FORBRUGERRÅDET

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Nye fødevarer (novel food)

Fødevarestyrelsen har den 21. januar 2008 (j.nr.: 2008-20-221-02835/HBO) sendt forslag til Europa-Parlamentets og Rådets forordning om nye fødevarer og om ændring af forordning (EF) nr. XXX/XXXX [fælles procedure] i høring.

Forbrugerrådet har følgende kommentarer (på engelsk):

Generally, too many definitions are lacking. Instead the document will need several explanatory documents which the Commission will have to write. The explanatory documents will be regarded as "technical documents", which means that the Commission can act without officially involving parliament/stakeholders - this is unacceptable.

Main points:

- ***Keep medicine and food separate.*** Products which are only fit for a very small part of the population should NOT be accepted as food, but as medicine
- ***Daily intakes should be co-ordinated and distributed into food groups like additives***
- ***The boundary between novel foods and additives needs further clarification***
- ***The common procedure should be known before accepting the revised novel food***
- ***Nano food needs specific nano risk assessment***
- ***Approval of cloned animals must include a system of traceability***

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Scope (Article 2): Before the application is accepted as a novel food application, there should be a procedure where it is decided by EMEA (European Medicines Agency) (and NOT the procedure mentioned in Article 2, 3) whether the food is actually a food or indeed a medicine according to 65/65/EEC and 92/73/EEC.

It is not clear whether fibres are falling into the novel food regulation or the regulation for vitamins and minerals 89/398 2002/46/EC. There is a need for a definition of fibre. In case of a new fibre the procedure should be to get novel food approval first and thereafter a registration under the vitamin and mineral legislation.

There should be a set of criteria for determining what is an additive and what is not. As food producers do not want to use E numbers (they think consumers will not accept it), they try to circumvent legislation by registering as novel food. For example Lucopene (additive E160d) has also been approved as a novel food under 2006/721/EC. The approval does not allow the use of lucopene as a food colour - but how should this be assessed in practice?

Alfa-cyclodextrin is in the process of being approved as a novel food. At the same time beta-cyclodextrin (E459) is accepted as an additive, and gamma cyclodextrin was refused a novel food approval, because beta cyclodextrin is an additive. Again it is difficult to see a clear line between additives and novel food.

This might have a major impact on future additives, as they all might seek approval under the novel food legislation by downplaying technical purposes and focusing on health benefits (the two examples mentioned above)

Definitions (Article 3):

The definition of "nano" should be much more detailed – in order to assure that all nano food is included. Further it should be stressed that the method for risk assessment of nano food and nano ingredients should be specifically designed for nano characteristics.

As also mentioned under (6) and article 3, 2 a) ii), offspring of clones is not seen as novel food, only the clones themselves. In reality this means that there will be no further safety evaluation or registration of meat, milk and eggs derived from offspring of clones. We think that it makes sense to approve the cloned animal, but with the novel food approval traceability of off-spring and products thereof should be guaranteed.

Food with a new or intentionally modified primary structure and food consisting of or isolated from micro-organisms, fungi and algea should *always* be considered novel food.

Specific legislation does exist for genetically modified cultures and for cultures for infant and follow-on formulae. For probiotic cultures for animal feed completely harmonised and very detailed EU legislation has existed since 1994. Thus, for the time being there is no regulation on cultures in food.

There is a lack of regulation on micro-organisms. They should undergo a novel food approval, because the amounts (concentration into single cultures) and specifications they are used in today differ from traditional food.

A risk assessment specific for micro-organisms at strain level should be carried out. For example *enterococcus faecalis* is used as a probiotic, but is also being associated with endocarditis, bacteraemia, intra-abdominal, urinary tract and central nervous system infections in hospitals[1].

Developments in biotechnology are also making it possible to add cultures to food which produce for example the bacteriocin Nicin. Nicin is a food additive, but when the culture is added, the additive legislation is circumvented. In the future we might see more cases of cultures being added to circumvent additive regulation.

This clearly demonstrates the need for regulation of the new use of micro-organisms (the new being the concentration of micro-organisms into pure cultures). Micro-organisms should be approved at ***strain*** level, because it is at strain level that the specific characteristics are found.

Traditional foods on the fast track: novel foods which are approved under the fast track model should be time-limited (e.g. 5 years). During this period they should be monitored and thereafter re-evaluated for a full novel food approval.

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[1] S. Wessels et al.:" The lactic acid bacteria, the food chain, and their regulation". Trends in Food Science & Technology 15 (2004) 498–505

Use of food for human consumption before 15/5 1997 (Article 4)

Food that has not been used for human consumption to a significant degree: according to (29) and article 4. 2. the Commission shall establish the criteria under which foods may be considered as having been used for human consumption to a significant degree within the community before 15 May 1997. We cannot support this, but think that the criteria should be part of article 3 in this revised regulation.

Conditions for inclusion into Community list (Article 6)

The food can only be included in the Community list if it does not pose a safety concern to health.

To this article should be added that the food should be safe for *all* consumer groups. We *do not* want marketing of foods like phytosterols which according to EC no **608/2004 have to have a statement that reads:**

1. "the product may not be nutritionally appropriate for pregnant and breastfeeding women and children under the age of five years"

2. "there shall be a statement that the product is intended exclusively for people who want to lower their blood cholesterol level"

3. "there shall be a statement that patients on cholesterol lowering medication should only consume the product under medical supervision"

This fact should be underlined by the German phytosterol report (VZBV) and the Danish Consumer Council's analysis report where it is clearly illustrated that everyday food is not separated. Once it is in a household all members of the household will consume it. Food that is targeted at very specific groups and not fit for the majority should be a medicine.

There should also be a public list of foods/food ingredients that applied for novel food and did not pass the risk assessment or was withdrawn for other reasons. This is a matter of transparency. Industry was against this point for the additive regulation. For NGOs it is a good tool, for example when comparing risk assessments between EU and third countries.

Content of Community list (article 7)

It is very difficult to comment since the procedure is not laid down yet (4-pack). The information given in the Community list should be the same as EC 1852/2001:

”(a) Name and address of the applicant;

(b) Description allowing the identification of the food or food ingredient;

(c) Intended use of the food or food ingredient;

(d) Summary of the dossier, except for those parts for which the confidential character has been determined in accordance with Article 1(3);

(e) Date of receipt of a complete request.”

Further we should ask for a re-evaluation after 5-10 years.

Novel food ingredients should get approved in certain food categories and at different concentration (in case it is an ingredient). ADIs (acceptable daily intake) should not be given to a single company. In case of phytosterols other companies have applied for different uses later on – so there is a risk of over-dosing.

Traditional food from a third country (article 8)

There is a need for a clear set of criteria. The quality of data should be defined, dietary exposure should be assessed. The fast track procedure should result in time-limited approvals and re-evaluation hereafter. It is not acceptable that Member States will have to proof (with scientific evidence) that something is unsafe (“reversal of the burden of proof”) while the food business operator planning to bring this food on the EU market only has to show a "safe history of use as food in a 3rd country". Especially as there are no criteria listed within the regulation on how to demonstrate a safe history.

Obligations on the food business operators (article 11)

An article should be added which states that food businesses must pay a fee in order to have their application processed. EC 178/2002 (57) is mentioning this possibility.

Post-market monitoring: the post-market monitoring should be long-term post-market monitored. Reviewed every 5 years. Post-market monitoring should be *paid* for by the business but *conducted* by national authorities, an independent risk assessment institute or EFSA.

Data protection (article 12)

It should be stated that toxicological data cannot be protected.

Med venlig hilsen

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