European Food Law Association
Association Européenne pour le Droit de l'Alimentation

EFLA COMMENTS ON REFIT OF REGULATION 178/2002

1. General comments

Integrity of food legislation
The review of Regulation 178/2002 should be considered together with other food legislation as the respective provisions might overlap or contradict. This is e.g. the case of the responsibility of operators under Article 17 of Regulation 178/2002 and Article 8 of the Food Information Regulation (do e.g. final retailers or mass caterers have an obligation to carry out sample testing in order to comply with those provisions?), fragmented labeling provisions (provided in Food Information Regulation and also in specific legislation), the status of processing aids (not defined in Article 2(h) of Regulation 178/2002 and thus should currently be considered as 'residues and contaminants', which might be contrary to the definition of 'processing aids' in Regulation 1333/2008 and to their technical purpose) etc.

Concept of EU manufacturer and EU importer
The review of Regulation 178/2002 should include a definition of 'manufacturer' and 'importer' who should both be persons established in the EU and who are responsible for ensuring that food law requirements are met with respect to manufactured and imported foods. This is in line with the 'new legislative framework' package adopted in 2008 and also in line with the current recast of the general product safety legislation related to non-food products. This concept should be used together with the current concept of 'feed business operators' who are responsible for business under their control.

2. Concept of food safety and (un)safe food: Inconsistent terms in Regulation 178/2002 itself, inconsistency of enforcement

Under the current Regulation, the terms related to the concept of food safety and (un)safe food are unclear and inconsistent, causing legal uncertainty and inconsistent enforcement by MS authorities. In addition, the legal status of related EC Guidance should be clarified (as it is not followed by the MS in some cases – see below).

One can indeed find no less than 5 different terms / expressions designating the concept of food safety. These terms are not (or approximatively) defined:

- Article 7(1) refers to the possibility to adopt provisional risk management measures within the precautionary principle in case the food has or may have 'harmful effects on health.' This term is not defined;

- Article 10: Public information by authorities trigger if food 'may present a risk' for health. The term 'risk' is defined as a probability of an 'adverse health effect'. This term is not defined and it is inconsistent with the above;

- Article 14(2) General food safety requirement - Prohibition to market 'unsafe food', which is food that is unfit for human consumption and that is injurious to health. The term 'injurious to health' is not defined;

- Article 14(2) (unfit for human consumption). Inconsistent interpretation of the term "unfit for human consumption" by enforcement authorities. For example, Austrian authorities consider

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food as "unfit for human consumption" under the assumption that the consumer would refuse the consumption if he knew a certain fact about a product, e.g. a certain threshold value – not legally required - is exceeded (residues, pesticides ...). Other authorities (e.g. in Italy) use the concept of "unfit for human consumption" broadly in relation to conditions other than those that fall within the classic system of risk analysis (e.g. withdrawal of mozzarella with altered organoleptic characteristics (blue colored due to the presence of a harmless bacteria)) . That leads to the forced withdrawal from the market of food which is not injurious to health and edible because the concept of unfit for human consumption falls within the scope of the definition of "unsafe food". Arguably, the criterion of "unfit for human consumption" might not be included in the definition of "unsafe food".

- Article 50 - The Rapid Alert System concerns foods with 'serious direct or indirect risk to human health.' The term 'serious' risk is not defined;

- Article 19(1)
  It is unclear what is supposed to be covered – in the secondary legislation - by the term 'food safety requirements'. Most of the time, secondary legislation contains provisions which are both governed by safety and consumer information concerns (e.g. Food Additives Regulation, FIC Regulation). In practice, it is therefore sometimes a delicate exercise for the FBOs to identify if a specific provision of a same Regulation constitutes or not a 'food safety requirement'.

- In addition, it is unclear whether there is an obligation to withdraw food that is not in breach with any '*food safety requirement*' but which is unfit for human consumption (see Art. 14). The respective terms may indeed be contradictory.

3. Difficulty to have an harmonized implementation of risk assessment

Article 14(6) (batches):
This article provides that the entire batch/lot is considered as unsafe '*unless following a detailed assessment there is no evidence that the rest of the batch, lot, or consignment is unsafe*'. In the practice, it appears that food business operators do not have a possibility to demonstrate that the rest of the batch is '*not usafe*'. In particular, Austrian authorities do not consider whether the qualification of a single product as unsafe allows the conclusion that all products of the same batch are unsafe as well. For example: a nematode in one single fish lead to the assumption that the whole batch was unsafe and the importer had to destroy the whole batch. Or, one cardboard strip in a salad was sufficient for the authorities to request the withdrawal of the whole batch.

4. Traceability

Article 18 (traceability):
Regulation 178/2002 read in combination with the related EC guidelines of January 2010 requires that a traceability system is set up each time the food changes owner (transfer of ownership *versus* mere delivery). However, Belgian law goes beyond this requirement as it imposes a traceability system each time the food is delivered to another entity (even if within the same company). This raises specific practical issues when same company has various branches amongst different countries.

5. Miscellaneous comments on Regulation 178/2002

Powers of EFSA
Article 9: does the transparency requirement apply also to EFSA's opinions? Article 23 : there should be a possibility for operators concerned to challenge incorrect public information issued by EFSA.
Article 28(9)(g): it should be established under which circumstances EFSA must organize a public hearing.

Article 29: operators should have a possibility to challenge or request review of scientific opinions of EFSA.

Confidentiality issue
There should be a procedure for handling confidentiality requests received from the operators, including the right to challenge decisions by EFSA in this respect (see ECHA for chemicals).

Missing harmonized rules for withdrawal/recall of foods by the authorities
Regulation 178/2002 provides merely rules for operators' own withdrawal/recalls. A possibility for the authorities to withdraw food is provided in Article 54 of Regulation 882/2004 (Market Surveillance Regulation), however no harmonized rules are provided There should be safeguard measures for the operators aligned with the General Product Safety legislation (including its ongoing recast), including among others a period to be heard, obligation to lift measures under certain conditions etc.

Deletion of RASFF notification
There are no rules for the deletion of RASFF notifications and warnings. This question has major importance in case of different opinions in different Member States.

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