



EFCEM

European Federation of
Catering Equipment Manufacturers

Welcome

**Drinking Water Directive Recast & FCM Developments in
the UK & China**

11 May 2021

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EFCEM

European Federation of
Catering Equipment Manufacturers

FRANCE



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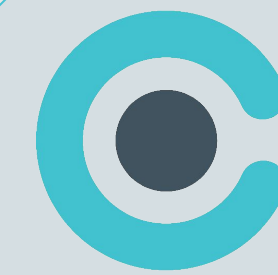
EFCEM and Compliance & Risks Join Forces

Compliance & Risks and EFCEM partner to support catering equipment manufacturers get compliant products to market faster

EFCEM

European Federation of
Catering Equipment Manufacturers

- Advocates & influences current legislation
- Anticipates regulations
- Active in the formulation of standards for the industry



compliance & risks

- End-to-end global regulatory solutions provider
- Regulations, standards & requirements management
- Reliable legislative information, insights & actions

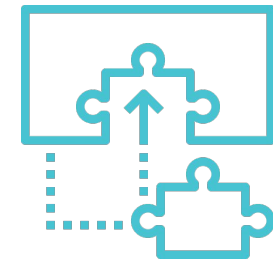
At Compliance & Risks

We help our clients monitor and manage regulations, standards, requirements and evidence to better mitigate risk.

- Peace of mind
- Brand protection
- Increased market access
- Future proofing of the business by aligning with global trends

End-to-End Regulatory Solutions

Market Access



- Customized research
- Consider new products & countries
- Compare obligations in multiple jurisdictions
- Understand regulations at a high level or deep analysis



C2P Platform

- Regulations, standards & requirements
- Proposed & enacted regulations
- Global daily monitoring and alerts
- Efficient workflow tools
- Knowledge Management
- SME support

