

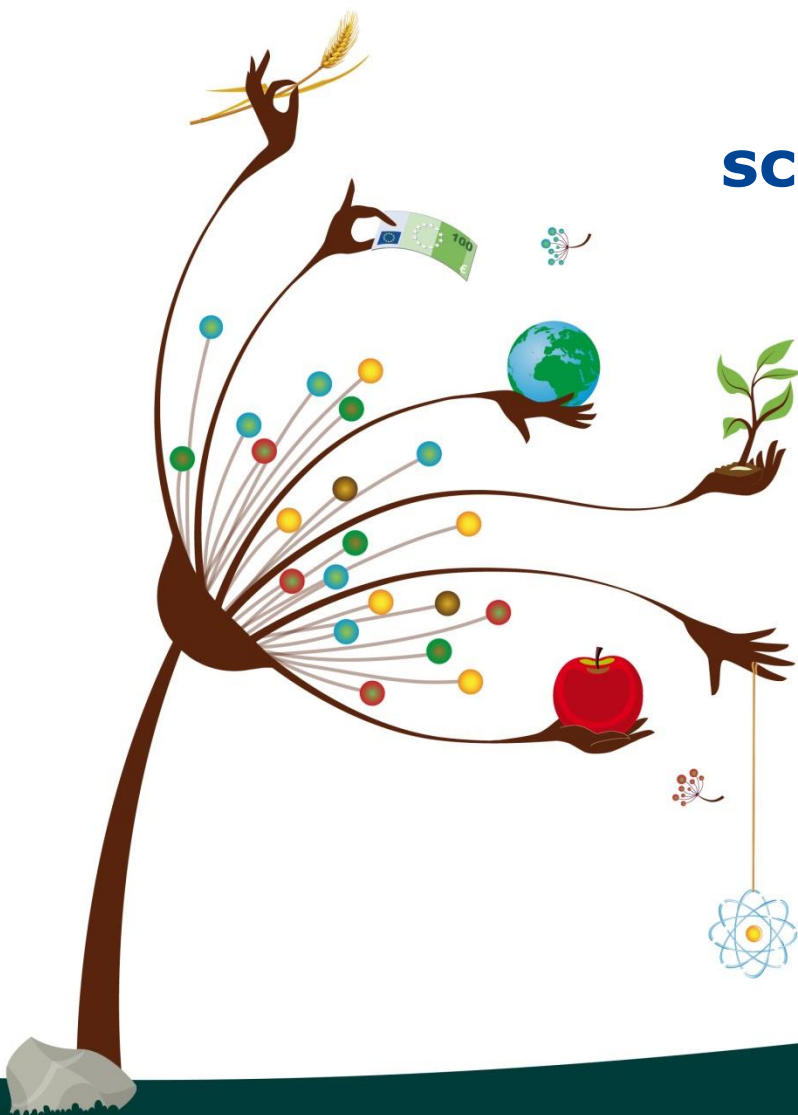
The European Commission's science and knowledge service

Joint Research Centre

*State of play for coatings from the
FCM baseline study*

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EFSA Interest Group on coatings



National measures on coatings

- **Coatings : regulated by 10 MSs and from the CoE.**
Belgium, the Czech Republic, Germany, Greece, Spain, France, Croatia, Italy, the Netherlands, Slovakia and Sweden.
- **By lists of authorised substances**
- **Implementation tools: limits – different types are used (SML, QM, compositional)**
- **At least two definitions and a difference in the categorisation of materials.**

National measures

➤ **Note: "regulated" taken in broadest sense**

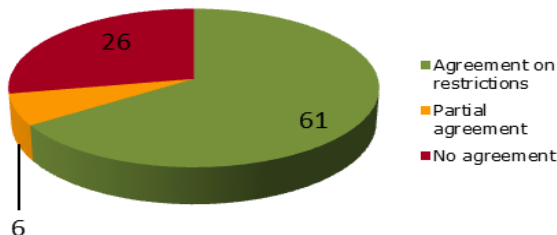
- ✓ Varying **definitions** and fields of application
- ✓ Substances not univocally **identified** (generic/cumulative descriptions)
- ✓ EFSA ESCO : risk assessed 456 substances (data list = only NL)
- ✓ **Regulated at national level: >1 720**
 - total from each MS ca. 2146 with some convergence across substances
 - What is crossed from plastics?
 - BE: Royal Decree (DRAFT): monomers /starting substances = EU 10/2011 => **not** in table
 - IT: D.M. 21/3/73 takes the whole 10/2011 Annex I list => **not** in table
 - NL: Commodities Act Regulation: **some** substances refer to chapter where **some** are taken from the EU 10/2011– **inserted** in table
 - SK: 1799/2003: "plastics pursuant to the requirements of Division Five" (a list with the implementation of EU 10/2011, even if not clearly stated) - **not** in table
 - CoE ResAP2004: substances from List 1 of additives and List 1 of monomers from the CoE document that are also present in the in EU) No 10/2011 are **not** inserted in our table
 - What else from plastics?: Of the 1720, 27 have an FCM number, and 48 have had a PM number (total 75)
- ✓ Discrepancy regulated vs. risk assessed? (426 RA/1720 Regulated = 26%)
- ✓ **88 substances (5 %) are common to 3 or more MSs** (or 2 or more MSs + CoE).

