Alþingi
Erindi nr. Þ 137/99
komudagur 8.6. 2009

Reykjavík, 8. júní 2009

Umhverfisnefnd Alþingis
Alþingi við Austurvöll
150 Reykjavík

Efni: Umsögn um frumvarp til laga um breytingu á lögum nr. 18/1996 um erfðabreyttar lífverur (þingskjal nr. 2, mál nr. 2 á 137. löggjafarþingi).

Kynningarátak um erfðabreyttar lífverur (en að því standa Landvernd, Matvæla- og veitingafélag Íslands, Náttúrulækningafélag Íslands, Neytendasamtökin og Vottunarstofan Tún ehf.) og ***Slow Food Reykjavík*** hafa fjallað um ofangreint mál.

Fyrir hönd þessara aðila er hér með lagt fram meðfylgjandi skjal með sameiginlegum athugasemdum þeirra um frumvarpið. Aðilar benda einkum á tvo alvarlega ágalla á frumvarpinu sem farið er fram á að lagfærðir verði við nánari vinnslu frumvarpsins.

Í fyrsta lagi að kveðið verði afdráttarlaust á um rétt almennings til upplýsinga og athugasemda um umsóknir um sleppingar erfðabreyttra lífvera, svo sem skýrt er kveðið á um í tilskipun Evrópusambandsins nr. 2001/18/EB. Á þetta einkum við um 7. gr. og 15. gr. frumvarpsins. Meinlegar villur í íslenskri þýðingu nefndrar tilskipunar kunna að skýra þennan ágalla á frumvarpinu.

Í öðru lagi að kveðið verði á um að fram fari mat á félagslegum og siðferðilegum álitaefnum varðandi umsóknir um sleppingar erfðabreyttra lífvera, svo sem markmið laganna gefa tilefni til. Á þetta við um 10. gr. frumvarpsins.

Virðingarfyllst,

Fyrir hönd Kynningarátaks um erfðabreyttar lífverur og Slow Food Reykjavík

TÚN

NÁTTÚRULÆKNINGAFÉLAG ÍSLANDS

Athugasemdir um
frumvarp til laga um breytingu á lögum nr. 18/1996 um erfðabreyttar lífverur
(Þskj. 2, 2. mál á 137. löggjafarþingi.)

Almennar athugasemdir um frumvarpið

Frumvarpinu er ætlað að leggja grunn að innleiðingu á tilskipun Evrópusambandsins nr. 2001/18/EB um sleppingu erfðabreytta lífvera, sem tekin var inn í samninginn um Evrópska efnahagssvæðið skv. ákvörðun sameiginlegu EES-nefndarinnar nr. 127/2007 þann 28. september 2007.

Samrýmist frumvarpið eigin markmiðum?
Frumvarpið tekur ekki að fullu mið af því markmiði laganna að framleiðsla og notkun erfðabreyttra lífvera fari fram á "samfélagslega ábyrgan hátt", þar sem ekki er tilskilið að mat fari fram á samfélagslegum álitamálum sleppingar eða markaðssetningar erfðabreyttra lífvera.

Uppfyllir frumvarpið ákvæði tilskipunarinnar?
Í athugasemdum með frumvarpinu er megintilgangur þess sagður að innleiða þurfi ákvæði tilskipunar nr. 2001/18/EB um aukinn rétt almennings til upplýsinga og aðkomu að ákvörðunum um sleppingar og markaðssetningu erfðabreyttra lífvera.

En þegar að er gáð uppfyllir frumvarpið ekki ákvæði tilskipunarinnar hvað varðar samráð við almenning um fyrirhugaðar sleppingar erfðabreyttra lífvera, og virðist sem það stafi af mistökum við þýðingu á 9. gr. tilskipunarinnar.

Tillögur og ábendingar um breytingar á einstökum ákvæðum

7. grein
Þessari grein er ætlað að bæta og skýra ákvæði um rétt almennings til upplýsinga og athugasemda. Í hana skortir þó tilfinnanlega afdráttarlaust ákvæði um rétt almennings til upplýsinga um umsóknir um sleppingar erfðabreyttra lífvera, sbr. og aths. við 15. gr. Hvergi er minnst á það í 7. grein frumvarpsins, heldur segir einungis (í boðaðri nýrri 9. gr.) að Umhverfisstofnun beri að upplýsa almenning "þegar erfðabreyttum lífverum er sleppt ..." sem mundi fela í sér að almenningur hefði ekkert um málið að segja fyrr en leyfi til sleppingar hafi verið veitt.

