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New Attack on GM Food Safety Testing Standards

Bio-industrial Pollution of the Food Chain

A fundamental principle of food safety testing is under fire. The pressure comes from GM plant developers that are bypassing a key safety test, despite the novelty of the products.

Traditional food plants that have been genetically modified to make industrial and pharmaceutical products, or animal feed, can very easily contaminate the food supply. Developers are trying to get them approved as a legal food to avoid trade disruptions.

The baseline for assessing the safety of a GM food has always been to compare its genomic changes and composition with its closest non-GM relative, usually the parental variety from which the GM crop was made. This non-GM 'comparator'[1] is the standard baseline because it has a long history of safe use as a food for people.

An audacious bid is now being made to abandon this baseline by having a GM crop assessed for safety by comparing it to another GM variety that has no history of safe use. Regulators that ignore the normal requirement risk exposing themselves to litigation by developers of future GM crops should they try to re-assert the proper standard again later.

The test case is an application by Monsanto for a GM corn called LY038, designed as an animal feed. This and hybrid varieties are being assessed by food regulators worldwide, including the EU, Australia, New Zealand, Malaysia and Japan. Applications for a range of other GM bio-industrial crops can be expected to follow.

LY038 is unlike GM corn varieties commercialised to date. It would be the first GM food overtly designed to be substantially different in its nutritional profile. Its novelty should be driving adherence to the highest standard of review. Instead, the developer has provided regulators with safety studies comparing LY038 to another variety labeled LY038(-), a sibling of the modified corn line that is also a GM variety, and which has no history of safe use.

International guidelines for food safety testing have been laid down by a joint WHO/FAO body - the Codex Alimentarius Commission. The Codex test protocol for biotech foods[2] specifies that testing be carried out by comparing characteristics of the new GM food with a "conventional counterpart".[3] The 2003 guideline further notes that "for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts". If GM varieties are accepted as comparators for safety assessments, then the fundamental rationale of the testing protocol is undercut, because there is a lack of evidence of the safety of the comparator that is being used to

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[1] The comparator is the non-GM relative used in all tests, including compositional studies from side-by-side field-grown samples and all molecular descriptions of insert number and structure.

[2] Codex Alimentarius Commission, standards CAC/GL 44-2003 and CAC/GL 45-2003 found at: www.codexalimentarius.net/web/publications.jsp?lang=en . Accessed 1 October 2006.

[3] Defined in the guideline as one "for which there is experience of establishing a safety based on common use as food" (p 8).

validate the product.[4]

In particular, if LY038 sets a precedent that a GM comparator is acceptable, then regulators may lose the ability to challenge future GM crops that use the same type of comparator.

There are compelling reasons to believe that LY038 could produce a unique spectrum of food hazards because LY038 has extremely high concentrations of the free amino acid lysine and its derivatives. When cooked, these substances form chemicals that are strongly implicated in causing certain diseases or their symptoms, including diabetes, Alzheimer's and cancer. Monsanto is applying for approval on the assertion that only very small proportions of the new corn will mix with human food. However, even small quantities of such substances pose food safety risks. Moreover, once approval is given, regulators lose the ability to hold Monsanto to any upper limit on the proportion of the corn that can legally enter the human food supply.

The product was never intended to be a human food. Permission is being sought for it to enter the human food supply in order to minimise legal and regulatory risks for the developer and users of the GM corn. Such risks were clearly demonstrated by another GM corn variety called Starlink that was also intended only as an animal feed, was not approved as a human food, and was supposed to be strictly segregated when grown. However, segregation proved ineffective and it contaminated a large proportion of US corn production, triggering the most costly food product recall in US history.

At the point one GM bio-industrial product is accepted as a food on the basis of it being tested against another GM variety, the stage is set for a raft of other products – including biofuels and industrial and medical substances – to be approved using the same principle. For example, Syngenta has already applied to one regulator for approval of a GM corn variety that is designed for biofuel production, based on a comparator that is not the non-GM parent.[5] The Codex guideline specifies (p 5) that "A consistent approach should be adopted to characterise and manage safety and nutritional risks …". So if a regulator approves Monsanto's use of a GM comparator, it can be expected to be pressured to allow the same benchmark to be used with other GM crops not intended as foods. In this way, authorities may become progressively trapped by the precedents they set.

The implications of widespread approval of LY038 are far reaching. Regulators need to require Monsanto to provide new compositional and molecular studies using the appropriate non-GM comparator (a corn variety called H99 that is the closest relative of LY038). This is consistent with the approach set out in the Codex guideline and is a principle that should not be abandoned.

The Centre for Integrated Research in Biosafety (University of Canterbury, New Zealand) has produced several analyses of Monsanto's application and the food safety issues raised by LY038. See: http://www.inbi.canterbury.ac.nz/ly038.shtml

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[4] This is irrespective of the interpretation placed on the following statement in the guideline: "This document does not address animal feed or animals fed with the feed" (p 7).

[5] http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa580foodd3243.cfm