ES	111
IT	2
NL	643
FR	58
DE	131
CoE	577
HR	34
EL	574
SK	16

Convergence across MSs on restrictions

- For same substance, differences across MSs on:
 - types of limits (QM/SML) for same material
 - numerical values across MSs for one material
- Same substance, same MSs: different limit for different materials
- Limitations of transpositions of CoE lists

Agreement of restrictions agreed by three or more MSs for varnishes/coatings

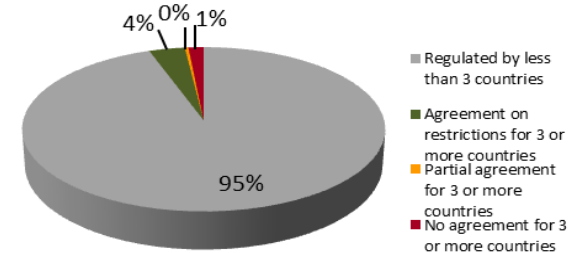


For the 88 Substances regulated by

- two or more MSs and the Coe or
- three or more MSs

Green : 61 substances converge for their restrictions (green)
Orange : partial convergence
Red: no convergence on restrictions.

Harmonisation of restrictions for varnishes and coatings

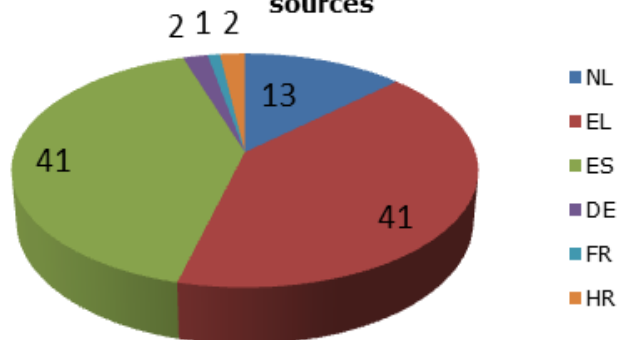


Same substances

- as a % of the total number of substances regulated
- including the substances that are regulated only in one or two MSs (in grey).

Transposition of CoE?

Countries matching CoE restriction for V&C for substances with three or more sources



Substances regulated by

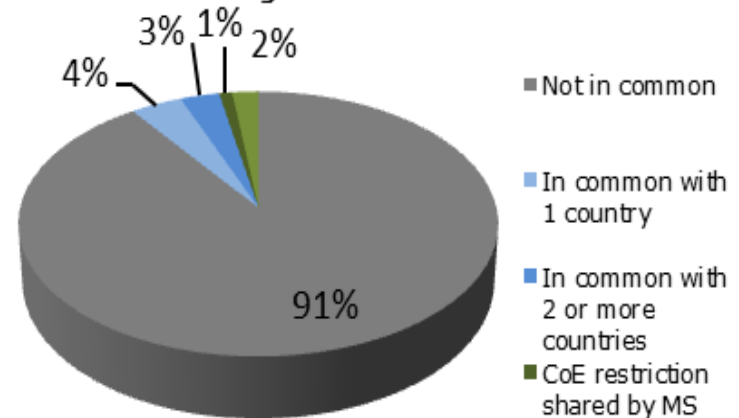
- two or more MSs and the CoE or
- three or more MSs,

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Convergencies with CoE for V&C



Same substances

- as a % of the total number of substances regulated
- including the substances that are regulated only in one or two MSs (in grey).

Standards (e.g. ISO, CEN or national)

- can be limited in their scope,
 - migration from substrates (e.g. coating on paper, metal)
 - individual substances (e.g. BADGE etc)
- Mostly on
 - epoxy coatings (e.g. EN 13130, 15136, 15137)
 - polymeric coatings on paper (e.g. EN 14234, 14235)
 - thermally sprayed coatings (e.g. DVS 2317)
 - drinking water (e.g. EN 16058, EN 12873-4, EN 15768)
 - steel with organic coatings for food applications (e.g. FR NF 36 713:2004)

Additional info/requirements (MSs)