Ákvæði um þetta þarf að bæta inn í texta hins nýja kafla IV og virðist rökrétt að gera það með viðbót við nýja 8. gr.:

a. *(8.gr.)*

Umhverfisstofnun skal kynna fyrir almenningi útdrátt úr umsóknum um sleppingu eða dreifingu erfðabreyttra lífvera og úr umsókn um að setja erfðabreyttar lífverur eða vöru sem inniheldur erfðabreyttar lífverur ...

10. grein

Markmið laga um erfðabreyttar lífverur, með þeirri breytingu sem frumvarpið tiltekur, er m.a. að tryggja að framleiðsla og notkun erfðabreyttra lífvera fari fram á "siðferðilega og samfélagslega ábyrgan hátt í samræmi við varúðarregluna og grundvallarregluna um sjálfbæra þróun". Við mat á umsóknum þarf að taka mið af öllum þessum markmiðum, þar með töldu hinu samfélagslega, sbr. t.d. lagareglur Norðmanna sem áskilja sérstakt mat á samfélagslegum áhrifum sleppingar (sjá **Viðauka II** við umsögn þessa), svo og mat á siðferðilegum álitamálum hennar. Því er lögð til þessi breyting, til samræmis við markmið laganna:

2. mgr. 13. gr. laganna, sem verður 16. gr., orðast svo:

Umsókn skulu fylgja nauðsynlegar upplýsingar um eiginleika og einkenni hinnar erfðabreyttu lífveru, mat á umhverfishættu, fyrirhugaðar öryggisráðstafanir og mat á félagslegum og siðferðilegum álitaefnum ásamt öðrum gögnum sem ráðherra kveður á um í reglugerð.

15. gr.

Hér virðist stuðst við ranga íslenska þýðingu á frumtexta 9. gr. tilskipunar nr. 2001/18/EB, kafla B um sleppingu erfðabreyttra lífvera. Þar af leiðandi er samráð við almenning um sleppingu erfðabreyttra lífvera ekki gert að skilyrði, heldur er það einungis í formi heimildar til Umhverfisstofnunar. Því er lagt til eftirfarandi breyting, sem taki til beggja málsgreina 27. gr. laganna:

(1. og 2. mgr.) 27. gr. laganna, sem verður 31. gr., orðast svo:

Umhverfisráðherra getur kveðið nánar á um með reglugerð hvernig Umhverfisstofnun skuli haga samráði og leita umsagna áður en leyfi fyrir starfsemi samkvæmt þessum lögum er veitt.

Umhverfisstofnun skal hafa samráð við almenning og, eftir því sem við á, tiltekna hópa, um alla þætti hinnar fyrirhuguðu sleppingar eða markaðssetningar erfðabreyttra lífvera. Umhverfisstofnun er heimilt að mæla fyrir um að efnt skuli til opins áheyrnarfundar áður en endanleg ákvörðun um leyfisveitingu er tekin. Slíkur fundur skal auglýstur sérstaklega.

Hér að neðan í **Viðauka I** er enskur texti 9. gr. tilskipunar 2001/18/EB borinn saman við opinberu íslensku þýðingu, auk þess sem tillaga er gerð, að höfðu samráði við löggiltan skjalaþýðanda, um leiðréttingu á þýðingu þessari.

Viðauki I:
Skekkja í íslenskri þýðingu 9. gr. tilskipunar 2001/18/EB um samráð við almenning

Enskur texti tilskipunar nr. 2001/18/EB:

Article 9
Consultation of and information to the public
1. Member states shall, without prejudice to the provisions of Article 7 and 25, consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, Member states shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion.
2. Without prejudice to the provisions of Article 25:
   - Member states shall make available to the public information on all part B releases of GMOs in their territory:
   - The Commission shall make available to the public the information contained in the system of exchange of information pursuant to Article 11.

Opinber íslensk þýðing textans:

9. gr.
Samráð við almenning og miðlun upplýsinga til hans
1. Aðildarríkin skulu, með fyrirvara um ákvæði 7. og 25. gr., hafa samráð við almenning og hópa, eftir því sem við á, um fyrirhugaða sleppingu. Ef til þess kemur skulu aðildarríkin mæla fyrir um tilhögun þessa samráðs, þar á meðal um hæfilegan frest, til þess að gefa almenningi eða hópum tækifæri til þess að láta álit sitt í ljós.
2. Með fyrirvara um ákvæði 25. gr.:
   - skulu aðildarríkin upplýsa almenning um öll tilvik, sem heyra undir B-hluta, þar sem erfðabreyttum lífverum er sleppt á yfirráðasvæði ríkjanna,
   - skal framkvæmdastjórnin veita almenningi aðgang að þeim upplýsingum sem finnast í upplýsingaskiptakerfinu á grundvelli 11. gr.

