Rules and Regulations on GMO-derived food products in the European Union

Lynn Insall

UK Food and Drink Federation

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About the UK Food and Drink Manufacturing Industry

• gross output of over £69 billion, accounting for 15.5% of the total manufacturing sector
• employs some 500,000 people, around 13% of the UK manufacturing workforce
• exports about £10 billion of food and drink, of which 63% goes to EU countries
• imports about £21 billion of food and drink, of which 66% comes from EU countries
• buys some two-thirds of all the UK's agricultural produce
Key Principles

• providing consumers with a wide choice of safe, high quality, wholesome and enjoyable food and drink products.
• labelling goods clearly and informatively so that people know what they are buying and how best to store and prepare what they buy.
• helping consumers make informed choices through science-based information programmes such as food fitness, food future, food link and National Food Safety Week.
• complying fully with existing food and drink legislation and relevant codes of practice.
Biotechnology, including genetic modification, offers enormous potential to improve the quality and quantity of the food supply....
GM BENEFITS

• Improved crops and increased yield
• Saline and drought resistance
• Environmental benefits
• Food Safety
• Nutritional benefits

…….but
PROCEED WITH CAUTION

- Robust controls are essential to protect the consumer and the environment.
- The food safety and environmental impacts of novel technologies must be objectively assessed through scientific investigation.
- Continuing consumer education and information are fundamental to public acceptance of new technologies.
- Labelling is an important means of informing consumers about which foods have been produced from or contain, genetically modified ingredients.
- Schemes to preserve the identity of conventional crops and their derivatives facilitate consumer choice.
Science based food production
Informing consumers
Balanced, science-based resources
Schools resources
FIRST GM FOOD PRODUCT

In 1996 the first GM product was introduced in two major UK supermarkets, a tomato purée produced from GM tomatoes, labelled as such and giving an explanation as to the benefits.
EU approach to regulating GMOs

- Protection of human health
- Provision of consumer information
- Protection of the environment
Halt on GMOs in Europe

• Authorisations for placing GMOs on the market suspended in 1998

• European Council decided in 1999:
  - to adopt more stringent and more transparent rules for the commercial approval for marketing GMOs
  - to introduce rules on labelling and traceability
New European Regulatory Regime: The Framework

- New assessment and authorisation procedures - Directive 2001/18/EC (Deliberate release of GMOs into the environment)
- Regulation 1829/2003 - GM Food and Feed
- Control of Transboundary Movement – Regulation 1829/2003
- Traceability and Labelling of GMOs – Regulation 1830/2003
Assessment and Authorisation of GMOs

• Decisions made at EU level and binding on all Member States

• Procedures for assessing applications, including timetable for different stages, are mandatory requirements

• Commercial importation, cultivation or use in food or feed of a GMO prohibited without consent
Assessment and Authorisation - GMOs

• Transparent process, case-by-case assessment based on sound scientific evidence to avoid adverse effects on human health or the environment from GMOs

• Strengthened provisions concerning risk assessments, public consultation and conditions to any consents granted
Regulation 1830/2003 of the European Parliament and of the Council on the traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms

- Establishes traceability requirements for GMOs
  - to facilitate the withdrawal of products in the event that unforeseen adverse effects to human or animal health or the environment are established;
  - to monitor their effects, particularly on the environment;
  - and to facilitate the labelling of food and feed products;

- Requires that pre-packed products consisting of or containing GMOs be labelled “This product contains genetically modified organisms”, and that this information be passed along the chain in subsequent transactions;

Regulation 1830/2003 Cont’d..

• For products produced from GMOs, the following information must be provided:
  (a) An indication of each of the food ingredients, including additives and flavouring(s), which is produced from GMOs;
  (b) An indication of each of the feed materials or additives which is produced from GMOs;
  (c) In the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

• Requires business operators to maintain systems to allow the identification of the source of the product (GMO or produced from a GMO) for a period of five years (the EP says ten) from the transaction, except where lot or batch marking systems are in place and traceable for a similar period, or where the product is being delivered to the final consumer;

• Requires the establishment, by the Commission, of a system for the development and assignment of unique identifying codes for GMOs, as set out in the Cartagena Protocol;

• Requires the Commission to develop technical guidance on sampling and testing.
Traceability and Labelling

- Trace GMOs or GM products through the production and distribution chain

- Monitor potential effects on health or the environment

- Possible to withdraw GMOs from the market in case of a new risk

- Facilitate labelling
Traceability and Labelling

- Records must be kept for 5 years
- Unique identifiers required for a product that “contains or consists” of a GMO – not derived products

- Establishes a new procedure for the safety assessment, by the European Food Safety Authority (EFSA) and authorisation, for a period of ten years (renewable), of all food and feed consisting of, containing or produced from GMOs;

- Requires the labelling, irrespective of the detectability of modified DNA or protein in the final product, of a food or feed which consists of, contains or is produced from GMOs;

- Provides for a 0.9% threshold for the adventitious, or technically unavoidable contamination during cultivation, harvest, transport and processing, of conventional food and feed, which will not be subject to the labelling requirements;

(Official Journal reference L268/1, 18.10.2003)
Regulation 1829/2003 Cont’d..

