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GM FREEZE
the campaign on
GM food, crops and patents

3 March 2014

RE: Docket ID: APHIS-2013-0042 - Dow AgroSciences LLC; Environmental Impact Statement for Determination of Nonregulated Status of Herbicide (2,4-D) Resistant Corn and Soybeans

GM Freeze, a membership-based not-for-profit public campaign in the UK sceptical of GM food, crops and animals and the patenting of genetic material for agriculture, wishes to submit the following comments to the above consultation.

We object in the strongest possible terms to the proposed deregulation and commercialisation of 2,4-D resistant soya and maize (corn). We note this is the USDA's "Preferred Alternative".

Our objection is rooted in three areas hinging on an objection to the unscientific nature of the US regulatory doctrines of "substantial equivalence".

Material differences

These crops are clearly different from their conventional counterparts. For example when the FDA assessed the AAD-1 protein expressed by maize in question "as safe as conventional corn varieties…and not materially different" from other maize, it also reported statistically significant differences in amino and fatty acids, vitamins and minerals, including:

- Alanine
- Cysteine
- Glutamic acid
- Methionine, phenylalanine
- Oleic acid
- Vitamin B1
- Vitamin C
- Niacin
- Magnesium
- Manganese
- Phosphorus
- Zinc[1]

Brazilian researchers have also found significant differences in the molecular composition of GM crops compared to conventional varieties. Agapito-Tenfen found 32 differences in proteins involving molecular functions attributed to energy metabolism, metabolism of plant response, metabolism of genetic information processing, and metabolism of stress. The study also found that these differences were highly dependent on environmental conditions so were difficult to predict.[2]

Such differences have not been studied in the determination of their safety, nor has the identification of these differences triggered investigation into other unexpected differences caused by the GM event. This is not scientific, so is not a sound determination of safety, and the crops should not enter the food chain or wider environment until such study genuinely determines safety.

Differences in performance

We note with considerable interest the findings of the recent study by Heinemann showing that Western European non-GM agriculture outperforms North American GM production in terms of both higher yield and lower chemical use.[3] Heinemann himself said of the study:

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> "We analysed yield data in corn/maize, rape/canola and wheat, crops that are grown in both regions at large scales. Our findings were consistent for all three crops. Over the 50-year period we found that the 'biotechnology package' (which includes options in germplasm improvement and management approaches) that comes from the Western European innovation strategies in agriculture result in higher yields than those achieved in North America. The robust trends indicate that this will continue. Yield improvement was not due to higher pesticide use because countries such as France have used comparatively less of both herbicides and insecticides per area under production than countries such as the US.
>
> "An obvious difference between the two regions is that the North American innovation strategy was compatible with a switch from conventional to genetically modified (GM) crops adopted in the mid 1990s. Western Europe has and continues to raise yields and reduce the use of pesticides without GM."[4]

The Agapito-Tenfen study also found that conventional maize is more stable, or has less variability, than GM varieties in different environments.[5]

The differences in performance are another demonstration of the failure of substantial equivalence to fully describe the nature of these crops.

Differences in impact

We note the USDA states, "The primary purpose of Enlist™ corn and soybean varieties is to help growers manage GR weeds."[6] We also note the USDA states:

> "Based on the existing trend of increased used of 2,4-D over the last decade (ie, without these 2,4-D resistant crops), APHIS projects that 2,4-D use will increase by nearly 75% by 2020 under the No Action Alternative. If EPA registers Enlist Duo™ herbicide for Enlist™ corn and soybean and APHIS adopts the Preferred Alternative, APHIS expects that 2,4-D use will further increase by ***another*** two fold to six fold (depending on the assumptions made) relative to current use."[7]

Taken together these are an astonishing admission that previously deregulated GM crops have not only failed to perform as expected, but that they have caused such serious agronomic difficulties that the USDA now feels compelled to take the dramatic action of knowingly increasing the toxic load on our bodies and habitats despite the clear evidence that this approach is ultimately futile (as the development of further, spreading weed resistance is effectively assumed by USDA throughout the EIS[8]). Coupled with the ongoing failure to properly assess known compositional differences in GM crops (which clearly demonstrates that we know GM itself is causing something fundamental to happen in the crops but we don't fully understand what, how much, how severe, where or its implications, again rendering substantial equivalence seriously problematic as a concept) this response based on escalating reliance on GM technology for such large swathes of food production and economic activity is seriously flawed.

