GM food and feed: EU legislation and post-market monitoring

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- what is the legislation on GM food and feed?
- what does the legislation say about post-market monitoring?
- how does it work in other areas of EU legislation?
- what is the current thinking re PMM and the safety of GM food and feed?

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Regulation (EC) 1829/2003 on GM food and feed

"one-stop-shop" for approval (and re-authorisation) of GM crops / GMOs used for food and feed

This regulation covers:

- Cultivation of the crop
- Import of the GMO
- Marketing of food and feed
- Labelling of food and feed

Implementing acts cover:

- authorisation requests
- low level presence [in feed] etc

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Criteria for authorisation

GM food and feed must not:

- Present a risk
- Mislead
- Be nutritionally disadvantageous*

Validated detection methods must be available

** compared with the food/feed they might replace*

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Directive 2001/18/EC on deliberate release of GMOs

- provides the definition of “GM”
- sets out criteria for environmental aspects
- framework for regulating crop trials (at national level) and for non-food crops

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Evaluation of legislation

- Legislation is kept under review
- Two evaluation reports were published by Commission in 2011
  - 1829/2003: GM food and feed
  - 2001/18: deliberate release
- No legislative changes are being proposed
- Commission seeks to improve implementation of existing legislation

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POST MARKET MONITORING

Legislative requirements for GM food/feed

How does it work in other areas? (examples)

Current thinking

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GM food and feed

Regulation 1829/2003 refers to PMM in relation to:

- the application for authorisation
- the EFSA opinion
- the authorisation decision

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Requirements for GM food & feed

Regulation 1829/2003, recital 35:

> "it is necessary to introduce, where appropriate and on the basis of the conclusions of the risk assessment, post-market monitoring requirements for the use of GM foods … and GM feed …"

Note: in the case of GMOs, monitoring concerning environmental effects is compulsory

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Applications for GM food and feed

Regulation 1829/2003, article 5(3)

"The application shall be accompanied by the following:

…

(k) where appropriate, a proposal for post-market monitoring regarding the use of the food for human consumption"

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EFSA opinions

Regulation 1829/2003, article 6(5):

"In the event of an opinion in favour of authorising the food, the opinion shall also include

…

(e) where applicable … post-market monitoring requirements based on the outcome of the risk assessment …"

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Obligations on authorisation-holders

Regulation 1829/2003, article 9(1):

> "… Where post-market monitoring … has been imposed on the authorisation-holder, the authorisation-holder shall ensure that it is carried out and shall submit reports to the Commission in accordance with the terms of the authorisation."

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Examples of PMM questions

Usage

- How much is produced? In what foods is it present? At what levels?

Exposure

- Who are the consumers? How much are they eating?

Effects

- Is it having effects (beneficial or adverse) on consumers?

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What is the value of monitoring?

Results of post-market monitoring can help refine

Risk assessment

and/or

Risk management

How does it work in other areas?

(a) pesticides – (b) food additives – (c) novel foods

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(a) pesticide residues in food

Regulation 396/2005:

- each member state must have a national monitoring programme
- member states must also take part in a EU harmonised programme for specified pesticides in particular foods

Purpose is primarily to check residues against mandatory limits. In some cases, illegal residues may raise health concerns

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(b) food additives

Regulation 1333/2008

- producers or users may be requested to produce data on the actual use of a food additive (Article 26)
- member states need to maintain systems to monitor the consumption and use of food additives on a risk-based approach and report their findings (Article 27)

Purpose is primarily to check exposure against Acceptable Daily Intakes set of individual additives

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(c) novel foods

post-market monitoring is a possibility for any novel food, as a condition of authorisation

two examples to date:

- phytosterols
- lycopene

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Novel food: phytosterols

authorised as an ingredient in yellow fat spreads

- uncertainty about levels of consumption of products that contain the new ingredient
- the applicant was required to provide a report after 18 months, for review by SCF
  - Results were reassuring; additional uses of phytosterols have been approved
  - surveys of usage have been conducted by national authorities in IE, UK and, most recently, BE

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Novel food: lycopene

- applications from different companies for use of new lycopene preparations in foods

  (already approved as a food colour)
- EFSA advised that average users will stay below the ADI but some users could exceed the ADI
- Commission and MS agreed that
  - authorisation should proceed, but
  - monitoring should be carried out

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lycopene (continued)

Each applicant should provide monitoring reports for July 2009 to June 2012:

- quantities supplied
- product launches (+ levels of use + portion sizes)
- info on intake of Lycopene used as a food colour
- new scientific information for a reconsideration of safety
- updated intake assessments based on the above

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Examples of PMM questions

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GM food and feed: current discussions

Draft Commission Regulation on requirements for applicants

- based on latest EFSA guidance on GM food/feed from GM plants
- includes an article that would clarify how applicants should address PMM

Regulation 1829/2003, article 5(3)

"The application shall be accompanied by the following:

…

(k) where appropriate, a proposal for post-market monitoring regarding the use of the food for human consumption"

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PMM: when?

Commission's **draft** proposal:

"The applicant shall submit a proposal … when it is appropriate to confirm:

(a) that the specific recommendations of uses are followed by the consumer / animal owner;

(b) the predicted consumption of the GM food or feed; or

(c) the relevance and intensity of effects and side-effects detected during the pre-market risk assessment which can only be further characterised by PMM."

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PMM: how?

Commission's **draft** proposal (not verbatim):

- PMM information shall identify whether any (adverse) effect on health may be related to consumption of GM food/feed
- information will be collected from relevant stakeholders, including consumers, and may involve particular foods or age groups
- the proposed approach will be justified and thoroughly described

Putting the cart before the horse?

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thank you

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