GM THRESHOLD FOR NON-GM FOODS

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In October 1999, the European Commission (EC) published proposals on *de-minimis* thresholds for labeling of genetically modified (GM) foods. These recognise that even where manufacturers attempt to exclude GM ingredients from their products some 'accidental contamination' may occur. The new proposal is to require labeling only where the GM content of an ingredient obtained from non-GM sources exceeds a 1% threshold.

This briefing note reviews the background to the Commission's proposed threshold and examines the issues that arise.

REGULATORY BACKGROUND

Within the EU, regulation of GM foods occurs at three main levels[1]:

- the contained use of GM micro-organisms (e.g. in laboratories and production facilities) through Directive 90/219;
- deliberate release of GM organisms into the environment (e.g. by planting GM crops or marketing GM foods) through Directive 90/220;
- approval/labeling of foods containing detectable amounts of GM material (either protein or DNA) through the Novel Foods Regulation (258/97) and Council Regulation 1139/98.

Implicit in this final area of regulation is a requirement to distinguish between GM and non-GM ingredients. The Commission's new proposals (see **Box 1**) represent the first attempt at setting some technical regulations in this area. Among the most important of the proposals is the introduction of a *de-minimis* 1% threshold for GM content in supposedly GM-free foods.

THE NEED FOR A THRESHOLD

Consumer reluctance to accept GM foods in Northern Europe has helped create a demand for 'non-GM' ingredients. Until recently however, companies wishing to supply such ingredients had no formal definition of what constitutes 'non-GM'. Ideally, one might expect 'non-GM' to mean '100% GM-free'. However, GM material has been detected in organic (non-GM) soy grown under strict guidelines that require (*inter alia*) segregation from GM plants. Such cases illustrate how difficult it is to completely separate non-GM and GM crops.

BOX 1 THE COMMISSION'S NEW PROPOSALS

The Commission's new proposals cover various amendments to Council Regulation 1139/98. This was introduced in 1998 to require compulsory labeling of certain foodstuffs produced from GM organisms (GMOs). Among the main proposals are:

- The setting of a 1% *de-minimis* threshold for the GM content of ingredients obtained from non-GM sources.
- Changing the labeling requirements in Regulation 1139/98 to apply not only to foods supplied "*to the final consumer*", but also to foods supplied to "*mass caterers*".
- To set up a 'negative list' of ingredients containing neither protein nor DNA. Such ingredients would be exempt from the labeling requirements in Regulation 1139/98; the content of such a list is under consideration by the Commission's Joint Research Centre.

A related set of proposals covers foods that contain additives/ flavourings that are genetically modified or have been derived from GMOs. The new proposals will require labeling to inform consumers of the presence of certain GM (or GMO derived) additives / flavourings. Again, this applies to foods marketed direct to consumers as well as those sold to caterers. The Commission is considering whether the 1% threshold should also apply to those companies seeking to use non-GM additives/flavourings.

Both sets of proposals were agreed at the Standing Committee for Foodstuffs on 21/10/99, and should enter into force in early 2000.

Strictly speaking, the Commission's proposed threshold applies only to the two GM lines covered by Regulation 1139/98: Roundup Ready (RR) soy and (Novartis) Bt maize (see **Box 2**). However, in practice the current proposals for these two specific cases will set a precedent for labeling all GM foods approved under the Novel Foods Regulation. Ingredients derived from non-GM soy or maize may thus contain up to 1% total GM content without triggering the labeling requirements in Regulation 1139/98. It applies to ingredients rather than finished products and covers only those obtained from 'non-GM' sources: companies buying ingredients from unknown sources will have to label their products. In order to avoid labeling, companies using soy and/or maize will have to:

- demonstrate to the satisfaction of the enforcement authorities that their ingredients come from non-GM sources;
- show they contain less than 1% total GM content (of varieties approved under the Novel Food Regulations).

GM CROPS APPROVED BY THE EU

To date, the EU has approved 6 different GM crops for use in animal feed and human food (see Box 2). These involve two different traits (insect resistance [IR] and herbicide tolerance [HT]) in maize, soy beans and oilseed rape. GM maize and soy beans

1 See POST report GM Foods: Benefits and Risks, Regulation and Public Acceptance, May 1998 for more details.

BOX 2 GM CROPS APPROVED IN THE EU

The EU has approved 6 different GM crops for use in animal feed and human food (see **Table**). They include four GM maize varieties, and one each of soy and oilseed rape. Two traits are involved:

- **Herbicide Tolerance (HT)** – a novel gene is inserted into the plant that confers tolerance to a specific weedkiller (e.g. Roundup or Liberty). Treatment of the crop with that herbicide kills weeds leaving the crop unaffected.
- **Insect Resistance (IR)** – *Bacillus thuringiensis* genes coding for so-called Bt toxins are inserted into plants. These toxins are harmless to humans, but kill the larvae of many common insect pests. For instance, one of the Bt genes produces a toxin lethal to insects such as the European corn borer, while another targets those such as the Colorado beetle.

