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How to modernise Europe's regulations on chemicals in food contact materials

Chemical Watch Food Contact Regulations Europe 2020
11-12th February 2020, Brussels

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About CHEM Trust

- A charity working mainly at EU level to protect humans & wildlife from harmful chemicals
- Working with scientists, technical processes and decision makers, in partnership with other civil society group
- Focus on identification of, and action on, endocrine disrupting chemicals
- See our blog & twitter for more:
<https://chemtrust.org> @chemtrust

The screenshot shows the CHEMTrust website homepage. At the top left is the CHEMTrust logo with the tagline "Protecting humans and wildlife from harmful chemicals". To the right is a search bar with the placeholder text "Search the site ...". Below the logo is a navigation menu with the following items: Home, About us, Our work, Problem chemicals, Chemical impacts, Chemicals policy, and Take Action (which is highlighted in green). The main content area features a headline: "New investigation finds harmful PFAS chemicals in UK food packaging" with a sub-headline "February 11, 2020 By Julie Schneider". Below the text is a photograph of several cookies in a paper bag. On the right side of the page, there is a "Sign Up To The CHEM Trust Newsletter" form with three input fields: "First Name", "Last Name", and "E-Mail Address".



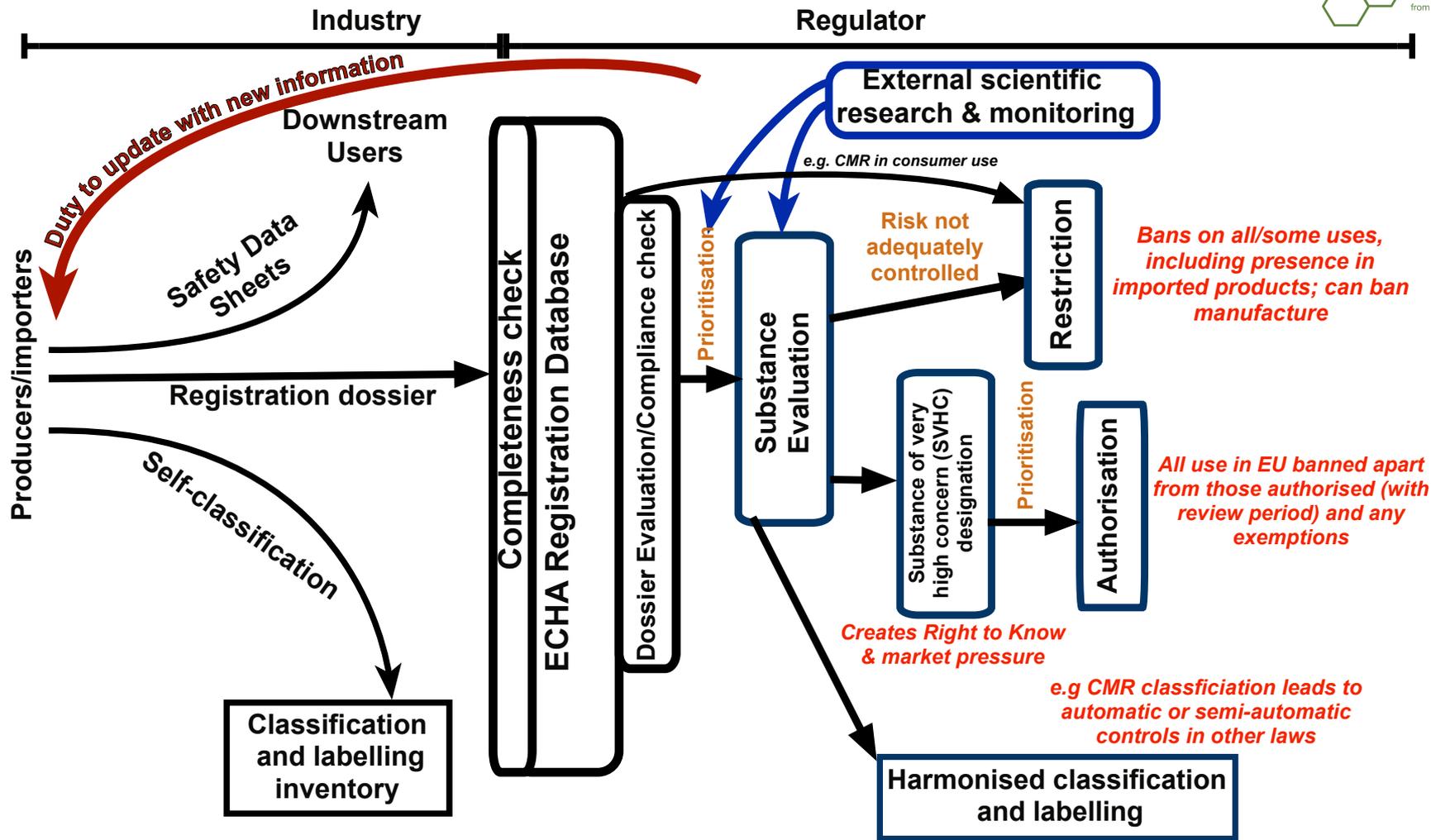
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Starting with REACH