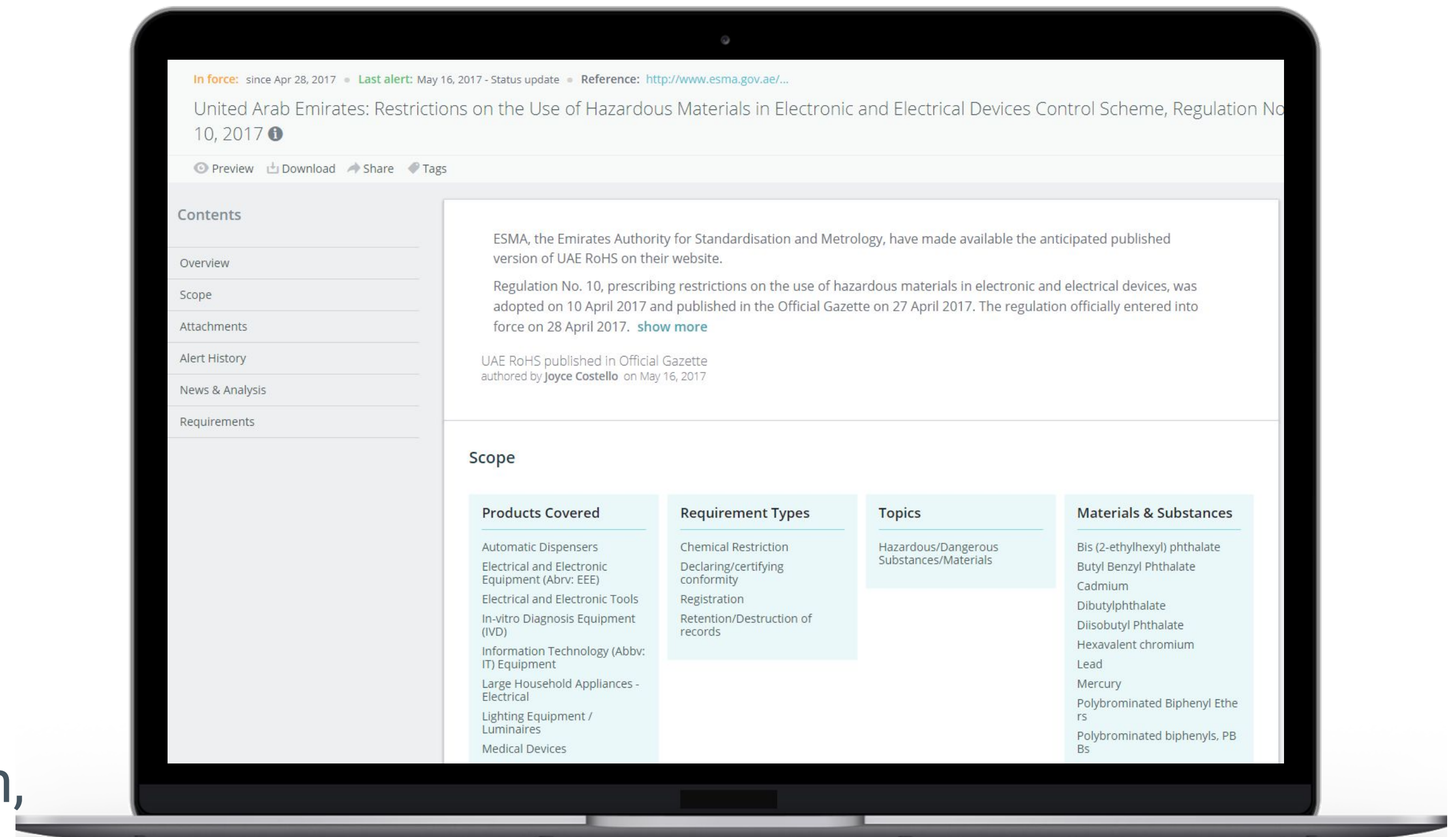
Managed Services



- Fulfil specific compliance functions
- Full suite of compliance skills
- 23 languages
- On-site and/or off-site delivery

Benefits for your Team

- **Sooner:** advanced warning of trends and proposed regulations
- **Faster:** understanding of regulations that matter with structured content, English summaries and the support of our regulatory compliance experts and knowledge partners
- **Better:** all relevant content in one platform, along with the team's analysis and actions



