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Dear Madam,

Environmental Liability Directive – Consultation on the Draft Regulations and Guidance Implementing Directive 2004/35 in Environmental Liability with regard to the prevention and remedying environmental damage

Thank you for the opportunity to comment on the draft regulations and guidance.

This response is submitted on behalf of GM Freeze and covers our answers to the questions raised in the consultations, and general comments and specific GMO issues where we feel this appropriate. We are also signatories to the joint NGO response submitted under a separate cover and refer you to that also.

GM Freeze

GM Freeze is an alliance of 55 organisations from across the UK *calling for a moratorium on GM foods, the growing of GM crops for any purpose and on patents on genetic resources in agriculture, food production and forestry until the need for and safety of GM technology has been established and alternative approaches have been fully evaluated.*

Our members include consumer groups, farming organisations, environmental groups, development agencies, religious groups, animal welfare groups and food companies.

Summary

GM Freeze welcome the decision of the Welsh Assembly Government (WAG) to drop the permit defence for GMOs in the Environmental Damage (Prevention and Remediation) (Wales) 2008. We are pleased that the Welsh Assembly Government has also extended the scope to include SSSIs but we are also disappointed that the scope has not been extended to cover BAP species and habitats to ensure areas where GMOs are most likely to be grown are covered by the provisions of the Regulations. We also believe that Assembly Government should also drop the state of knowledge defence for GMOs to reflect that the fact that the long term impacts are poorly understood and not predictable.

General Comments

GM Freeze welcome the intention to implement Directive 2004/35 in Wales. The principles behind the Directive and the draft Regulations are sound in that, in theory, they implement the polluter pays principle and introduce liability for harming the environment. If drafted to achieve their maximum potential the Regulations the possibility of changing the attitude within

organisations about pollution and biodiversity destruction towards one much closer to the precautionary principle. However, the proposals on which WAG is currently consulting om misses opportunities to ensure that those carrying out potentially harmful activities will be more thorough in assessing the risk of those activities before they commence them. The draft Regulations for Wales could be stronger in respect of GMOs if they:

- Did not allow the state of knowledge defence.
- Extended the scope to Biodiversity Action Plan (BAP) species and habitats
- Extend remedies to 75 years instead of 30 years

It is over 50 years since organo-chlorine insecticides were first used on farmland and yet scientific papers are published every year adding to our knowledge of their environmental impact. Would the behaviour of the companies who first sold DDT , aldrin, dieldrin, endrin, pentachlorophenol , endosulphan and gamma BHC been any different if the current draft of the Regulations was in force? We conclude the current draft Regulations would have made the companies more cautious but may not have prevented dangerous releases taking place altogether. Limiting remedies to 30 years and allowing companies to fall back on state of knowledge defence may have provide sufficient confidence to proceed with releasing organo-chlorines.without carrying out the extensive studies on the food chain and biological activity of the compounds which hindsight clearly showed were needed.

Paragraph 1/13 of the draft Guidance states

An important point to note is that the Regulations are a 'backstop', only applying when something has 'gone wrong' and there is an imminent threat or actual 'environmental damage' within the scope of the Regulations.

If this is the WAG's intention then the short coming we have identified in the bullet points above strongly suggest that the Regulations need to be tightened in respect of GMOs and pesticides.

GM Freeze is concerned that the diffuse nature and multiplicity of potential GMO releases in the future will mean damage may not be picked up very early, especially as some of the impacts may be unexpected. Some impacts may arise from two or more GMOs cross pollinating and , again, this may take some time for problems to emerge. Also more than one company may also be involved and there may be a considerable time lapse between two releases which eventually combine to create an environmental problem It is clear to us that 30 years may not be sufficient time for problems to emerge. We urge The WAG to think again and extend this to 75 years

We are concerned that the limited scope of the proposed Regulation will mean that farmland, the area of Wales where the harmful impacts of GMOs are likely to be most likely to occur, will not be covered. Hence companies selling GMO seeds will not be liable.