- Establishes a 0.5% threshold, for a transitional period of three years, for the adventitious or technically unavoidable presence of unauthorised GM varieties, which have received a favourable scientific assessment in the EU.

- Introduces post-market monitoring requirements, when indicated as necessary by the risk assessment, of GM foods for human consumption and GM feeds for animal consumption;

- Provides for the establishment of a register of GM food and feed authorised under the Regulation;
Regulation 1829/2003 Cont’d..

• Requires all products falling within the scope of the Regulation, but already on the market under the terms of Directive 90/220/EEC or Regulation 258/97/EC (the novel foods Regulation), to be notified to the EFSA within six months of the Regulation coming into force and, after a period of nine years on the market, to apply for renewal of authorisation under this Regulation
Transboundary Movement

• Implementation of the global Biosafety Protocol
• Requires notification and subsequent importing country’s agreement prior to the first transboundary movement of a GMO
• Information exchanged through the Biosafety Clearing House
Scope of EC Regulation 1829/2003

• Authorisation of GMOs for food, feed and environmental release
• Thresholds for adventitious presence of GM material
• Labelling
• Reauthorisation every 10 years
SCOPE: Authorisation and Supervision

• GMOs for food use
• Food containing or consisting of GMOs
• Food produced from or containing ingredients produced from GMOs
SCOPE: Labelling

Applies to foods that:

- contain or consist of GMOs; or
- are produced from or contain ingredients produced from GMOs.
Exemptions from labelling

Recital 16 distinguishes between:

- food and feed produced “from” a GMO
- food and feed produced “with” a GMO
Excluded from scope

Products of animals fed on GM feed
Micro-organisms

The Council and the Commission:

• agree that the status of food produced by fermentation using genetically modified micro-organisms not present in the final product, needs to be clarified, at the latest in the context of the report to be presented by the Commission as foreseen in Article 46 of the Regulation;

• note that the status of enzymes used as processing aids will be clarified in the context of the proposal which the Commission is currently elaborating to provide a regulatory framework for enzymes for food use.
What to label

Labelling requirements apply to all foods which:

(a) contain or consist of GMOs, e.g. a *flavr savr* tomato; or

(b) are produced from or contain ingredients produced from GMOs, e.g. derivatives of GM soya or GM maize, ingredient produced from genetically modified micro-organisms (GMMs).
Specific additional information

(a) where the food is different from its conventional counterpart:
   (i) composition;
   (j) nutritional value or nutritional effects;
   (k) intended use of the food;
   (i) implications for the health of certain sections of the population;

(b) where a food may give rise to ethical or religious concerns.
Thresholds

• 0.9% for **authorised** GM material provided the presence of GM material is **adventitious or technically unavoidable**.

• 0.5% for adventitious presence of **unauthorised** GM material, but for which a favourable EU scientific assessment exists.
Adventitious or technically unavoidable – ‘appropriate steps’

- Operators must be in a position to provide evidence to the Competent Authorities
Traceability

Defined as “the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains”.

Review process

QUESTIONNAIRE FOR MEMBER STATES ON THE IMPLEMENTATION OF REGULATION (EC) 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON GENETICALLY MODIFIED FOOD AND FEED

European Commission January 2005
Review process - What we said

• European Commission should undertake a reassessment of the intentions and anticipated impact of Regulation 1829/2003.

• If it was the intention to inform consumers about the origin of products derived from GMOs, it has in practice resulted in more widespread use by the food industry of identity preserved non-GM supply streams.

• Companies are under increased pressure to either label products of animals fed on GM feed as “GM” or to avoid the use of GM feed, not possible in the EU on a widespread basis.
• Impact is out of line with the Commission’s Strategy on Biotechnology, itself linked to the Lisbon Strategy, which has recently been the subject of refocus.

• Either the EU needs to reassess the scope of the Regulation or undertake a massive consumer education programme to reverse the impact of media scare stories and the undermining of confidence in the safety of GM derived food products.

• The current situation is not sustainable within a global food market and prejudices EU production against the import of finished product from third countries.
The Principles of Good Regulation

• Necessary;
• Based on achieving safety, clear communication, free movement of goods and fair trade;
• Technically sound;
• Clear and unambiguous;
• Applicable to large and small companies;
• Subject to uniform implementation;
• Subject to equitable enforcement.
Biotechnology and the Economy

• European market worth €100 billion by 2005
• The Lisbon Strategy – 3% GDP to R&D by 2010
• Currently 1.9% - and falling!
• Global 4.6% growth in GDP 2004
• Europe less than 2% growth average
Life sciences
and biotechnology
A strategy for Europe
Life sciences and biotechnology offer opportunities to address many of the global needs relating to health, ageing, food and environment, and to sustainable development. How can Europe best attract the human, industrial and financial resources to develop and apply these technologies to meet society’s needs and increase its competitiveness?

