GenØk - Centre for Biosafety

Vår ref:2013/h104
Deres ref: 2013/1391 ART-BI-DHT

Direktoratet for naturforvaltning
Tungasletta 2
7485 Trondheim
Dato: 11.03.2013

Vedlagt er inspill fra GenØk – Senter for Biosikkerhet om høringer **EFSA/GMO/ES/2012/104** for GHB614 bomull fra Bayer CropScience AG

Vennligst ta kontakt hvis du har noe spørsmål.

Med vennlig hilsen,

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GenØk - Centre for Biosafety

Vår ref:2013/h104
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Assessment of the technical dossier submitted under EFSA/GMO/ES/2012/104 for approval of GHB614 Cotton from Bayer CropScience AG

Submitted to

Direktoratet for Naturforvaltning

by

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Centre for Biosafety – GenØk
March 2013

KONKLUSJON PÅ NORSK

Vi trekker frem mangler i dossieret som ikke gir grunnlag for en konklusjon om sikker bruk, samfunnsnytten og bidrag til bærekraftighet av GHB614 bomull. Søker har ikke inkludert noe av den informasjonen omkring samfunnsnytten og bærekraftighet til GHB614 bomull som kreves i den norske genteknologiloven (Appendix 4) for godkjenning i Norge.

Hovedkonklusjon og anbefalinger
Genøk –Senter for Biosikkerhet viser til brev fra Direktoratet for naturforvaltning (DN) angående høring som omfatter GHB614 bomull for bruksområdet dyrkning.

Selv om søker konkluderer med at det ikke er behov for en overvåkningsplan på bakgrunn av tidligere godkjenning av GHB614 for mat og fór, er vår vurdering at det er behov for en overvåkningsplan.

Søker gir ikke opplysninger som adresserer vurderingskriteriene bærekraft, samfunnsnytte og etiske aspekter som forutsettes anvendt i den norske genteknologiloven. I denne sammenheng er det viktig å få dokumentert erfaringer med hensyn på effekter på miljø, helse og samfunnsaspekter. Denne type dokumentasjon er ikke vedlagt søknaden om omsetting av mat produsert fra GHB614 bomull eller inneholdende ingredienser produsert fra GHB614 bomull.

Vår konklusjon er at norske myndigheter ikke godkjenner bruk av GHB614 bomull for dyrkning som det søkes om.

SUMMARY OF THE ASSESSMENT OF THE TECHNICAL DOSSIER RELATED TO EFSA/GMO/ES/2012/104

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 GHB614, setting out the risk of adverse effects on the environment, including other consequences of proposed release under the pertinent Norwegian regulations.

The molecular data presented in H_104 is the same as in H_51 that has already been considered (application for GHB614 in food and processing). What is new however, is the proposal for environmental release in this application. We have targeted our critique to address the information needs under the "Post marked monitoring (PMM) of food and feed derived from GM plants" p. 95 in the dossier.

Specific recommendations

Based on our findings, we propose a few specific recommendations, summarized here and detailed in the critique below.

- The applicant should provide a case-specific monitoring plan to monitor potential unintended but anticipated exposure routes and levels, and to verify the assessment of exposure routes and levels into the environment.

- The applicant should provide a description on the methods, locations and local considerations that should be identified for the establishment of baseline data, including specifics on how existing monitoring networks would be utilized to generate data that would be part of a general surveillance monitoring plan.

- The Applicant should submit required information on the social utility of GHB614 and its contribution to sustainable development, in accordance with the Norwegian Gene Technology Act.

Overall recommendation

From our analysis, we find that the deficiencies in the dossier do not support claims of safe use, social utility and contribution to sustainable development of GHB614. **Critically, the Applicant has not included any of the required information to assess social utility and sustainability as required in Appendix 4 of 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. A new application or reapplication should only be reconsidered with the delivery of the information requests recommended here, including any additional information deemed significant by the Norwegian authorities.

Therefore, in our assessment of GHB614, we conclude that based on the available data supplied by the Applicant, the Applicant has not substantiated claims of environmental safety satisfactorily or provide the required information under Norwegian law to warrant approval in Norway at this time.

