Independent Science Panel

Re: Docket No. 2004D-0369

Dear Commissioner Crawford,

I am writing on behalf of the Independent Science Panel (ISP) to urge you to withdraw the proposals contained in FDA's draft "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use". We are especially concerned at FDA's apparent intention, as detailed in a recent speech you gave, that this Guidance will provide " *an international model to address the presence of low levels of bioengineered plant material in non-bioengineered crop fields* ."

The ISP, launched 10 May 2003 at a public conference in London, UK, consists of dozens of prominent scientists from 11 countries spanning the disciplines of agroecology, agronomy, biomathematics, botany, chemical medicine, ecology, epidemiology, histopathology, microbial ecology, molecular genetics, nutritional biochemistry, physiology, toxicology and virology (http://www.indsp.org/ISPMembers.php)

. As their contribution to the global GM debate, the ISP reviewed the evidence on the hazards and problems of GM crops as well as the proven successes of sustainable agriculture, and published its report in June 2003 [1].

The key findings of the ISP report are as follows:

- Regulations over the releases of GM crops and products have been highly inadequate.
- Few feeding studies have been carried out, but they raised serious doubts over the safety of the transgenic process itself, which have yet to be followed up by dedicated research.
- GM varieties are unstable; and this may enhance the horizontal spread of transgenes, with the potential to create new viruses and bacteria that cause diseases, and to disrupt gene function in animal and human cells.
- Many GM crops contain gene products known to be harmful. For example, the Bt proteins that kill insect pests include potent immunogens and allergens, and food crops are increasingly engineered to produce pharmaceuticals, drugs, and vaccines in the open environment, exposing people to the danger of inappropriate medication and their toxic side effects.
- Herbicide tolerant GM crops - accounting for 75% of all GM crops worldwide - are tied to the broad-spectrum herbicides glyphosate and glufosinate ammonium, and will likely increase their use. Both herbicides are systemic metabolic poisons linked to spontaneous abortions, birth defects and other toxicities for human beings and laboratory animals, and also harmful to wild life and beneficial organisms in the soil.
- GM crops have resulted in no benefits to the environment. There has been no reduction in the use of pesticides, while herbicide tolerant weeds and volunteers have emerged, and highly toxic herbicides have had to be brought back in use.

Since its publication, all the major findings of the ISP report have been further corroborated; and the inadequacies of the US regulatory system identified by two US scientists [2].

New evidence confirms that most, if not all GM varieties may be unstable. French government scientists examined five GM varieties already commercialised, and found *all* the GM inserts had rearranged themselves. Belgian government scientists confirmed those results, and found some of the GM varieties were also non-uniform [3-5].

A paper published in 2002 [6] reported that 22 out of 33 transgenic proteins have runs of 6 or 7 amino acids identical to known allergens. These include all the Bt toxins (Cry proteins), the CP4 EPSPS and GOX conferring glyphosate tolerance, the coat protein of the papaya ringspot virus, and even marker proteins such as GUS (β-glucuronidase). A follow-up study confirmed those results [7], highlighting the inadequacy of current methods to predict the allergenic potential of proteins new to our food chain and the need to take these positive findings seriously until they can be ruled out by further tests to be "false positives" [8]. This warning is particularly significant as a string of anecdotal evidence – including feeding trials presented by companies to regulatory authorities under "confidential business information" – continue to raise serious doubts over the safety of GM crops and GM food and feed [9].

More reports from the scientific literature indicate that the natural toxin is not the same as, or "substantially equivalent" to, the GM toxin. Green lacewings suffer significantly reduced survival and delayed development when fed an insect pest (lepidopteran) that has eaten GM maize containing the Bt toxin Cry1Ab, but not when fed the same pest treated with much higher levels of the natural toxin in bacteria [10,11]. These findings again suggest that the genetic modification process itself may be unsafe.

Finally, a new report drawing on 9 years of US Dept of Agriculture data concludes that overall, GM crops have *increased* pesticide use by 122 million pounds weight since 1996 [12].

In view of all these known problems and uncertainties over the safety of GMOs, it would be irresponsible for the FDA to yet further relax regulation, which will almost certainly result in widespread transgene contamination.

In our view, the new FDA policy sets out loose "food safety evaluation" guidelines under which a company may voluntarily consult with the FDA to have new proteins from experimental GM crops intended for food use deemed "acceptable" as a food contaminant. The early "food safety evaluation" suggested consists largely of paperwork. The proposed scientific evaluation is highly inadequate, as it fails to specify the tests to be conducted, and does not include animal feeding trials or tests for unintended effects caused by genetic modification. In the absence of a specific and mandatory test protocol, companies will fail to prove safety beyond reasonable doubt; but the FDA's new policy will nevertheless give biotech companies the legal cover for their experimental GM crops to enter the US food supply.

These US proposals to effectively legalize contamination from GM experimental crops are a clear breach of the Precautionary Principle enshrined in the Cartagena Protocol on Biosafety, the only international law regulating genetic engineering; they are ignoring the threat of serious irreversible damage to human health from unknown and untested GM material.

Once released into the environment, people will be eating these foods for generations, so there is a need for safety assessments to be long term, intergenerational and on the whole food, not on just the new substance that the GM organism is designed to produce.

It is already virtually impossible to test for the presence of experimental GM food crops in foods imported from or processed in the US, because over two-thirds of US field trials of experimental GM crops involve one or more genes classified as confidential which therefore cannot be detected.

Not only should the FDA withdraw the policy changes proposed in its Draft Guidance for Industry, it should be devising strict rules and procedures to prevent contamination of the food supply with experimental transgenic proteins and to replace its current non-rigorous "voluntary consultation" process with a mandatory, science-based review process designed to guarantee that the GM crops are safe for food and feed.

Yours sincerely,

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