Leiðrétt þýðing íslenska textans (sjá undirstrikanir):

9. gr.
Samráð við almenning og miðlun upplýsinga til hans
1. Aðildarríkin skulu, með fyrirvara um ákvæði 7. og 25. gr., hafa samráð við almenning og, eftir því sem við á, hópa um fyrirhugaða sleppingu. Við framkvæmd þess skulu aðildarríkin mæla fyrir um tilhögun þessa samráðs, þar á meðal um hæfilegan frest, til þess að gefa almenningi eða hópum tækifæri til þess að láta álit sitt í ljós.
2. Með fyrirvara um ákvæði 25. gr.:
   - skulu aðildarríkin upplýsa almenning um öll tilvik, sem heyra undir B-hluta, þar sem erfðabreyttum lífverum er sleppt á yfirráðasvæði ríkjanna,
   - skal framkvæmdastjórnin veita almenningi aðgang að þeim upplýsingum sem eru í upplýsingaskiptakerfinu á grundvelli 11. gr.

Viðauki II:
Norskar lagareglur varðandi mat á samfélagslegum og siðferðilegum álitamálum o.fl.

Neðangreindur texti er 4. viðauki í reglugerð norsku krúnunnar dags. 16.12.2005 um matsáhrif í samræmi við lög um erfðatækni, lýsir kröfum sem gerðar eru þar í landi til mats á mögulegum afleiðingum sleppingar og markaðssetningar erfðabreyttra.

Appendix 4
Evaluation of ethical considerations, sustainability and benefit to society, cf section 17 of the regulations

Introduction

This appendix explains what should be included in an account of other consequences of the production and use of genetically modified organisms pursuant to section 17 of the regulations. To the extent necessary, such an account should as far as possible include all the elements listed in the appendix. However, the appendix is not exhaustive, and not all the elements will be relevant in every case.

The purpose of the Gene Technology Act, as set out in its section 1, is to ensure that the production and use of genetically modified organisms and the production of cloned animals take place in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effects on human and animal health and the environment. Section 10, second paragraph, of the Act lays down that the deliberate release of genetically modified organisms may only be approved when there is no risk of adverse effects on human or animal health or the environment, and that considerable weight is to be given to whether the deliberate release of genetically modified organisms will be of benefit to society and is likely to promote sustainable development. The comments on the objects clause of the Act in Proposition No. 8 (1992 to 1993) to the Odelsting make it clear that the precautionary principle is to be used as a basis in evaluating potential adverse effects on human and animal health and the environment, and that ethical considerations must be given considerable weight when making decisions on applications for approval pursuant to the Act. The comments on section 10, second paragraph, make it clear that when applications for deliberate release pursuant to the Act are considered, any benefits to society and contributions to sustainable development are to be used both as independent criteria for the evaluation of applications and as criteria that may make result in less strict application of the requirement that the release of genetically modified organisms must not have adverse effects on health or the environment. An evaluation of benefits to society and contribution to sustainable development should be based on the principles of cost-benefit analysis.

I. Procedure for the evaluation

The evaluation should be organised as follows:

1. *Risk of adverse effects on human and animal health and the environment:*
   a) *what are the possible adverse effects?*
   b) *how probable are these effects?*
2. *Precautionary principle:*
   a) *is there justified uncertainty associated with the risk assessment?*
   b) *is there a possibility of substantial or irreversible harm?*
3. *Will the project*
   a) *tend to promote or hinder sustainable development?*
   b) *have favourable or unfavourable social consequences?*
   c) *be ethically justifiable?*

In assessing the questions in item 3, it can be useful to distinguish between the following three elements:

- *the characteristics of the product*
- *its production*
- *its use*

II. Risk of adverse effects on human and animal health and the environment

A. Checklist

- *Does the application provide sufficient documentation for evaluating possible adverse effects?*
- *Is it reasonable to assume that there will be a major or significant risk to health or the environment?*
- *Is it reasonable to assume that there will be major or significant adverse effects on health or the environment?*
- *Is it reasonable to assume that there will be major or significant adverse cumulative effects on health or the environment?*

B. Comments

If the answer to question 1 is no, the application shall be evaluated in relation to question 2 in part I above on the precautionary principle.