ASSESSMENT OF THE TECHNICAL DOSSIER RELATED TO EFSA/GMO/ES/2012/104

About the event

The genetically modified GHB614 cotton was developed through *Agrobacterium*-mediated transformation to provide tolerance to the herbicide glyphosate by expressing the *2mepsps* gene. The Applicant is requesting the authorization for *cultivation* in the EU of glyphosate tolerant GHB614 cotton. GHB614 cotton has been assessed by EFSA in the frame of an application for food and feed import and has been approved in the EU since June 2011 for food and feed and processing.

Assessment findings

Post marked monitoring (PMM) of food and feed derived from GM plants (p. 95)

Although the applicant has concluded that there is no need for a Post-market monitoring Plan on the basis of approval of GHB614 for food and feed, Chapter 4 of the 2005 Revised regulations of the Norwegian Gene Technology Act, § 13 clearly indicates the requirement for including "a monitoring plan and a proposal for the time period of the plan in accordance with the requirements set out in Appendix 3".

In the development of a monitoring plan, an important aspect to keep into focus is what monitoring methodologies and plans will generate added value to the objective. Experience from environmental monitoring has indicated that unless all of the details of the monitoring methodology, hypothesis formulation, data quality, and statistical power are well described from the start, the monitoring will not likely produce information that is meaningful and useful to the risk assessment. The liability here is that there will be the illusion that something useful has been done when in reality the monitoring methodology implemented could not have actually identified meaningful changes in the first place. Perpetuation of faulty monitoring programs that fail on the basis of design rather than the potential for identifying changes give can be the strongest reasons why most monitoring activities to date have not produce meaningful results.

The Ad-Hoc Technical Expert Group under the Cartagena Protocol on Biosafety has provided guidance on the development of a monitoring plan, and recommended this as a basis for developing the plan. The guidance document is available at: http://bch.cbd.int/onlineconferences/guidance_ra/monitoring.shtml

Specific points to consider for the monitoring plan are given below.

Case-specific GM plant monitoring

The case-specific monitoring (CSM) plan focuses on strategies for herbicide-resistance management and evaluating their efficacy as an identified potential risk of weed resistance. However, CSM may also be utilized to verify the assumptions or conclusions regarding exposure of GHB614 or its products in the environment. This includes a) accidental spillage or exposure during transport, storage, or processing or other approved uses, b) persistence and accumulation into the likely receiving environments into the environment, and c) transgene expression (quantity and quality) under varying environments.

Recommendation: The applicant should provide a case-specific monitoring plan to monitor potential unintended but anticipated exposure routes and levels, and to verify the assessment of exposure routes and levels into the environment.

General surveillance for unanticipated adverse effects

In addition the requirement of the Norwegian regulations, Directive 2001/18/EC indicates that general surveillance is a compulsory. This would require that the applicant specifications of parameter definitions, methods (including sampling), statistical approach(es), baselines establishment, frequencies of observations, adaptability of monitoring plans to local conditions, external network use and integration to a level of detail to implement the monitoring activities and ensure the activity will produce meaningful results.

Recommendation: The applicant should provide a description on the methods, locations and local considerations that should be identified for the establishment of baseline data, including specifics on how existing monitoring networks would be utilized to generate data that would be part of a general surveillance monitoring plan.

Reporting the results of monitoring

The applicant suggests that reporting would come in the form of synthesis report to competent authorities. However, reporting of the data obtained and made available for independent analysis would strengthen the confidence and robustness, and transparency of the analysis

Reporting is essential to provide not just results, but critical feedback its efficiency and efficacy towards meeting the stated objectives in the monitoring plan. Second, it can help make sure that results will support further assessment, changes to risk management or decisionmaking.

Recommendation:
The applicant should describe how the monitoring report will allow the review and evaluate the effectiveness, relevance, efficiency, and scientific quality of data derived from monitoring, including the continuity of the monitoring activities as it was described in the monitoring plan. Any unusual observations or identified adverse effects that are identified should be reported in a timely manner so that the appropriate response may be undertaken. These reports should also include a scientifically rigorous analysis of the results and conclusions, also considering site-specific conditions. The report should further highlight results that indicate adaptation of the monitoring plan, further research or review of risk management options or decisions.

