Discussion topic: Approach of using positive authorised lists of substances to regulate FCMs

A brief history

Prior to Directive 76/893/EEC, several Member States made efforts to enact their own legislation on food contact materials. In general, there were two different approaches that prevailed among Member States in the early 1960s, namely:

1. Toxicological approach (adopted by Italy, France, Belgium and Luxembourg), in which binding law applies in the form of overall and specific migration limit (OML and SML); and

2. Technological approach (adopted by Germany and supported by the Netherlands), in which no binding law applies in the form of separate lists for OML and no list of SML.

Subsequently, the Council of Europe initiated some efforts toward harmonisation by proposing the establishment of an OML for plastics and the development of positive lists of plastics based on toxicology.

The "first framework directive" Directive 76/893/EC was introduced in 1976, aimed at creating a common framework for Member States legislation. Throughout the 1980s, work was done aimed at consolidating national lists and resulted in the first EU harmonised list of substances for plastic FCMs in 1990 (Directive 90/128/EEC).

With further verification of substances in accordance with SCF guidelines, Directive 2002/72/EC was introduced in 2002 and subsequently, and to date, the authorised list of substances set out in the annex I to Regulation 10/2011 with restrictions and other relevant rules on plastic FCMs based on assessments by EFSA.

In addition to Regulation 10/2011, legislation concerning authorised lists has been introduced on regenerated cellulose film, active and intelligent packaging and recycling processes.

For other FCMs, Member States have been free to introduce national measures comprising lists of authorised substances. Thirteen additional materials were identified in the JRC baseline study as having lists of authorised substances across a number of Member States.

What are the issues?

1 Safety

Advantages?	Disadvantages?
Each substance is evaluated: **if authorised it will be restricted to safe use**	**Derogations** (based on common approach) for certain substances intentionally used (colourants, PPAs, ATPs) **Only substances used in initial manufacturing steps** **NIAS (impurities, reaction products) not evaluated** **Final materials are not evaluated** (evaluations increasingly detailed, listing becoming application specific) **Business operators focus only on whether it is listed** (is it actually safe, based on the most up to date science?)

Discuss!

2 Burden and costs

Advantages?	Disadvantages?
Operators use listed substances without evaluation (Low cost, stimulates innovation) **Authorities can prepare** (Testing methods, Efficient controls; the substances are known)	**What is the bill for the tax payer?** "Back of the envelope calculations" = 16.000 Eur taxpayers money per substance/use/material 4 uses, 4 materials, 1000 substances = 256 Mio Euro, 50 cents per EU inhabitant **Authorisation procedure not included** **Long term management of lists not included** **Businesses** (Preparation of dossiers, lost market opportunities (time to market + 4 years), loss of proprietary information (transparency))

Discuss!

3 Legal status, compliance and enforcement

Advantages?	Disadvantages?
Operators know which substances they are permitted to use, and how (Certain basis for investments, Easier exchange in the supply chain) **Authorities know which substances may be used, according to which restrictions and specifications** (Stronger position if non-compliance found)	**Substance is not authorised without restrictions** (limits are necessary to ensure safe use, restrictions are also product of authorisations; they originate from the scope of the evaluation) **Requires complex rules on verification of compliance** (migration limits + conditions of use, analytical methods + accreditation, other types of restrictions, e.g. to a certain type of use complex documentation)

Discuss!

4 Approach to risk assessment, management and communication

Advantages?	Disadvantages?
Substances are centrally evaluated and authorised **Assessments are transparent and accountable** **Common rules for risk assessment, evaluated by experts** (RA quality, consistency and fairness ensured, business operators do not need to have expertise)	**Maintenance of dossiers** **Difficult Risk Communication** (those substances are safe for use, but… substances of concern may be listed (as starting substances) → **expensive and complex evaluations** **New scientific insights → updates** (new data, new data requirements, updated assessment approaches, new end-points, re-evaluations required, removal of substances from the list **Available expertise** (present EFSA capacity is 25 substance /yr, EFSA uses significant number of EU experts, rules on conflicts of interest, transparency, confidentiality

Discuss!

Key questions

1. Does the current approach of authorising substances provide a sufficient base on which to **ensure the safety** of the final material or article?
2. Is the current approach of authorising substances justifiably **efficient** in terms of the **costs and burdens**, including to the taxpayer versus the safety benefits and benefits to Member States' authorities and business operators?
3. Do the benefits of the **legal status and certainty** of using authorised substances sufficiently outweigh the costs and burdens, in particular as regards complex compliance and enforcement work, including **SMEs**?
4. Are the advantages of the current approach to **assessing and managing the risk** based on lists of substances enough to justify the challenges that such an approach brings?
5. For those Member States who have their **national lists of authorised substances**, what is your own experience; how well do they work?
6. **Is this approach still relevant and how feasible is it to maintain and expand upon for other materials using Regulation 1935/2004? What are the possible alternatives?**