The current proposals apply to Birds Directive species and the Habitats Directive plus SSSIs and Ramsar Site. We welcome the inclusion of the latter two following our own and other responses to the first consultation in 2006. However, very little arable land is designated SSSI in Wales. Many farmland species are threatened largely by intensive farming including birds, mammals, insects and plants. The species list included to be covered by Special Protection Areas under the Birds Directive includes only two bird species which have been affected by intensive farming, the Lapwing and the Bean Goose. The Red List of farmland bird species contains 11 species – Reed Bunting, Grey Partridge, Quail, Skylark, Tree Sparrow Yellowhammer, Corncrake, Stone Curlew, Turtle Dove, Linnet and Corn Bunting. Kestrel, Lapwing, Stock Dove and Barn Owl are on the Amber list.

Several arable weeds would also not be covered by the present proposal despite the fact that many are endangered in Wales, for example Red Hemp Nettle, Cornflower and Shepherd's Needle¹ and BAP species.

Within the life span of the proposed legislation there is a possibility the GM fish may be released into the environment on a commercial scale. Once again there are examples of how exotic fish have had a deleterious effect on native species, for example the zander. There are several BAP fish species, for example Allis Shad, Twaite Shad, European Eel, Gywniad, River and Sea Lampreys, Smelt, Atlantic Salmon, Brown trout, Sea Trout and Arctic Charr, as well as freshwater invertebrates which could be impacted upon by a GM fish escaping from fish farms. This prospect underlines the importance of extending the scope of the regulations to BAP species because GM fish would be mobile and have the potential to contaminate any water body.

The Regulations may also have to cover the release of GM trees. This makes it all the more important that the limit on remedies should be extended to at least 75 years to allow for the longevity of tree species – many species would be only half grown at 30 years including those already subject to genetic engineering such as birch, poplar and pine.

Specific Questions in the Consultations

Question 1: do you have any comments on the definitions, in particular the definition of 'activity' to which the regulations apply (regulation 2)?

GM Freeze is concerned that the definition of 'activity' for GMOs need to be made clearer because at present it would be farmers who carry out the activity of releasing a GMOs and therefore would be liable for environmental damage. We believe that it should be made clear in the regulation that the operator in the case of GMOs is the biotechnology company(ies) who hold marketing consents and that the 'activity' is placing GM seeds on the market. If biotech companies felt that harm caused by a GMO was the fault of the farmers who had been sold the seeds that would be a matter between them and the farmers but liability should always lie with the company(ies).

Question 2: do you agree that the Regulations should apply to all species and habitats within a SSSI for which that SSSI has been notified as well as to EU listed species and habitats (regulation 4)?

GM Freeze strongly supports the inclusion of SSSIs and Ramsar sites. Please see our above comment relating to BAP species and habitats relating in relation to the release of GMOs into the environment.

Question 3: do you agree that the test of damage within SSSIs should be based on site integrity (Schedule 1)?

GM Freeze support the test for damage being based on the integrity of the site. However, greater clarity is needed in the guidance as to what constitutes damage caused by a GMO bearing in mind that the history of the introduction of exotic plants becoming invasive (and hence pests of protected areas) is highly unpredictable. There have been a considerable time lapses between: the introduction of plant species: its escape from managed areas into unmanaged areas; and it becoming an invasive weed of unmanaged areas, Japanese knotweed being a very good example and one which is major problems in Wales.

¹ <http://www.plantlife.org.uk/uk/plantlife-wales-back-from-the-brink.html>

Question 4: do you agree that any damage which would be consistent with a drop in WFD status class should be classified as damage for the purposes of ELD (regulation 4)?

Please see the joint NGO response for our comments on this question.

Question 5: do you agree that the definition of water should be limited to water bodies as identified for the purposes of WFD (regulation 4)?

GM Freeze believe that all water bodies should be covered by the Regulations. Recent research has shown a possible link between the cultivation and GM Bt crops and the health of aquatic invertebrates¹ in the headwaters of river systems. Small waters courses, such as these, are an integral part of freshwater ecosystems and the impact any damage to them may be felt downstream , for instance fish spawning may be affected.

Question 6: do you agree with the proposed approach to the threshold for land damage (regulation 4)?

No comments.

Question 7: do you agree with the proposed approach for deciding remediation for land damage? (Schedule 4)?

No comments.

Question 8: do you agree with the proposed approach to the overlap with other legislation (regulation 6)? If you prefer an alternative approach please give details of how you think it should work and why you favour it.

No comments.