The applicant should also specify how the report will provide information on the practical experience from the monitoring and suggest the ways the plan may be revised as needed, as specified by the Competent Authority, and implemented by the Applicant. These may include adaptation of the monitoring plan, the establishment and/or adaptation of risk management measures, or the imitation of new investigations or more in depth studies (in the case where follow up studies are needed, how they should be designed and who should be responsible for their implementation should be decided by the Competent Authority, in accordance with the monitoring provisions adopted by the Party of Import).

The applicant should indicate how monitoring reports could be made available on a central, openly accessible storage and presentation interface (e.g. a publically available website, housed by the Competent Authority) so that it may be more broadly disseminated (including for public awareness and participation). Raw data should be stored by the Applicant and made available for independent review of the data, its interpretation, and conclusions drawn from the monitoring activities. Reporting should also be disseminated, as determined in the monitoring plan, via GMO registers established by the Competent Authority and other public databases.

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 GHB614. 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 GHB614 may achieve 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. For instance, it is difficult to extrapolate on hazards or risks taken from data generated under different ecological, biological, and genetic contexts as regional growing environments, scales of farm fields, crop management practices, genetic background, interactions between cultivated crops, and surrounding biodiversity are all likely to affect the outcomes. Hence it cannot be expected that the same effects will apply between different environments and across continents.

Recommendation: The applicant should submit required information on the social utility of GHB614 and its contribution to sustainable development, in accordance with the Norwegian Gene Technology Act.

Conclusion

Available information for risk assessment evaluation

This evaluation is based on the Applicant's own submitted information, along with our own expertise in related fields. The relevant scientific literature is very limited in some cases, yet we have tried to extract information from the peer-reviewed literature that may inform the scientific validity of the information under consideration. In situations where lack of knowledge, complexity and uncertainty are high, particularly in relation to unknown adverse effects that may arise as a result of approval for release of a living modified organism into the environment or food supply, the available information may not be sufficient to warrant approval. Further information may address some of these issues, however an accurate description of uncertainties provided by the applicant would provide a more useful basis for assessing the level of risk that may come with regulatory approval of the GMO, taken on a case-by-case basis.

In all cases, product-related safety testing should have an independent and unbiased character. This goes both for the production of data for risk assessment, and for the evaluation of the data.

The lack of compelling or complete scientific information to support the claims of the Applicant documented here highlights the need for independent evaluation of the dossier as performed here, including the raw data produced by the Applicant. We therefore support better transparency and independent review of information to ensure high standards within the regulatory process. This would include any information provided by the Applicant used to justify confidentiality claims on any scientific data. We encourage the authorities to insist on this level of transparency and accessibility to all scientific data (including raw data) to ensure the scientific validity of the information presented.

Overall recommendation

Above we highlight a number of issues in relation to the questionable safe use of GHB614 that do not justify a conclusion of safe use, social utility and contribution to sustainable development. Critically, the Applicant's environmental monitoring plan lacks sufficient details and descriptions to support the required monitoring activities, and has not included any of the required information to assess social utility and sustainability as required in Appendix 4 of the Norwegian Gene Technology Act, which would be necessary for consideration of approval in Norway. Taken together, these deficiencies fail to address the necessary safety regulations under Norwegian Law, and thus the application is incomplete and should not be approved. A new application or reapplication should only be reconsidered with the delivery of the information requests recommended here, including any additional information deemed significant by the Norwegian authorities.

Therefore, in our assessment of GHB614 we conclude that based on the available data, the Applicant has not substantiated claims of safety satisfactorily to warrant approval in Norway at this time.

References

CBD (2003). Cartagena Protocol on Biosafety. http://www.cbd.int/biosafety/

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Codex (2003a) Codex Work on Foods Derived from Biotechnology. In CAC/GL 45-2003. Codex. http://www.who.int/foodsafety/biotech/codex_taskforce/en/.

Codex (2003b) Codex Alimentarius Commission, Alinorm 03/34: Joint FAO/WHO Food Standard Programme, Codex Alimentarius Commission, Twenty-Fifth Session, Rome, Italy, 30 June- 5 July, 2003. Appendix III, Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants, and Appendix IV, Annex on the assessment of possible allergenicity, pp. 47-60

Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Official Journal of the European Communities, L268, 1-23, Available from http://eur-lex.europa.eu/JOHtml.do?uri¼OJ:L:2003:268:som:en:html

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