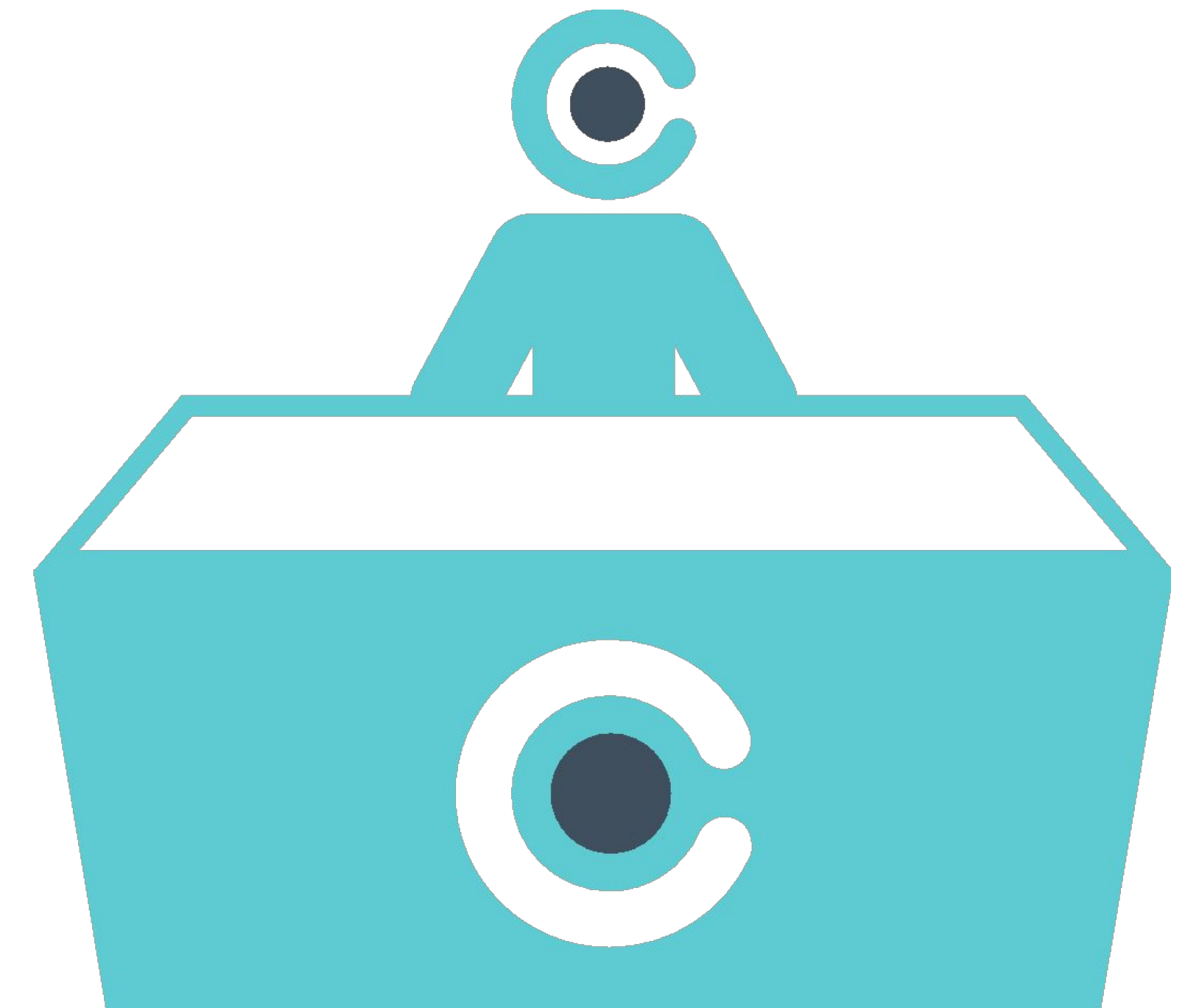
Answering Your Questions

Ask Our Experts

- Premier access to our global regulatory compliance team
- Your questions answered about regulations

Knowledge Partners

- Our global network shared with you
- Legal, business, supply chain and environmental specialists
- Providing 'on the ground' expert knowledge on hot topics
- Breaking news and analysis via your alerts



Compliance & Risks

Globally, we work with...



8 of the top 10
electronics companies



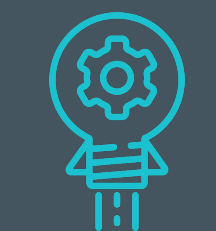
3 of the top 4
telecommunications
equipment companies



The top 4
computer vendors



The top 2
industrial machinery companies



5 of the top 10
best CSR companies

60,000+

In force & pending
regulations/documents

200

Regularly monitored
countries

30

Global Knowledge
Partners

23

Languages spoken
on the GRC team

1,686

Ask our Experts queries
answered in 2020

Industry sectors

Consumer goods and retail
Technology
Industrial goods
Life sciences
Public sector
Services providers

Awards



Inc. 5000 List of Europe's Fastest
Growing Companies 2017 & 2018



10 Fastest Growing Compliance
Solution Providers SR 2017



CIOReview Most Promising
Compliance Solution Providers 2018

Drinking Water Directive Recast



Drinking Water Directive 98/83/EC

- Its objective is to protect human health from adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean.
- It requires Member States to establish safety precautions to maintain safe water quality with Article 10 regulating materials in contact with drinking water.
- The DWD actions provide for a rather general EU framework setting quality standards and demanding that Member States ensure monitoring, compliance with the standards and provide the appropriate information to consumers. Concrete actions are left to the Member States

Problems with the Existing DWD 98/83/EC

- Multiple national requirements aiming at ensuring protection of consumers' health and the quality of drinking water and a lack of EU-wide harmonised provisions on materials and products in contact with drinking water and a non-harmonised European regulatory framework.

- Different national test methods and procedures for conformity assessment of the safety of materials and products in contact with drinking water and the high costs for hygienic testing of materials and products

Austria



Belgium



Finland



France



Problems with the Existing DWD 98/83/EC

- More than 15+ certification and test centers with their respective national test criteria, such as the products' compliance with materials composition or the effects of the materials on microbiological growth, differ to varying degrees
- Undermines free trade, conflicting consumer protection regulation and the current practice at present to demand compliance with national regulations when launching products in the domestic markets of individual states contravenes the principle of mutual recognition.

- [Mandate \(M/136\)](#) issued in 2001 by the Commission to the EU standardisation bodies (CEN/CENELEC) to establish common European standards at least for construction products in contact with drinking water such as pipes, tanks, fittings, safety devices, adhesives, joints, valves, taps, meters, pumps, membranes, water conditioning equipment inter alia.
- [4MS Initiative](#): Germany, France, the Netherlands and the United Kingdom of Great Britain and Northern Ireland agreed on collaboration in the harmonization of tests for the hygienic suitability of products in contact with drinking-water.

Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (Text with EEA relevance)



Article 11: "Minimum hygiene requirements for materials that come into contact with water intended for human consumption"

" 1. For the purposes of Article 4, Member States shall ensure that materials that are intended to be used in new installations or, in the case of repair works or reconstruction, in existing installations for the abstraction, treatment, storage or distribution of water intended for human consumption and that come into contact with such water do not:

- (a) directly or indirectly compromise the protection of human health as provided for by this Directive;
- (b) adversely affect the colour, odour or taste of the water;
- (c) enhance microbial growth;
- (d) leach contaminants into the water at levels that are higher than necessary in view of the intended purpose of the material.

