not provided the required information under Norwegian law to warrant approval.

Overall recommendation

Based on our detailed assessment, we find that the informational deficiencies identified in the dossier do not support an ethically defensible acceptance of **DAS-**

40278-9. **Critically, the Applicant has not included any of the required information to assess social utility and sustainability as required in Appendix 4 of the revised reguations (2005) under the Norwegian Gene Technology Act, which would be necessary for consideration of approval in Norway.** Hence at minimum, the dossier is deficient in information required under Norwegian law.

References

Dolezel M, Miklau, M., Eckerstorfer, M., Hilbeck, A., Heissenberger, A., Gaugitsch, H., 2009. Standardising the Environmental Risk Assessment of Genetically Modified Plants in the EU / Standardisierung der Umweltrisikoabschätzung gentechnisch veränderter Pflanzen in der EU. BfN – pp. 259.