If the answer to one or more of questions 2-4 is yes, the application shall be refused. If the answer to all of questions 2-4 is no, the application shall be evaluated in relation to the precautionary principle.

III. The precautionary principle

A. Checklist

- *Is there a reasonable degree of doubt about existing risk assessments, and is there a danger that the risk may be higher than these assessments indicate?*
- *Is there a reasonable degree of doubt about existing probability assessments, and is there a danger that the probability of adverse effects is higher than these assessments indicate?*
- *Is there a reasonable degree of doubt about existing impact assessments and is there a danger of even more serious effects on health and the environment than these assessments indicate?*
- *Is there a reasonable degree of doubt about possible serious cumulative effects on health or the environment?*
- *Is there a reasonable degree of doubt as to whether proposed mitigating measures and instruments will function as intended?*

B. Comment

If the answer to one or more of these questions is yes, this indicates that the application can be refused with reference to the precautionary principle.

IV. Sustainable development

A. Checklist

1. Global impacts

- *Will there be global impacts on biodiversity?*
- *Will there be impacts on ecosystem functioning?*
- *Will there be differences between the impacts of production and use in these respects?*

2. Ecological limits

- *Will there be any impact on the efficiency of energy use?*
- *Will there be any impact on the efficiency of other natural resource use?*
- *Will there be any impact on the proportions of renewable and non-renewable resources used?*
- *Will there be any impact on emissions of global and transboundary pollutants?*
- *Will there be any particular impact on greenhouse gas emissions)*
- *Will there be differences between the impacts of production and use in these respects?*

3. Basic human needs

- *Will there be any impact on the degree to which basic human needs are met?*
- *Will there be differences between the impacts of production and use in these respects?*

4. Distribution between generations

- *Will there be any impact on the distribution of benefits between generations?*
- *Will there be any impact on the distribution of burdens between generations?*

- *Will there be differences between the impacts of production and use in these respects?*

5. Distribution between rich and poor countries

- *Will there be any impact on the distribution of benefits between rich and poor countries?*
- *Will there be any impact on the distribution of burdens between rich and poor countries?*
- *Will there be differences between the impacts of production and use in these respects?*

6. Economic growth

- *Will there be any impact on the use of energy and other natural resources for economic growth?*
- *Will there be any impact on the global/transnational environmental impacts of economic growth?*
- *Will the there be any impact on the distribution of economic growth between rich and poor countries?*
- *Will there be differences between the impacts of production and use in these respects?*

B. Comment

An evaluation of whether a project is in accordance with the principle of sustainable development must be based on an overall assessment and discussion of all these questions. However, not all the questions will be relevant in all cases.

V. Favourable or unfavourable social consequences

A. Checklist

1. Characteristics of the product

- *Is it reasonable to say that there is a demand or a need for the product?*
- *Is it reasonable to say that the product will solve or help to solve a social problem?*
- *Is it reasonable to say that the product is significantly better than similar products that are already on the market?*
- *Is it reasonable to say that there are alternatives that are more suitable than this product for solving or helping to solve the social problem in question?*

2. Production and use of the product

- *Will the product have a positive effect on industrial development and wealth creation, including new employment opportunities?*
- *Will the product have a positive effect on industrial development and wealth creation, including new employment opportunities, in rural areas in particular?*
- *Will the product have a positive effect on industrial development and wealth creation, including new employment opportunities, in other countries?*
- *Will the product tend to create problems for existing production that should be maintained?*
- *Will the product tend to create problems for existing production in other countries?*

B. Comment

An evaluation of whether a product is of benefit to society must be based on a discussion of the answers to all these questions. However, not all the questions will be relevant in all cases.