2. For the purpose of ensuring the uniform application of paragraph 1, the Commission shall adopt implementing acts to establish the specific minimum hygiene requirements for materials that come into contact with water intended for human consumption on the basis of the principles set out in Annex V. (...) "

- ECHA working with the Commission currently to develop EU-wide positive lists of chemicals, compositions or constituents that can be safely used to produce materials that come into contact with drinking water within the domestic distribution system.
- ECHA will also be responsible for implementing risk assessment methodologies and information requirements for reviewing starting substances, compositions and constituents that could be added to the positive lists, as well as administrative procedures for the updating of the positive lists.

ECHA Timeline



- **12 July 2021:** Member states will submit their national positive lists, other provisions and available assessment documents.
- **12 January 2025:** The first European positive lists **adopted** - these will be based on existing national lists and are expected to cover around 1 500 chemicals for different types of materials. According to the ECHA, all entries in the lists will be reviewed within 15 years and the ECHA will prioritise substances for review based on their hazardous properties and the relevance of their risk assessments. It will also recommend expiry dates for them. ECHA have stated that they will continue keeping the lists up to date, by adding new entries and amending or removing existing entries. These lists are not static.

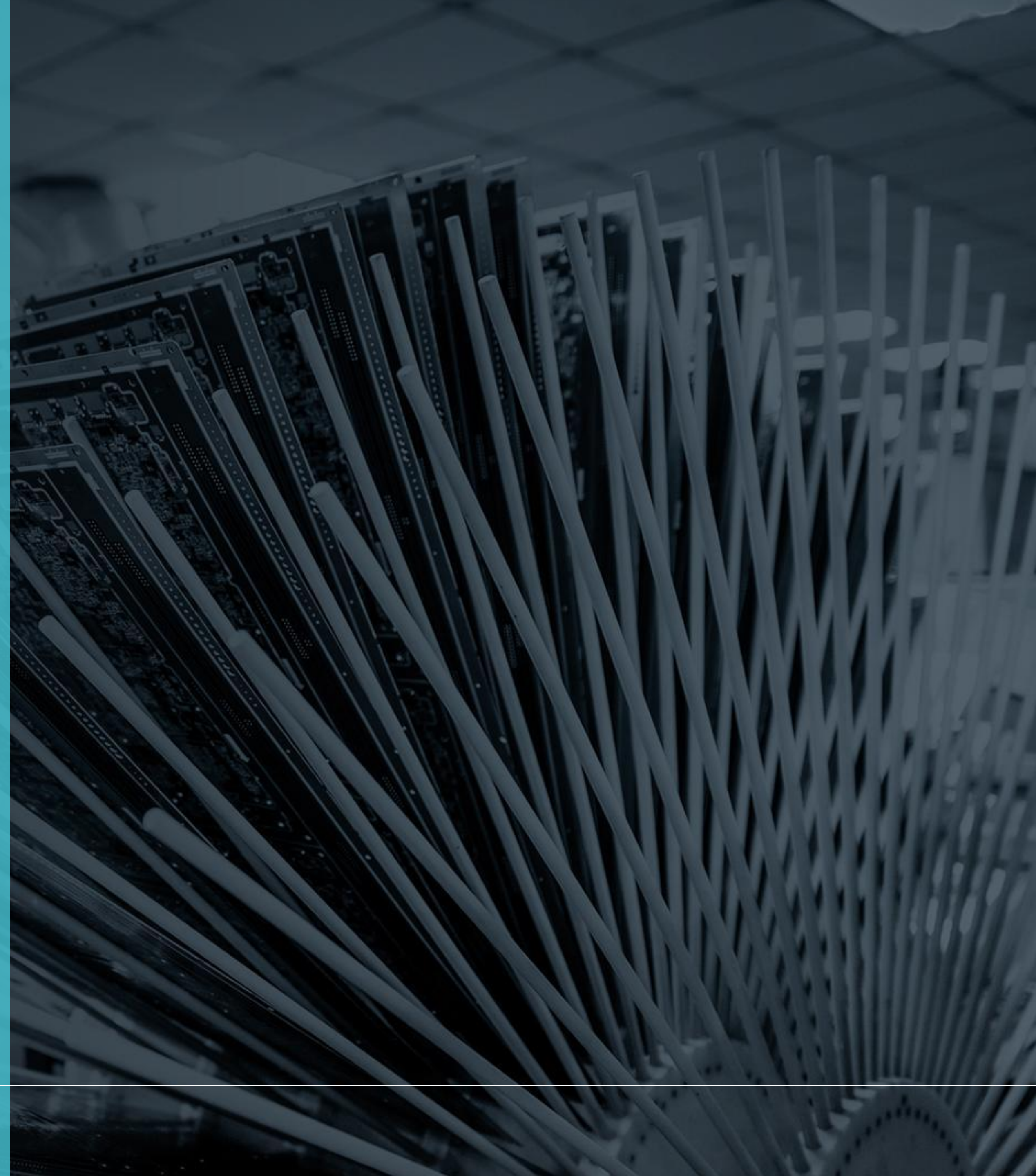
European Positive Lists - What to Expect?