The lessons of this approach are wearing through now, as weeds and pests resistant to alleged GM "fixes" are now serious problems for US farmers. US farmers simply would not be facing the astonishing superweed and superpest problems they now grapple with, or any of the economic penalties they bring, if GM was not there. The USDA itself says:

> "Because of the likely adverse socioeconomic impacts that would result in the event that 2,4-D resistant weeds would be selected from the expected increased 2,4-D use on Enlist™ crops, APHIS believed these impacts may be significant."[9]

The rise and ongoing spread of superweeds are sufficient plant pests for USDA to reject these crops outright. Further exacerbating the problem cannot be justified as a "Preferred Alternative".

We also object because Europeans will be directly affected by these problems, including because

Europe imports a good deal of GM material, particularly for animal feed, which we also oppose.

The insufficiently-studied impacts of the expected rise in chemical residues on human and veterinary health pose an additional unwelcome risks of our farming and public health. 2,4-D is a Highly Hazardous Pesticide, subject to calls from UN agencies for a progressive ban.[10] 2,4-D carries well-known serious health impacts ranging from "serious eye and skin irritation" to "long-lasting or even permanent symptoms" to "significant chromosomal damage occur[ing] in human cells cultured in the presence of 2,4-D".[11] 2,4-D also causes mutations in chromosomes of other creatures, including for example freshwater snails,[12] as well as in human lymphocytes.[13] It causes birth defects in animals[14] and humans, including those demonstrated by a human epidemiological study conducted in areas of the US where 2,4-D is extensively used on wheat: "[I]nfants conceived during April-June – the time of herbicide application – had an increased chance of being diagnosed with circulatory/respiratory (excluding heart) malformations compared with births conceived during other months of the year."[15] 2,4-D is an endocrine disruptor, and it has impacts on the thyroid gland,[16] production of the leutinising hormone from the pituitary gland[17] and oestrogenic activity.[18] Recent research concluded 2,4-D was associated with changes in biomarkers that, "[B]ased on the published literature, have been linked to risk factors for acute myocardial infarction [heart attack] and type-2 diabetes."[19]

This is not a complete list of health concerns, but it more than enough to raise serious alarm bells about the substantial equivalence of crops designed to withstand this chemical and to halt increased intake of residues until safety is demonstrated.

Conclusion

The predication of this consultation on substantial equivalence and related doctrines renders the entire exercise problematic.

Science has moved on since the theory of "substantial equivalence" was developed. Regulators need to recognise this, and politicians need to heed to wishes of their citizens, not the companies with a clear vested interest in continuing to apply an outdated theory that poses considerable risks. The 200+ page Environmental Impact Statement prepared by the USDA is in itself a litany of the impacts these crops will bring on people, their livelihoods, habitats and animals.

While these differences may not have been known or detectable in the early years of GM uptake, surely the USDA cannot persist in applying a doctrine of "substantial equivalence" that is so clearly seen to be incorrect now.

Globally there has been insufficient study of these differences or their impacts on human and veterinary health or the environment, partly because private companies control the genetic material involved and access to it. These crops cannot be commercialised until the long-term low-level interactions and risks are identified, studied and understood.