These may be imported into the EU, stored and processed into food and feed in the same way that non-GM varieties are used. A seventh GM product (GM tomato paste) was approved in 1995 under different regulations. This product is imported as a paste rather than as a viable organism; it thus did not require marketing consent under the Deliberate Release Directive.

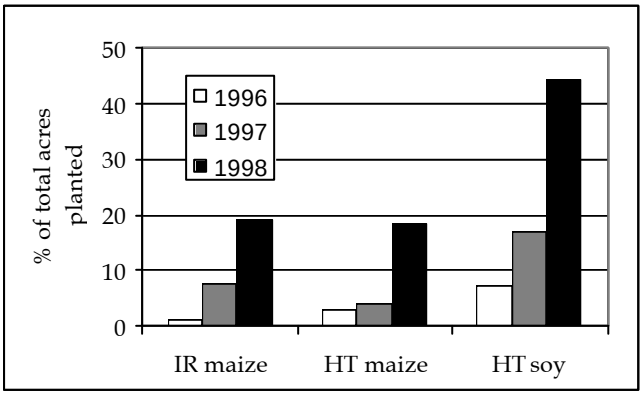
None of the crops in the Table is grown in the EU on a commercial basis. Consent was sought to grow three of the GM maize varieties in the EU; decisions on these are pending judgement on certain issues by the European Court. At the end of October 1999, a further 11 applications to market GM crops (5 types of rapeseed, 2 of maize and one each of chicory, beet, tomato and potato) for food use in the EU were still under consideration.

TABLE GM CROPS APPROVED FOR MARKETING IN THE EU

CROP	MAIN TRAITS (No.)	TOTAL
Maize	HT (1), IR (2), HT+IR (1)	4
Soybean	HT (1)	1
Rapeseed	HT (1)	1

Source: Trade Analysis Committee of the United Soybean Board

FIGURE 1 UPTAKE OF GM SOY / MAIZE IN THE US



Source: USDA Economic Research Service

have proved particularly popular with US farmers accounting for an increasing proportion of total acreage planted since their introduction in 1996 (see **Figure 1**). Estimates for 1999 are that GM (HT) soy beans accounted for ~55% of total soy acreage; the figure for GM (IR and/or HT) maize is at least 40%. Farmers often plant a range of varieties (some GM and some non-GM) depending on factors such as soil condition and micro-climate; a typical farmer might plant 6-10 different varieties of soy beans.

BOX 3 THE US BULK STORAGE/DISTRIBUTION SYSTEM

Bulk commodities are transported by road to one of 10,000 country elevators and then on to one of 700 terminal elevators where they are loaded onto barges holding ~1,500 tonnes each. These are towed down river to one of 60 export elevators, which load ocean going freighters with capacities of up to 50,000 tonnes.

The whole system is designed to achieve maximum economies of scale by bulking up crops to a larger and larger extent. This means that it is inevitable that crops from one farm or region will be mixed with those from another. The example of soy beans illustrates the extent to which mixing occurs, and the difficulty of trying to segregate crops within the bulk export system. According to the US Department of Agriculture (USDA), soy beans are grown on a small scale by a large number of farmers, with the average area planted being 186 acres per farm. On this basis, it would take the yields from around 7 farms to fill a single barge and nearly 300 farms to load an ocean going freighter.

US SOY / MAIZE EXPORTS

Much of the GM soy and maize imported into the EU originates from the US (although Argentina is also a significant exporter). Soy and maize are grown on a huge scale in the US – mixing of GM and non-GM varieties is inevitable, since the crops enter a bulk transport/distribution system after harvesting (**Box 3**). In 1998, some 80M acres of maize were grown, producing just under 300M tonnes of corn. Most (60%) was stored on farm and used locally (as cattle feed); the remaining 40% entered the bulk system. Half of this was processed within the US into a range of food, feed and industrial products and half exported unprocessed. 1999 estimates for soy suggest that some 75M acres were planted yielding around 75M tonnes of beans. Around one third of this was exported as whole beans; some 10% of all US soy exports are to the EU, of which ~1% enters the UK.