Question 9: do you agree with the proposed approach to damage caused by emissions which are ongoing at the date of coming into force of the Regulations?

GM Freeze believe that the regulations should apply from the date the Directive 35/2004 came into force – 30th April 2007 – and agree with the comments in the wider NGO submission regarding the legality of adopting the date the Regulations should come into force.

Question 10: do you have any comments on the meaning of the term 'natural disaster' particularly in the context of flooding (regulation 7)?

GM Freeze does not support the time limit of 30 years (Regulation 7.4) which we regard as inadequate to deal with the release of GMOs into the environment because harm arising from such releases may take longer than this period to occur. The invasiveness of several exotic plants took far longer than 30 years to become an established fact and GM Freeze support 75 years being applied to GMOs. This is the period proposed by the Scottish Government.

Question 11: do you agree that commercial sea fishing activities which are in accordance with the CFP should be excluded from the scope of the Regulations?

No comment

Question 12: do you agree with the proposed division of responsibilities between competent authorities (regulations 9 and 10)?

GM Freeze is satisfied that the Environment Agency and the Countryside Council for Wales (CCW) are the appropriate agencies to be the competent authorities (CA) although in the case of GMOs neither issues the marketing or release consents and therefore in-house expertise may be lacking. We believe in the case of GMOs it makes sense for the CA to be CCW. It will be very important that the capacity and expertise within CCW is sufficient to deal with the widespread cultivation of GMOs especially if the scope of the Regulations is extended to BAP species and habitats. There is provision for post market monitoring of GMOS in Directive 2001/18 and Regulation 1829/2003 but the effectiveness of this system has yet to be tested. There is no incentive for biotechnology companies to monitor for unpredictable outcomes of GMO releases. Would they have checked for GM oilseed rape crossing with charlock if their risk assessment said it did not happen under natural conditions? In fact during the Farm Scale Evaluations, government funded monitoring did find such as "impossible cross". It is clear to GM Freeze, that independent monitoring will be needed to provide a back stop if industry funded monitoring does prove to be ineffective. Logically this should be carried out and designed by the Competent Authority.

Question 13: do you think the Regulations should contain special provisions about handling emergencies and if so, what should they be?

No comment.

Question 14 (Wales only): do you agree with extending liability to GMO permit holders (i.e. the GMO producers) as well as operators (such a farmers) who purchase GMOs from them (regulation 13 of the Welsh regulations)?

GM Freeze warmly welcomes the WAG proposals to extend liability to permit (consent) holders as well as operators. This is not only sensible but also fair. Farmers are entirely reliant on the word of biotechnology companies regarding the safety of GM crops and are not in any position to monitor for unpredictable outcomes of their release or the collective impact of several GMOs being released over time.

To ensure that liability is fully covered for the release of GMOs, GM Freeze strongly support the extension of liability to consent holder under EU Regulation 1829/2003 and the Contained Use Regulations (under Directive 90/218) in Wales.

Question 15: do you agree with the way in which the 'defences' in the Directive have been applied (regulation 14 in England, regulation 15 in Wales)?

GM Freeze strongly opposes the state of knowledge defences (Regulations 14/15) and supports the view in the NGO submission "are contrary to the provisions of the ELD itself, and will constitute a breach of the ELD"

In the case of GMOs, we do not believe the scientific basis for approvals is strong enough to justify the adoption of either permit or state of knowledge defence, even if compatible with ELD. Our submission to the first consultation sets out examples of why we feel the state of scientific knowledge is insufficient to be able to predict the impact of GMOs on the environment, eg the longevity of oilseed rape seed in the soil is being found to be much longer than first thought.

Question 16: do you agree with the proposed procedures for assessment and identification of remedial measures, and for the service

of remediation notices (regulation 15 in England, regulation 16 in Wales)?

See NGO response comments.

Question 17: do you agree with the proposed appeal procedures (regulations 14 and 16 in England, regulations 15 and 17 in Wales)?

See NGO response comments.

Question 18: should appeal procedures be specified or left at the discretion of the appointed person?

No comment.

Question 19: should remediation notices be suspended pending appeal?

GM Freeze strongly opposes proposals which would allow remediation notices to be suspended pending an appeal because it may lead to worse damage arising which would cost more to rectify in the future or to become far less easy to repair.