- **REACH is the EU's main chemicals law**
- **Its creation was very controversial and many said that it would not work, there were too many chemicals etc etc**
- **REACH has worked – though it is not perfect and can be improved**
- **A major reason why REACH does work is the design of its core processes:**

CHEM Trust - REACH in one slide





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Reach is not perfect...some problems

- **Registration**

- Poor quality data
 - ECHA improving checks
 - “Echa is to quadruple the number of compliance checks it carries out to a fifth of all REACH registration dossiers”
- Lacking data on neurodevelopmental impacts – see chemtrust.org/brain

- **Evaluation**

- Too slow
- Too easy for industry to create delays e.g. by appealing or not delivering data

- **Restriction**

- Too slow
- Not enough grouping
- Little consideration of mixtures
- Too many exemptions

- **SVHC & Authorisation**

- Too slow
- Not enough grouping
- Safer alternatives not always recognised



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FCM: An old, unreviewed, law

- **The EU's overarching 2004 law on “*on materials and articles intended to come into contact with food*”**
 - This includes a general safety requirement:
 - “Materials and articles, ... shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not **transfer their constituents** to food in quantities which **could**:
(a) **endanger human health**;...”
 - This text originates from the EU's 1976 law on the issue
- **EU Commission has stated that the regulatory approach in this area has not been systematically assessed since it was introduced in 1976**
 - and that there has been ‘*No formal evaluation work or reports*’ done on the 2004 legislation - a huge contrast to other aspects of chemicals policy*

* Evaluation of legislation on Food Contact Materials - Regulation (EC) No 1935/2004, November 2017
http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429_en



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Time lines of REACH & FCM

Year	REACH	Food contact
2004		Framework law enters into force
2007	Enters into force	
2011		Plastics law enters into force
2012	First REACH review	
2017	Second REACH review	
2018	Final REACH phase-in deadline	Review of FCM laws starts



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Review and improve?

- **Many EU laws – e.g. in environmental policy – are reviewed every 5 years**
 - Reports are commissioned, improvements developed
- **What if the FCM law had been like this?**
 - 2009: **First report on effectiveness, first adaptation to REACH**
 - 2014: **Second report on effectiveness, relationship with REACH improved**
 - Now: **Third review concluding, some tweaks to the law**
- **But FCM law is not like other laws....**



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Some issues with EU FCM laws

- **Positive list of chemicals for plastics & a few other materials**
 - Data submitted, approved by EU regulator EFSA, not really updated
- **No EU positive list for other materials like paper, card, inks, glues, coatings**
 - Some national laws e.g. German Paper, Swiss ink, Dutch coatings
- **Plastic recycling processes regulated at EU level (at least in theory)**
- **Other recycled materials (e.g. paper) not covered in EU level regulation**
- **No direct link to REACH e.g. data sharing, controls on SVHCs**



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“Specific measures”

- **The 2004 Regulation has a provision for “Specific measures” on materials in Annex 1**
- **Santé/EFSA have failed to deliver on the vast majority**
- **Paper and other materials are not a new FCM, though the move away from plastic has made them more important**

ANNEX I

List of groups of materials and articles which may be covered by specific measures

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood



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The CHEM Trust view in Jan 2016



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Policy
Briefing

**Chemicals in food contact materials:
A gap in the internal market, a failure in public
protection**

1 Executive summary

Food packaging, factory equipment, food utensils - almost everything we eat has been in contact with one or more of these items. The EU's laws should ensure that chemicals used in these materials are safe, but they do not go far enough and contain holes.

These holes – for example a lack of harmonised rules on paper and card, inks, coatings and adhesives – mean that public health is not properly protected, and also lead to disruption of the internal market.

This briefing outlines the key problems, and proposes some solutions.

1.1 Key problems and recommendations:



For many food contact materials – including paper, board, coatings, inks and glues – there is no harmonised EU legislation on the chemicals that can be used. There are harmonised rules on food contact plastics and some other materials.

- There is also no obligation to assess the health impacts of uses in food contact materials in the EU's main chemicals legislation REACH.
- Research has found that chemicals identified as being of very high concern (SVHCs) in REACH are used in food contact materials.
- Public health is not being effectively protected.



Regulation of chemicals in non-harmonised materials is dependant on national legislation. This is inefficient and disrupts the EU's internal market.

- It's estimated that more than 5000 chemicals are used in inks, and Germany is working on an inks ordinance. If Germany bans inks used in other EU countries, how will this affect the internal market in food products?



In addition to thousands of deliberately used chemicals, a wide range of other chemicals migrates into food from food contact materials.