By mixing crops from different geographical areas (Box 3), the US bulk commodity system delivers maximum economies of scale. Given the extent of penetration of GM crops on the US market (Figure 1), it is inevitable that soy beans and maize imported into the EU by this route will have a significant GM content. Companies buying soy/maize ingredients through this route are thus subject to the GM labeling requirements in Regulation 1139/98.

IDENTITY PRESERVED (IP) SYSTEMS

Companies wishing to produce 'non-GM' soy and maize ingredients will thus have to keep their non-GM crops separate from GM varieties at all stages, from buying the seed, to supplying the end user with the final product. The US maize and soy industries call this **identity preservation** (IP). It involves a contract between the end user and the farmer that covers:

- Purity of the seed used by the farmer (commercial US seed is typically ~98% pure).
- Separate planting and cultivation arrangements – e.g. to minimise the possibility of 'pollen drift' from related varieties planted nearby.
- Separate harvesting arrangements – e.g. to minimise 'carry-over' from combine harvesters.
- Separate transport and storage arrangements to exclude the possibility of co-mingling with other varieties. This involves 'containerising' the harvested crop under seal on the farm and transporting it entirely separate from the bulk distribution system outlined previously.
- Separate processing arrangements, again to minimise co-mingling with other varieties. This may involve the use of dedicated processing plants; at the very least it requires cleaning of processing plant between 'batches'.

To date, the IP approach has been used for a number of high-value (non-GM) products, for which farmers receive substantial premiums. For instance, organic soy beans and beans grown for the Japanese tofu market are two IP lines that are currently grown by US farmers. They carry a high enough premium (up to four times the commodity price) to justify the additional costs. Trade bodies such as the US NCGA and the ASA[2] estimate that IP results in costs at least double those associated with non-IP varieties; much of this is additional transport costs. Such bodies see the setting up of IP lines for non-GM crops as feasible, but are doubtful whether European processors will pay the required premium.

ISSUES

Why 1%?

Whatever threshold value the Commission chose was likely to prove controversial. On the one hand, consumer and environment groups have pushed it to set the threshold as low as possible; on the other, the bulk maize/soy industries have lobbied for a 'feasible' threshold. In practice, the Commission hopes that the requirement to provide proof that ingredients are of non-GM origin should mean that levels detected fall well below the 1% mark.

The Consumers in Europe Group (CEG) have argued that labeling of GM food should be based on production method and 'traceability' through the food chain. It believes that this should be achieved by separation of GM and non-GM crops/products, accompanied by detailed records and an audit trail through the supply line. CEG accepts that some limited accidental GM 'contamination' of non-GM products may occur, but feels that any threshold should be set close to the detection limits of current GM protein/DNA tests. As outlined in **Box 4**, such a limit would suggest a threshold lower than the proposed 1%; some environmental groups have argued for a threshold as low as 0.01%.

In contrast, the US bulk commodity industry views the proposed 1% threshold as being too stringent. It suggests that thresholds of ~5% are the norm for bulk commodities. For instance, certified organic flour in the US may contain up to 5% non-organically grown material; the same 5% threshold is also the norm for IP soy beans grown for the Japanese tofu market. Overall, the industry has serious doubts whether even a fully segregated IP approach could comply with a 1% threshold (below).

BOX 4 DETECTING GM CONTENT IN FOOD PRODUCTS

Protein Detection – immunoassays are used to detect the presence of the protein(s) coded for by the GM 'event' (the product of the EPSPS gene in RR soy; the Bt toxins in IR maize). The tests use a specific antibody designed to bind to the 'GM protein'. This binding can be detected by an enzyme-linked reaction that produces a colour change; quantification may be achieved by comparing the test result with standard samples with a known GM content. Strategic Diagnostics Inc. (SDI) are marketing plate kits for RR soy that can detect down to 0.05% 'GM protein' in food fractions (e.g. different types of soy flour, soy protein isolates and concentrates). It has also developed a strip test – similar to a pregnancy testing kit – using the same technology to allow operators in the field to detect RR soy beans in raw materials down to a level of ~0.1%. Such kits are cheap (~£10 per test), rapid and reliable. They are not currently suitable for use with heavily processed foods /ingredients (processing degrades the GM protein), although SDI is currently developing tests that will detect highly processed GM protein.

