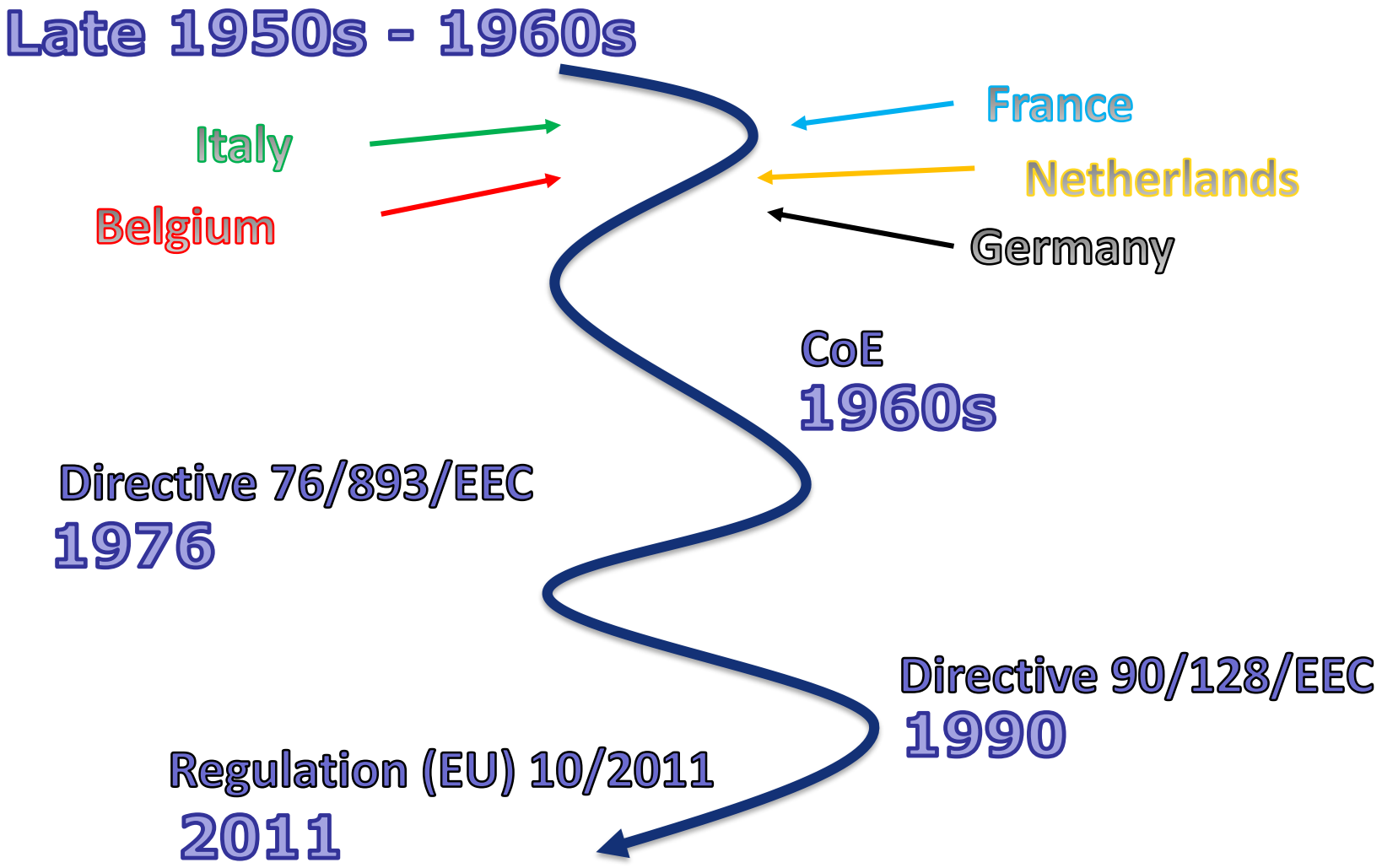
Overview of development of authorised list



Current EU authorised lists of substances

Authorised lists of substances	Related restrictions	Other rules
Plastic FCMs	Migration limits	Determine compliance
Regenerated cellulose film	Residual content	NIAS risk assessment
	Types of food	DoC
	End user	Supporting documentation
	Purity criteria	

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."*

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/	SML(T) [Gro icti o)	rictions and specifications	Notes on verification of compliance
1	12310	0266309-43-7	albumin	no	ye	n				
2	12340	—	albumin, coagulated by formaldehyde	no		no				
3	12375	—	alcohols, alpha saturated, linear, (C	no	yes	n				
4	22332		(40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate			no		(17)	1 mg/kg in final product expressed as isocyanate moiety.	(10)
5	25360	—	trialkyl(C_5-C_{15})acetic acid, 2,3-epoxypropyl ester	no	yes	no	ND		1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da.	

~ 950 more

National lists of authorised substances (JRC Baseline)

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

Adhesives	Cork	Glass	IER	Metals	Multi-materials	Paper & board
DE, ES, FR, HR, IT, NL	CoE, CZ, FR, NL, SK	BE, (IT), SK	CoE, ES, FR	CZ, EL, FR, IT, NL, SK	FR, IT, Norden	BE, CoE, CZ, DE, (EL), FR, IT, NL, Norden, SK

Printing inks	Rubbers	Silicones	Varnishes & coatings	Wax	Wood
CH, CoE, DE (draft), FR, NL, SK	CoE, CZ, DE, ES, FR, HR, IT, NL, SK	CH, CoE, CZ, DE, ES, FR, HR, IT	CoE, CZ, DE, EL, ES, FR, HR, IT, NL, SK	DE, ES, (FR), NL	FR, NL

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**?

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