Overview of development of authorised list

Late 1950s - 1960s

- Italy
- Belgium

France
Netherlands
Germany

CoE
1960s

Directive 76/893/EEC
1976

Directive 90/128/EEC
1990

Regulation (EU) 10/2011
2011

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Article 5 and Annex I to R 10/2011

“Only the substances included in the Union list of authorised substances ... set out in Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.”

<table>
<thead>
<tr>
<th>FCM substance No</th>
<th>Ref. No</th>
<th>CAS No</th>
<th>Substance name</th>
<th>Use as additive or polymer production aid (yes/no)</th>
<th>Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)</th>
<th>FRF applicable (yes/no)</th>
<th>SML (mg/kg)</th>
<th>SML (mg/kg) not compliant (reason and specifications)</th>
<th>Notes on verification of compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12310</td>
<td>02663509-43-7</td>
<td>albumin</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td></td>
<td>(17)</td>
<td>(10)</td>
</tr>
<tr>
<td>2</td>
<td>12340</td>
<td>—</td>
<td>albumin, coagulated by formaldehyde</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td></td>
<td>(17)</td>
<td>(10)</td>
</tr>
<tr>
<td>3</td>
<td>12375</td>
<td>—</td>
<td>alcohols, alphatic hydrocarbons, linear saturated,</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td></td>
<td>(17)</td>
<td>(10)</td>
</tr>
<tr>
<td>4</td>
<td>22332</td>
<td>—</td>
<td>n-butyl(40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate</td>
<td>no</td>
<td>no</td>
<td>(17)</td>
<td>1 mg/kg in final product expressed as isocyanate moiety.</td>
<td>(10)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>25360</td>
<td>—</td>
<td>trialkyl(C11-C17) acetic acid, 2,3-epoxypropyl ester</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>ND</td>
<td>1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da.</td>
<td>(10)</td>
</tr>
</tbody>
</table>

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National lists of authorised substances (JRC Baseline)

- Most legislation based on lists of authorised substances and restrictions
- Close to 8000 substances were found

<table>
<thead>
<tr>
<th>Adhesives</th>
<th>Cork</th>
<th>Glass</th>
<th>IER</th>
<th>Metals</th>
<th>Multi-materials</th>
<th>Paper &amp; board</th>
</tr>
</thead>
<tbody>
<tr>
<td>DE, ES, FR, HR, IT, NL</td>
<td>CoE, CZ, FR, NL, SK</td>
<td>BE, (IT), SK</td>
<td>CoE, ES, FR</td>
<td>CZ, EL, FR, IT, NL, SK</td>
<td>FR, IT, Norden</td>
<td>BE, CoE, CZ, DE, (EL), FR, IT, NL, Norden, SK</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Printing inks</th>
<th>Rubbers</th>
<th>Silicones</th>
<th>Varnishes &amp; coatings</th>
<th>Wax</th>
<th>Wood</th>
</tr>
</thead>
<tbody>
<tr>
<td>CH, CoE, DE (draft), FR, NL, SK</td>
<td>CoE, CZ, DE, ES, FR, HR, IT, NL, SK</td>
<td>CH, CoE, CZ, DE, ES, FR, HR, IT</td>
<td>CoE, CZ, DE, EL, ES, FR, HR, IT, NL, SK</td>
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<td>FR, NL</td>
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</tbody>
</table>
General discussion on positive lists

1. Introduction
✓ what are possible advantages and disadvantages of positive lists

2. Group work
✓ 5 groups
✓ 1 rapporteur per group

3. We provide you with questions
✓ (but not with our views)

4. We will use your answers in the evaluation
✓ effective – do positive achieve what they must achieve
✓ efficient – proportionate and low burden
✓ coherent – with the objectives of the legislation, other legislation

5. To have common understanding, a positive list is
✓ as intended under R 1935/2004 (e.g. Art 5 of R 10/2011)
✓ authorising the only substances that allowed manufacture a material
✓ authorised substances are evaluated using the EFSA approach
Advantage 1: Safety

*Each substance is evaluated*
- consistently, by a central authority
- if authorised, its use is restricted to safe use

*Operators have incentive to use listed – safe – substances*
- expensive to apply – first consider those already listed

*Positive lists directly ensure safety*

*What are your views?*
Disadvantage 1: all substances?

Derogations
• e.g. colorants, ppa’s, atp’s

also NIAS are not evaluated:
• thousands of possible substances
• impurities, reaction products, decomposition products
• interactions with food, aging, etc.

Final materials are not evaluated
• evaluations increasingly detailed
• listing becoming application specific
• complex system of information exchange in supply chain

Business operators focus only on whether it is listed
• other relevant matters overlooked, suitable?
• is it safe, based on the most up to date science?

What are your views?
Advantage 2: Lower Burden

*Operators use listed substances without evaluation*

- applications only necessary for a few substances
- low cost, stimulates innovation

*Authorities can prepare*

- testing methods
- efficient controls; the substances are known

*What are your views?*
Disadvantage 2: Costs

**Tax payer:**

- **Quick estimate, figures may need refining**
  - preparation by 3 experts for 10 hours = 30 hrs
  - evaluation by 14 experts for 5 hours = 70 hrs
  - adoption by 20 experts for 3 hours = 60 hrs
  - i.e. approximately 160 hrs work at 100 Euro/hr (includes overhead + costs)
  - = 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 – but competitors profit**
- **Lost market opportunities (time to market + 4 years)**
- **Loss of proprietary information (transparency)**

**What are your views?**
Advantage 3: Legal Certainty

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

What are your views?
Disadvantage 3: Complicated Compliance + Enforcement

*Substance is not authorised without restrictions*
- e.g. 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

*What are your views?*
Advantage 4: Single approach to RA

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

What are your views?
Disadvantage 4: Management

Maintain 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

Available expertise

- present EFSA capacity is 25 substance / yr
- EFSA uses significant number of EU experts
- rules on conflicts of interest, transparency, confidentiality

What are your views?
Balance
Do the advantages outweigh the disadvantages?
Key questions?

- Does this approach **ensure safety**?
- Is it efficient in terms of **costs and benefits**?
- How do you see the benefits of the **legal status and certainty** versus the complexities of **compliance and enforcement**?
- Do the advantages of such an approach outweigh the disadvantages in terms of **risk assessment, management and communication**?
- What is your experience with **national lists**?
- To what extent is this approach still **relevant and feasible** under Regulation 1935/2004? What are the possible alternatives?
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**Group work!**

**Group 1:** Germany, Lithuania, Cyprus, Greece, Czech Rep.

**Group 2:** Sweden, UK, Romania, France, Hungary, Finland

**Group 3:** Spain, Austria, Norway, Ireland, Netherlands

**Group 4:** Belgium, Denmark, Estonia, Slovenia, Latvia

**Group 5:** Italy, Luxembourg, Finland, Portugal, Slovakia

**Please give your views on the 4 pro’s and con’s**

**Please use the questionnaire**