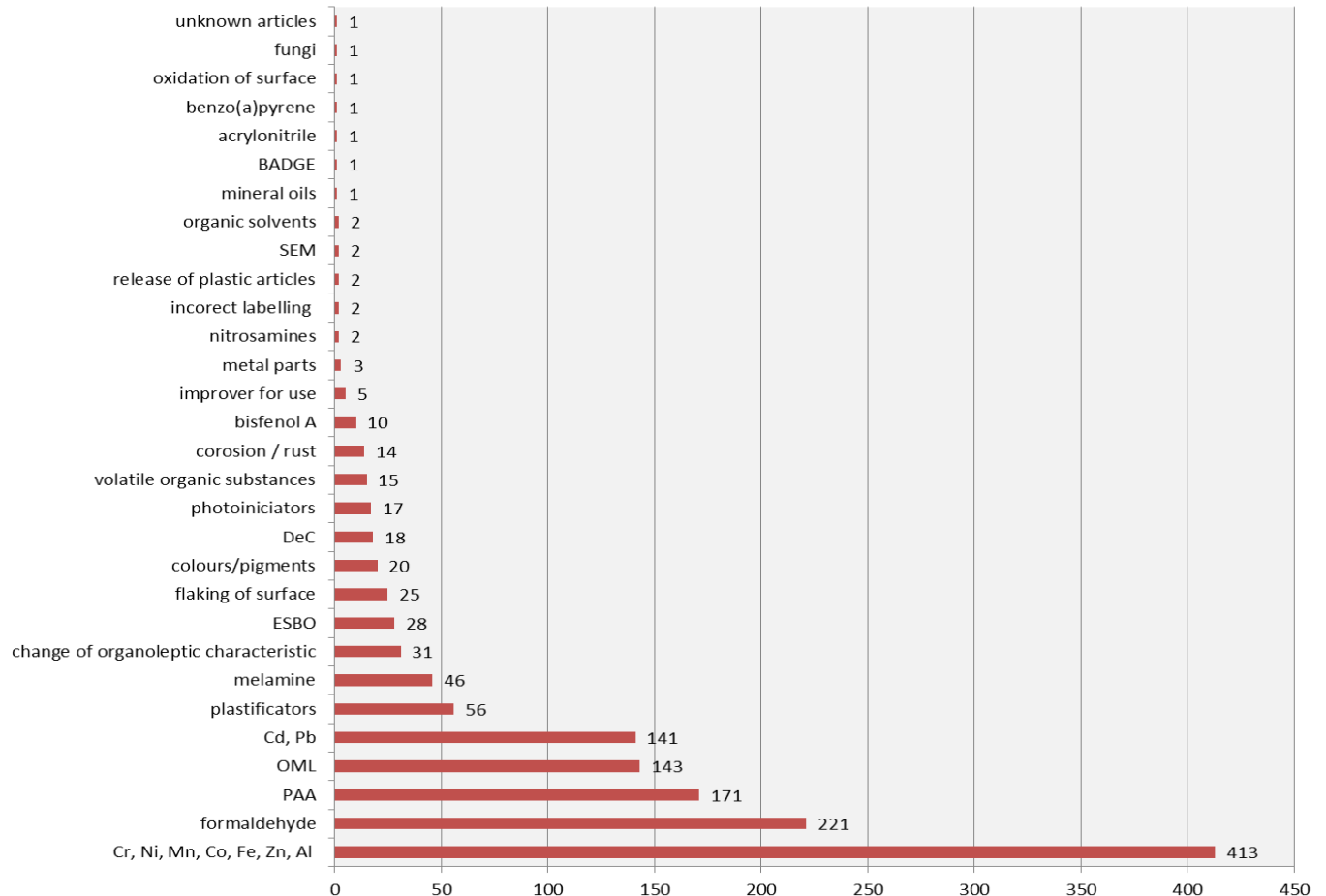
- **Only a few references for general safety requirements**
 - No MS presents exhaustive information and requirements
 - (e.g. declaration of compliance, basis for enforcement sanctions – specific to coating)
 - *CoE for GMP compliance,*
 - *Belgium and Greece for necessity of providing supporting documents and*
 - *Italy and Spain for sanctions*
- **NO specific documentations made available on specific protocol applied to coating for risk assessment**
- **Information on enforcement, testing methods test conditions**
 - Belgium, Germany, Croatia, Italy and the Netherlands (Spain)

Industry guidelines and references

- Sector-specific self-regulation guidelines on GMP (CEPE)
 - *GMP for the production of coatings intended to come into contact with food, 2010*
 - *GMP for the production of heavy duty coatings which come into contact with food (year?)*
- 3 separate codes of practice (CEPE)
 - *COP for coated articles where the food contact layer is a coating (am. 2009), COP annex (2007); COP for Coatings on finished light metal packaging articles for direct food contact*
- Guide on hygiene, guide on traceability (CEPE)
 - *Guide to good hygiene and manufacturing practices for metal cans, packaging and closures for foodstuffs, (no year)*
 - *Code of good industrial practices on traceability of materials and articles for food contact, 2004*
- The materials sector references most cited is the BfR Rec. XIV.
- Some sectors, but not all, also mentioned CH Ord. 817, ES 847/2011 and US FDA 21 175.300 or 320 so the convergence on the main national reference may vary depending on the sector.

Official controls

- Analysis of RASFF notifications according the subject of the control (2010-2015)
- No particular flags for coatings
- OM /metals - BPA or BPA and derivatives
- From NRL-SK research (M. Sycova, 2015)





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