- Per the “point of compliance” in the new DWD, any starting substance, composition or constituent used to manufacture a material that comes into contact with drinking water between the water source and the tap will need to be included in the European positive lists, After the tap, materials in contact with the water are managed under food safety regulations as a food contact material.
- Expected separate lists depending on whether a substance is organic, cementitious, metallic, enamels and ceramic or other another inorganic material etc. and limits may be potentially set on the concentration of a substance in water after leaving the tap however this has not not been confirmed.

*“The Commission shall adopt delegated acts in accordance with Article 21 in order to supplement this Directive by establishing harmonised specifications for a **conspicuous, clearly legible and indelible marking** to be used to indicate that products in contact with water intended for human consumption are in **conformity** with this Article”*

- Power to adopt these acts has been conferred on the Commission for a period of five years from 12 January 2021 and while there have been no specific information released regarding this marking/labelling requirement yet; it is important to note it is in the expected pipeline.

FCM Developments in UK & China



Outline

- The UK Development
 - New Guidance
 - AIMs and recycled plastic processes
 - New authorisations
 - Procedure
- China Development
 - Basic requirement
 - Positive list amendments
 - Declaration of conformity
 - Declaration of conformity - Final product manufacturers

The UK - New Guidance

- Guidance of Food Contact Materials Authorisation, 2020
- Specific regulations concerning:
 - plastic monomers and additives
 - active/intelligent materials (AIMs)
 - recycled plastic processes
 - regenerated cellulose film (RCF)
- Northern Ireland: continue to follow EU rules.

The UK - AIMs and recycled plastic processes

- At the present
 - the General Food Law Regulations
 - relevant criteria in the food contact materials' legislation
- From 1 January 2021
 - Applications for inclusion on the positive list can be submitted.
 - Transitional period is to be determined.

The UK - New authorisations

- Regarded Products Application Service
- The types of FCM requiring application:
 - plastic food contact materials
 - active and intelligent food contact materials (AIMs)
 - regenerated cellulose film (RCF) Material/Specific Regulations
- Materials required for application :
 - Samples, relevant data, analytical methods, Contact details

- 1. Complete the application form
- 2. Upload application documents
- 3. Send a sample and other relevant information
- 4. Include any supplementary documentation
- European Food Safety Authority (EFSA) guidance that relate to the development of dossiers remains relevant but not the application process.

China - Basic requirement

- GB 9685-2016
- Food Safety Standard for the Use of Additives for Food Contact Materials and Articles
- This is the most basic positive list published in China which contains 1,294 kinds of additives for food contact materials and products.

China - Positive list amendments

Types of changes:

- Adding new food contact additives
- Expanding use scope
- Adding new food contact resins.

So far, China National Health Commission has approved *133 types* of additives for food contact materials and products, including 61 types of additives for expanding the scope of use.

China - Declaration of conformity

Traceability of FCM - GB 4806.1

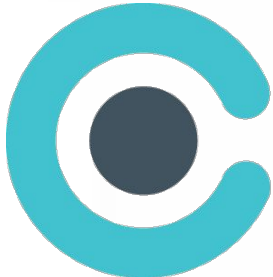
Compliance declaration documents for chemical substances to downstream - GB 31603

The declaration of conformity mainly contains basic information of the product, and the product technical information. It should provide the following information:

- Status of authorization;
- Use restrictions of food contact materials and products;
- Specific instructions on material safety and proper use (when applicable).

China - Declaration of conformity - Final product manufacturers

1. Request a declaration of conformity of chemical substances and intermediate materials from upstream;
2. Provide downstream customers with a declaration of conformity of the final product and retain supporting documents;
3. State the compliance of its products in the statement, and disclose substances subject to restrictions.



compliance & risks

Thank You

