Study supporting the Evaluation of Food Contact Materials (FCM) legislation - (Regulation (EC) No 1935/2004)

Focus group

Internal coherence between FCM legislation

Brussels, 3 May 2019

Working Group on Food Contact Materials of the Toxicological Safety Section of the Standing Committee on Plants, Animals, Food and Feed (Sc-Paff)

A brief history

Art 6 of 1935/2004 authorises MS to adopt **specific measures** for non-harmonised FCM. The development of such national regulations independently of each other could jeopardise both harmonisation and mutual recognition. Historically, the EU regulation on plastic FCM started from a compilation of national regulations. The substances were then submitted to a thorough evaluation process.

"*Since 1980 more than 3000 substances present in national laws were evaluated in view of their inclusion in the EU positive lists. Currently, these lists contain about 1000 substances. The huge diminution of the substances authorized at the EU level in comparison to those authorized or recommended in the past at the national level is not so surprising if the evolution of toxicological knowledge between the '60s, '70s and today is taken into account. In general the new evaluations are more protective because more severe scientific approaches always prevailed and also because new toxicity data became available*."

Silano, Rossi (2015): European Food and Feed Law Review, **10,** 6, 402

Examples of substances which are/were in national regulations and which are not in Union list:

- *Dibutyltin dilaurate* (DBTL)
  - In the initial compilation of national regulations
  - SCF considered that there were insufficient data for evaluation
  - NOT in Regulation (EU) 10/2011
  - The main metabolite of DBTL (dibutyltin dichloride) has been classified as Substance of Very High Concern by ECHA in 2012
- *Dicyclohexyl phthalate* (DCHP)
  - In the initial compilation of national regulations
  - SCF requested additional toxicity data
  - NOT in Regulation (EU) No 10/2011
  - DCHP has been classified as Substance of Very High Concern by ECHA in 2018

Format of the discussion

- 5 groups, with one rapporteur per group;
- 90 minutes in total: 50 minutes to discuss in groups, 40 minutes to present and discuss back together

The intention of the questions below is twofold:

- to draw a picture of coherence of the current national regulations (the "specific measures") on non-harmonised FCM and the EU FCM Union list on plastic FCM
- to illustrate possible coherence issues with some representative examples

Key questions

Please globally discuss the following questions and particularly consider similarities and differences in the group**: The main question is the last question – please reflect on this question using the elements obtained from the other questions**

Current approaches at EU or national level

1) Do you consider the separation between risk management and risk assessment for FCM at EU level appropriate and necessary? What is in your view the key difference? Do you apply the separation at a National level?
2) What are in your view the key elements of *risk assessment* for FCM legislation? What is specific to FCM?
3) Do you find the risk assessment (and/ or risk management) consistent between FCM and other legislation, such as REACH[1]?
4) According to what standards should substances be risk assessed to ensure an adequate level of health protection?
   a) Is the *current* EFSA approach adequate (is it too stringent or not stringent enough)?
   b) What are your views on EFSA's 2016 Opinion as regards its approach to risk assessment[2]?
   c) Are OECD testing methods alone adequate or too incomplete?
   d) Against which standards do you risk assess at a National level?
5) Does the current approach sufficiently address the safety of the *final material* and the risk to consumers?
6) With respect to potential information contained in application dossiers, e.g., toxicological information on the substance, on impurities, the manufacturing process, the intended use in a material, the intended use in contact with food, reasoning on the foreseeable use:
   a) Which of that information should be submitted by an applicant?
   b) Which of that information should be published following Authorisation?

[1] "Under EU legislation, a number of substances known to be both genotoxic and carcinogenic are allowed to be used in FCM, including some that are classified by the International Agency for Research on Cancer (IARC) as either carcinogenic to humans (vinyl chloride, ethylene oxide), probably carcinogenic to humans (butadiene, epichlorohydrin), or possibly carcinogenic to humans (acrylonitrile, propylene oxide). These well-known substances have been used in FCM worldwide for many years and are authorized for use under EU legislation on condition that they do not migrate into food in amounts that are detectable by an agreed sensitive method. In practice, this means that concentrations in food should be below 10 ppb" Barlow S. (2009): Food Additives and Contaminants, 26, 1526

[2] https://www.efsa.europa.eu/en/press/news/160128

c) To what extent should the reasoning of the experts of the assessing authority be published?

7) In your view, what is the contribution of the FIP Network to harmonisation of risk assessment?

Capacity in Member States (non-harmonised FCM)

8) Which kind of expertise is required when you do a risk assessment on FCMs at national level?

   a) E.g. toxicology only, expertise on chemistry, expertise on food, expertise on packaging, expertise on manufacturing processes, legal expertise?
   b) Do you have a specific risk assessment body or specific risk assessors who are able to come to a conclusion on the safety of FCM/ FCM substances?
   c) How should that expertise be organised, e.g. panels of external independent experts, or civil servants doing the assessments?
   d) Are experts involved, which are both national experts and EFSA experts?

9) Were new measures on non-harmonised FCM adopted in your MS since 2004 (year of adoption of Reg (EC) No 1935/2004)?

   a) Has there been an update of existing national regulations on non-harmonised-FCM since 2004?
   b) Are DBTL and DCHP still authorised in some regulation for non-harmonised-FCM in your MS?

10) With respect to your Nationally regulated substances:

   a) Do you publish the risk assessments relevant to these regulated substances and if so where?
   b) Do you consider the regulation (risk assessment + management) of these substances effective in view of achieving health protection and other objectives?
   c) Do you consider your national approach efficient (e.g. taking into account cost, resources)?

11) Overall, is there sufficient capacity at your national level, in particular to risk assess non-harmonised FCMs?

12) In conclusion, considering the above questions:

   a) Do you consider your national approach coherent at a national level with approaches other than FCM, and why?
   b) Do you consider your National risk assessment approach for FCM coherent with the approaches used in other Member States?
   c) Do you consider the national approach coherent with the EU approach on FCM?