VI. Ethical considerations

A. General considerations

1. Analysis of the situation

- *What alternatives are there?*
- *Which parties are involved? How will they be disadvantaged by or benefit from the different alternatives?*

2. Ethical reasoning

- *Which norms are applicable?*
- *How can any conflict between these norms be resolved?*

3. Implementation

- *How can the best alternative be implemented in practice?*

B. Checklist

1. Ethical norms and values relating to people

- *Will approval or prohibition of the product and its production and use be in accordance with the moral views of the general population?*
- *Will the product or its production and use come into conflict with the ideals of solidarity and equality between people, such as the need to show special consideration for weaker groups?*

- *Decisions made by mainstream society can have a serious adverse impact on indigenous peoples, people who live in highly traditional cultures, and weaker groups. Special account should be taken of the need of these groups to be able to control their own processes of social change.*
- *Will the marketing and sales, in particular, of the product come into conflict with ethical norms and values relating to people?*

2. Eco-ethical considerations

- *Will the product and its production be in conflict with any intrinsic value assigned to animal species?*
- *Will the production of the product cause unnecessary suffering to animals?*
- *Will the production of the product involve crossing species barriers in ways that are materially different from those otherwise found in cultivation or in the wild, and that must be considered incompatible with the value assigned to the integrity of species.*

C. Comment

An evaluation of other ethical and social considerations must be based on a discussion of the answers to all these questions. However, not all the questions will be relevant in all cases.

Kynningarátak um erfðabreyttar lífverur & Slow Food Reykjavík
2009-06-03

Memorandum

2009-06-08

GM Pharma Crop Trials in the EU 2002-2009

THE OFFICIAL EU WEBSITE, www.gmoinfo.jcr.ec.europa.eu LISTS 623 NOTIFICATIONS OF GMO RELEASES BETWEEN 2002-2009.

FIELD TRIALS

ONLY 10 OF THOSE RELEASES ARE FOR GM PHARMACEUTICAL FIELD TRIALS (SEE ATTACHED LIST). OUT OF THE 10 TRIALS, ONLY FOUR ARE STILL ON GOING, Iceland (barley on one hectare), France, (tobacco on a hectare), Germany, (potatoe on small land plots), and Hungary, (barley on less than half a hectare).

COMMERCIAL GROWING

THE EU HAS NEVER, AND MOST LIKELY NEVER WILL, AUTHORISE A GM PHARMACEUTICAL CROP FOR COMMERCIAL GROWING IN THE EUROPEAN UNION.

ICELAND

Iceland cannot grant a license to ORF to grow GM Pharmaceutical barley outdoors on a commercial basis because Iceland is a member of the EU via the EEA, and no commercial licenses for GM medicine crops have been authorised by the EU for commercial growing.

Iceland may grant a license to ORF to grow GM Pharmaceutical barley outdoors on a field trial, but the Ministry for the Environment and UST are responsible to assure that the harvest from the field trial are not used for commercial purposes – in other words, at harvest, the seeds from which ORF process proteins must be collected and destroyed.

GM PHARMA CROP TRIALS IN EU FROM 2002-MAY 2009

EU Number	Trial Dates	Trial Size	Purpose
Germany B/DE/02/146	01/01/2003 31/12/2004	100 sq/m 2003 500 sq/m 2004	Potatoes as bioreactors for non plant spider silk proteins
Iceland B/IS/04/01	01/05/2003 30/09/2008	40sq/m up to 200.000 sq/m in 2006-2008	Field trials with marker gene in barley followed by 6 year research program (2003-2008)
Germany B/DE/04/160	01/04/2005 31/10/2005	2000 sq/m	Potatoes as bioreactors for non plant silk proteins
France B/FR/05/03/04	01/04/2005 31/10/2006	15,000sq/m	Maize expressing monoclonal anti bodies for medical uses in cancerology
Germany B/DE/05/176	01/05/2006 31/10/2008	832 sq/m 2006 2176 sq/m 2007 1584 sq/m 2008	Potatoes with pharmaceutical traits
France * B/FR/06/12/ 04-CON	01/04/2007 31/10/2009	10,000 sq/m	Field trial of GM wild tobacco producing a taxnae diterpenoid
Germany B/DE/06/182	01/05/2007 30/09/2007	1000 sq/m	Antibody (ScFv) production in feed pea
Hungary * B/HU/08/2	01/05/2008 01/05/2017	4000 sq/m max.	Investigation of human serum albumin (the main protein of blood plasma) producing spring barley line 'Malt-619-5001' modified by gene Technology in field tests
Germany * B/DE/08/199	01/04/2009 31/10/2012	485 sq/m 2009 547 sq/m 2010-2012 190 sq/m 2009-2012	Potatoes with pharmaceutical traits
Iceland * B/IS/09/01	01/05/2009 01/10/2013	200 sq/m in 2009 to 10,000 sq/m by 2013	In field production of transgneic barley, comparison of cultivars, processing and purification of non-food, non feed proteins

Access above by notification number on EU website, www.gmoinfo.jrc.ec.europa.eu
* these are on-going trials, (the rest have finished)