Notes

[1] USDA Animal and Plant Health Inspection Service, October 2011. *Dow AgroSciences petition (09-233-01p) for determination of nonregulated status of herbicide-tolerant DAS-40278-9 Corn, Zea mays, Event DAS-40278-9: Draft Environmental Assessment* at Appendix A-2, Appendix A-3 and 3

[2] Agapito-Tenfen S, et al, 4 December 2013. "Comparative proteomic analysis of genetically modified maize grown under different agroecosystems conditions in Brazil". *Proteome Science 2013*, 11:46. doi:10.1186/1477-5956-11-46

[3] Heinemann J et al, 14 June 2013. "Sustainability and innovation in staple crop production in the US Midwest". *International Journal of Agricultural Sustainability* DOI: 10.1080/14735903.2013.806408

[4] Heinemann J, undated. "Author response to GMO Pundit David Tribe". University of Canterbury, available at www.inbi.canterbury.ac.nz/response.shtml

[5] Agapito-Tenfen *op cit*

[6] USDA Animal and Plant Health Inspection Service, January 2014. "Dow AgroSciences Petitions (09-233-01p, 09-349-01p, and 11-234-01p) for Determinations of Nonregulated Status for 2,4-D-Resistant Corn and

Soybean Varieties; Draft Environmental Impact Statement—2013" at iii

[7] USDA 2014 *op cit* at ix

[8] *Ibid* at vi ("APHIS has identified the possible selection of HR weeds resulting from the change in management practices associated with the adoption of Enlist™ corn and soybean as a potentially significant environmental impact. This impact is a cumulative impact because it would only result from the combined action of USDA on the subject petitions and of the EPA's action to register 2,4-D for use on Enlist™ corn and soybean."; ix ("The change in management practices expected under the Preferred Alternative is expected to increase the pressure for selection of 2,4-D resistant weeds."); x (" While the selection pressure for 2,4-D resistant weeds is expected to be greater under the Preferred Alternative, the selection pressure for GR weeds is expected to be greater under the No Action Alternative."); xi ("However, the eventual occurrence of weeds resistant to glyphosate, 2,4-D and glufosinate will over time limit the use of Enlist™ crops and any benefit to natural resources that may arise."); etc

[9] *Ibid* at vi

[10] Pesticide Action Network International. "PAN International List of Highly Hazardous Pesticides (PAN List of HHP)." January 2011

[11] Pesticide Action Network UK. "2,4-D fact sheet." Available at www.pan-uk.org/pestnews/Actives/24d.htm

[12] Estevam EC, et al, 2006. "Dominant lethal effects of 2,4-D in Biomphalaria glabrata". *Mutation Research* 611: 83-88

[13] Zeljezic, D and Garaj-Vrhovac V, 2004. "Chromosomal aberrations, micronuclei and nuclear buds induced in human lymphocytes by 2,4-dichlorophenoxyacetic acid pesticide formulation". *Toxicology* 200: 39-47

[14] Collins TFX and Williams CH, 1971. "Teratogenic studies with 2,4,5-T and 2,4-D in the hamster". *Bulletin of Environmental Contamination and Toxicology* 6:559-567

[15] Schreinemachers DM, 2003. "Birth malformations and other adverse perinatal outcomes in four US Wheat-producing states". *Environmental Health Perspectives* 111:1259-64

[16] Florsheim WH and Velcoff SM, 1962. **"**Some Effects of 2,4-Dichlorophenoxyacetic Acid on Thyroid Function in the Rat: Effects on Iodine Accumulation". *Endocrinology* 71, 1-16
and
Florsheim WH, Velcoff SM and William AD, 1960. "Some Effects of 2,4Dichlorophenoxyacetic Acid on Thyroid Function in the Rat: Effects on Peripheral Thyroxine". *Endocrinology* 72:327-333

[17] Garry VF et al, 2001. *Environmental Health Perspectives*, 109: 495-500

[18] Meulenberg EP, 2002. "A new test to identify endocrine disruptors using sex hormone-binding globulins from human serum". *European Journal of Lipid Science and Technology* 109:131-136

[19] Schreinemachers DM, 2010. "Perturbation of lipids and glucose metabolism associated with previous 2,4-D exposure: A cross-sectional study of NHANES III data,1988-1994". *Environmental Health* 9

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