DNA Detection – the most sensitive tests to date are based on the Polymerase Chain Reaction (PCR) DNA amplification technique; this is used to amplify gene sequences specific to GM crops up to detectable levels. Processing degrades DNA - the more highly processed a food, the more difficult it is to detect specific DNA sequences. This problem can be diminished by looking for very small fragments of the gene in question. Food components that block the PCR reaction may also need to be removed. By far the biggest problem however, is calculating how much GM content is present. A PCR-based test recently developed by RHM technology is the first that claims to give a quantitative result. It does this by amplifying two different gene sequences. One is unique to the GM variety; with soy the sequence used is part of a viral promoter gene that is included in the GM construct. And the other is present in both the GM and non-GM varieties (e.g. part of the soy lectin gene). The % GM content may be calculated by comparing the amount of these two amplification products. This method has detected GM soy contamination constituting ~0.01% of the product tested.

Can IP lines comply?

At least one US company (Protein Technologies International; PTI) has already set up an IP line to produce non-GM soy. It is offering growers a non-GM version of a herbicide tolerant soy bean that will

2 The National Corn Growers Association and the American Soybean Association respectively

be harvested separately and shipped to a dedicated plant for processing into soy protein isolate[3]. Growers will receive a small premium (~$6/tonne) for growing the non-GM bean. PTI hope that the product will contain less than 1% GM soy and thus not require labeling.

PTI have been running this non-GM IP soy line for some time on a small scale, and claim to be averaging ~0.5% GM content in the beans used for processing. Assuming this translates into a 0.5% GM content in the final product, there is little margin for error with the proposed threshold at 1%. There is also a possibility that the GM content might rise as the scale of operation expands. While the company may be able to 'live with' the 1% threshold, it emphasises that tests on the end product are only part of the story; achieving acceptable levels requires strict control measures over the entire system of production. By June 1999, PTI had ~800,000 acres (~1% of the US soy bean acreage) of the non-GM beans planted, although this will not necessarily all be processed through the IP line.

Others within the industry are doubtful whether compliance with a 1% threshold will be possible, even where fully segregated IP lines are set up. One concern is the issue of varietal purity of the seed used; US commercial seed varieties are typically no more than 98% pure. In theory, this in itself could lead to 'non-GM' soy varieties exceeding the 1% threshold; in practice, the GM content of commercially available 'non-GM' seed is not known.

Enforcement and testing

UK local authority (LA) food officers (trading standards and environmental health officers) will be responsible for ensuring foods containing soy and/or maize that are not labeled as 'GM' do not exceed the 1% threshold. Rapid, cheap and reliable tests are available to detect 'GM protein' in some soy products (Box 4), but these are most reliable when used on unprocessed ingredients. Detecting GM content in highly processed finished products requires more complex, sensitive and expensive (DNA) tests. Only one LA public analyst laboratory (Worcester) in the UK is currently accredited to perform such tests; even this laboratory cannot quantify the extent of any GM 'contamination' it might find. A quantitative test has recently been developed by RHM technology (Box 4), but the resource implications of equipping laboratories with it are likely to be considerable.

3 DuPont's STS (sulphonylurea tolerant soybean) soybean, a non-GM herbicide tolerant soybean derived using mutagenesis.

Maize varieties not approved in the EU

A separate GM 'contamination' issue that has yet to be resolved concerns the question of maize varieties that have not been approved in the EU. This situation arises because:

- US regulations allow farmers to grow 12 different GM maize lines;
- But only four of these are approved for import into the EU (Box 2).

Given the extent to which mixing of varieties occurs during bulk transport/storage, (Box 3) all (bulk) US maize may contain some non-EU approved GM lines.

To minimise these problems, the US corn industry is implementing procedures (by the year 2000) to '**channel**' non-approved GM lines out of the export chain. This involves ensuring that growers know which GM lines are approved in the EU and which are not, and encouraging them to ensure that only approved lines are shipped off-farm. Growers choosing to plant non-approved lines are advised that there will be a restricted market for their crop.

Channeling will **not** produce a product guaranteed free of non-approved lines. Indeed, it is doubtful that such a product could be achieved even using a dedicated IP approach, given the potential for co-mingling. A similar issue arises in Canada, where several varieties of GM oilseed rape are grown that have not been approved in the EU (this has prevented grain importers shipping Canadian oilseed rape into Europe). The bulk North American grain industry thus wants the Commission to propose further thresholds, setting permissible levels of non-approved GM content. The Commission has published no such proposals to date.

Overview

This proposal is likely to be the first of a number of technical regulations needed to 'flesh out' the EU food labeling requirements for GM foods. For instance, companies may require more detailed guidance on sampling, test verification, etc., as well as advice on what to do to "*satisfy competent authorities*" that they have avoided using GM ingredients (it is only assumed that a properly documented and audited IP line would satisfy this requirement).