Question 20: do you agree with the provisions dealing with requests for action (regulation 18 in England, regulation 20 in Wales)?

GM Freeze believes that this clause should be amended to bring it into line with the ELD (Art. 12.1) which gives rights to NGOs to submit observation on damage and demand action of the competent authority and to be given a reasoned response by the CA (12.4). This is particularly true of harm caused by GMOs where harm may occur in several locations around the country and may well be detected by NGOs.

Question 21: do you think 'sufficient interest' should be further defined and if so how?

See NGO response.

Question 22: do you think an NGO should be defined for these purposes and if so how?

See NGO response.

Question 23: do you agree that judicial review is an appropriate route for challenging decisions by enforcing authorities?

See NGO response.

Question 24: do you agree with the proposed power for the enforcing authority to take action (regulation 19 in England, regulation 21 in Wales)?

Yes.

Question 25: do you agree with proposed powers of entry (regulation 22 in England, regulation 24 in Wales)?

Yes.

Question 26: do you agree that there should be a charging provision in the Regulations (regulation 24 in England, regulation 26 in Wales)?

Yes.

Question 27: do you have any comments on Schedule 1?

See NGO response

Question 28: do you have any comments on Schedule 2?

Regulation 1829/2005 of genetically modified food and feed should be included in Schedule 2 because most GMO marketing consent will be granted under this Regulation rather than under Director 2001/18. Including 1829/2003 would rule out any possibility of any misunderstanding.

Question 29: do you have any comments on the authorisations listed in Schedule 3? In particular, are there any other authorisations to which the permit defence ought to apply in your view?

GM Freeze opposes the use of the permit defence for GMOs. The stage of development of GMOs means that it is impossible to predict how they will behave in the environment with any degree of certainty. They are also self replicating and can sexually reproduce with other species to produce novel hybrids. They can also be released over huge areas making them difficult to control should they become a threat to the environment. In this context, the use of the permit defence and state of knowledge defence is entirely inappropriate and risky. We strongly support the proposals from the Welsh Assembly Government to drop the permit defence.

We would fully endorse the comments made in the NGO response to also drop this defence for pesticides and biocides for similar reasons. Pesticides and their breakdown products have the capacity move between ecosystems and to be biological active at very low concentrations. Endocrine disruption is an area where our knowledge of the action of pesticides at very low concentrations is still insufficient to predict the outcomes. Pesticides are widely used throughout the environment. It would be wise, therefore, not to permit the permit defence or state of knowledge defence for pesticide and biocides as well as GMOs.

Question 30: do you have any comments on Schedule 4?

See NGO response

Question 31: do you have any comments on, or additional evidence for, the Impact Assessment?

GM Freeze believes that the WAG is risking failing to achieve both of the underlying objectives of the Directive – the Polluter Pays and Precautionary Principle. We believe that the WAG should go further in making GMOs a special case by taking further steps such as extending the scope the Regulations to cover BAP species so as to cover the areas of Wales where GMOs are likely to be grown and hence biotech companies will not be liable for any damage they may cause.

Question 32: do you have any comments on the guidance that are not already reflected in your answers to earlier questions?

None.

Conclusion

GM Freeze congratulates the WAG on dropping the permit defence for GMOs and extending the scope of The Environmental Damage Regulations to cover SSSIs and Ramsar sites . However, GM Freeze is disappointed that the draft Regulations has missed a major opportunity to make biotechnology companies liable for the GMOs they place on the market. We urge WAG to reconsider this draft and make the following changes:

- Drop the state of knowledge defence for GMOs and pesticides/biocides.
- Extend the scope of the Regulations to BAP species and habitats to ensure that land where GMOs are most likely to be grown are covered for Environmental liability.
- Extend the period of remedy for GMOs to 75 years to reflect the possible time scale before environmental problems with GMOs emerge.

Yours faithfully



Pete Riley
Campaign Director
On behalf of GM Freeze

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1. ¹ Rosi-Marshall EJ, Tank JL, Royer TV, Whiles MR, Evans-White M, Chamgers C, Griffiths NA, Pokelsek J and Stephen ML. Toxins in transgenic crop byproducts may affect headwater stream ecosystems. *PNAS* 2007, 104, 16204-8.