Broad public support is essential, and ethical and societal implications and concerns must be addressed. How can Europe deliver effective, credible and responsible policies which enjoy the confidence and support of its citizens?

The scientific and technological revolution is a global reality which creates new opportunities and challenges for all countries in the world, rich or poor. How can Europe best respond to global challenges, develop its domestic policies with a clear international perspective and act internationally to pursue its interests?

The importance of biotechnology in Europe

“By 2005 the European biotechnology market could be worth over €100 billion”
EU Strategy

“Biotechnology has the potential to deliver improved food quality and environmental benefits through agronomically improved crops”
EU Strategy and Action Plan

- Societal scrutiny and dialogue should accompany and guide the development of life sciences and biotechnology;
- Life sciences and biotechnology should be developed in a responsible way in harmony with ethical values and societal goals;
- Informed choice should facilitate demand driven applications;
- Science based regulatory oversight should enhance public confidence;
- Basic regulatory principles and legal obligations should be respected to safeguard the Community single market and international obligations.
Opening Europe to biotechnology?

“In order to apply fully the principle of freedom of choice for economic operators and to safeguard sustainability and diversity of agriculture in Europe, public authorities in partnership with farmers and other private operators need to develop agronomical and other measures to facilitate the co-existence of different agricultural practices without excluding GM crops.”

Source: EU Strategy for Life Sciences and Biotechnology
Environmental opposition

STOP Genetic Pollution!

HALT Genetic Testing!

FRIENDS of the earth

Foodfuture
Media focus

Question session on food genetics arrange

Genetically modified food for thought...

Grill the experts on genetic food

LEEDS is to host a major public forum to grill the experts on the controversial subject of genetically-modified food.

The event is one of a series of national Question Time-style debates on food in the future, organised by the Food and Drink Federation. It will be held in Leeds Town Hall on Wednesday starting at 7 pm and tickets are free.

The event has been organised in response to a national opinion poll which showed that almost three-quarters of Yorkshire people are very concerned and confused about the new technology a want it all clearly laid out.

In the hot seat in is will be experts such as Dr Tim Ward, of plant technology research at Advanced Tech (Cambridge) UF.

Anyone who should call for 030 87890.

Controversy over new biotechnology prompts heartfelt debate
GM Crop Trials

PRIVATE LAND
GMO TRIAL
KEEP OFF
Where do we go from here?

• Review of GM Food and Feed Regulation
• Co-existence debate
### Consumer attitudes
(Report to UK Food Standards Agency February 2005)

**Concerns about specific food issues (prompted)**

226. And are you concerned about any of the following issues?

<table>
<thead>
<tr>
<th>Issue</th>
<th>Percentage 2004</th>
<th>Percentage 2003</th>
<th>Change from 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>The amount of salt in food</td>
<td>57%</td>
<td>50%</td>
<td>+7</td>
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<tr>
<td>Food poisoning (e.g., Salmonella)</td>
<td>56%</td>
<td>60%</td>
<td>-4</td>
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<tr>
<td>The amount of fat in food</td>
<td>53%</td>
<td>53%</td>
<td>0</td>
</tr>
<tr>
<td>The amount of sugar in food</td>
<td>50%</td>
<td>53%</td>
<td>-3</td>
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<tr>
<td>The use of pesticides to grow food</td>
<td>46%</td>
<td>50%</td>
<td>0</td>
</tr>
<tr>
<td>BSE</td>
<td>44%</td>
<td>45%</td>
<td>+2</td>
</tr>
<tr>
<td>The use of additives</td>
<td>43%</td>
<td>43%</td>
<td>-2</td>
</tr>
<tr>
<td>Conditions in which food animals are raised</td>
<td>41%</td>
<td>42%</td>
<td>-1</td>
</tr>
<tr>
<td>Antibiotics in meat</td>
<td>40%</td>
<td>44%</td>
<td>+4</td>
</tr>
<tr>
<td>The feed given to livestock</td>
<td>39%</td>
<td>38%</td>
<td>0</td>
</tr>
<tr>
<td>GM foods</td>
<td>38%</td>
<td>38%</td>
<td>0</td>
</tr>
<tr>
<td>Irradiated food</td>
<td>22%</td>
<td>22%</td>
<td>+3</td>
</tr>
<tr>
<td>Healthy eating</td>
<td>18%</td>
<td>22%</td>
<td>-3</td>
</tr>
<tr>
<td>Food allergies</td>
<td>18%</td>
<td>17%</td>
<td>0</td>
</tr>
</tbody>
</table>

Base: All respondents - 2004 (3,229)  
Source: MORI
Consumer acceptance?

- Offer benefits
- Improvements in quality
- Healthier options
- Lower prices
What’s on the market?
Made from pest resistant Bt maize
New from FDF

Food for Our Future

Genetic modification, food & farming