- These 'Non Intentionally Added Substances' (NIAS) come from impurities in chemicals, and reaction and degradation products. They are often of unknown structure, and can be at levels far higher than pesticide residues.
- NIAS add to the complexity of the mixture of chemicals we are exposed to, and need to be addressed with urgency.

It's clear that the current situation is not tenable, either for public health or for the food industry. The European Commission – led by DG Santé – must now work on a harmonised system, that will provide a high level of protection for human health, and also facilitate the effective working of the internal market.

Without a new approach the risks to public confidence in Europe's food system and food manufacturers are high. There is no scientific justification for inaction in this area.

CHEM Trust briefing:

“Chemicals in food contact materials: A gap in the internal market, a failure in public protection”

Recommendations include:

- Harmonised regulations for chemicals in paper, card, inks, adhesives, coatings
- Action to substitute SVHCs and EDCs with safer alternatives
- Assessment of NIAS

<https://chemtrust.org/foodcontact/>



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Building pressure for a review

- **CHEM Trust wrote to Commissioner Borg in July 2014 pointing out the inadequacies of FCM regulation – we have continued to highlight these deficiencies.**
 - See <http://www.chemtrust.org/food-contact/>
- **European Parliament passed a detailed report calling for improvements in October 2016**
- **A detailed & very critical report from the Commission's Joint Research Centre was published in January 2017**
- **The Commission finally published a draft 'roadmap' for an 'Evaluation' of EU FCM laws in Nov 2017, appointed consultants Ecorys in 2018 & organised a stakeholder event in September 2018**



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A review of the FCM law

- **Current EU review has been looking backwards**
 - i.e. how is current law working (badly!)
 - Now unclear when it will be published as a result of apparent move to next stage of process
 - NB: EU also looking at how EDCs are addressed by chemical laws in a separate (but linked) review
- **New European Commission has prioritised “European Green Deal”, including increased action on chemicals**
 - This is providing additional momentum for real reform
- **A full review provides the opportunity to create a more protective and effective system**



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Commissioner Kyriakides accepts the problem

“it is clear that many stakeholders have concerns, particularly regarding the lack of specific rules in areas other than plastic FCMs and the need to ensure prioritisation and coherence with other legislation as regards the regulation of substances migrating FCMs at EU level.

Preliminary evaluation results also demonstrates issues with the current approach to regulating plastic FCMs as well as gaps in information flow and compliance in the supply chain and enforcement of the rules by Member States...

I am very keen to ensure that we take action where necessary in order the maximise the protection of human health” - letter to CHEM Trust, Feb 20

– <https://chemtrust.org/kyriakides-reply-fcm/>



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Seeking solutions

- CHEM Trust has organised two workshops examining the role that the EU's REACH chemical regulatory system could have in improving EU regulations on chemicals in Food Contact materials; both were attended by representatives of the European Commission, ECHA and others:
 - March 2016: <https://chemtrust.org/overlap-gaps-fcmlaws/>
 - September 2019: <https://chemtrust.org/workshop-fcm-reach/>
- **For more on our work on chemicals in food contact materials, see <https://chemtrust.org/food-contact/>**



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Working to establish principles

- **CHEM Trust led the development of “5 key principles for a new law” with other NGOs**
- **These principles are supported by groups including:**
 - Client Earth, EEB, HEAL, ChemSec, Zero Waste Europe
- **The principles:**



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<https://chemtrust.org/5-key-principles-fcm/>

Five key principles for new EU FCM laws:

- **A high level of protection of human health**
 - All substances used in food contact materials should have adequate safety data, provided by industry and should be regularly reviewed for this use by public authorities.
 - The presence of substances that are already restricted in the EU, and those meeting the REACH criteria for Substances of Very High Concern.. should be automatically prohibited.
- **Thorough assessment of chemicals in materials and final articles**
 - The presence in, and migration of, chemicals in food contact articles – including Non-Intentionally Added Substances (NIAS) – should be measured, assessed and controlled.
- **Effective enforcement**
 - National governments must ensure effective enforcement, including checks on both imported and EU-manufactured finished articles using the best available analytical methods.
- **A clean circular economy based on non-toxic material cycles**
 - As the EU's transition to a circular economy gains momentum, it is vital that the EU's efforts to encourage recycling do not perpetuate the use of harmful chemicals in FCM.
- **Transparency and participation**
 - Supply chains and final consumers should have a right to know the identity and safety information t on chemicals used in, and migrating from, food contact materials. Regulatory and policy processes should as a minimum adhere to the same standards of openness and stakeholder participation that have been established in REACH.



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One specific example

- **This talk is focussed on the overall regulations, not lots of examples of failings**
- **But here's one:**

- **PFAS, particularly in paper & board:**



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PFAS “Forever chemicals”

- **PFAS are a large group of persistent & mobile chemicals, which are found everywhere – often called “Forever chemicals”**
 - Two are being globally controlled (PFOS and PFOA), but thousands aren’t controlled
- **Getting increasing attention**
 - Dutch proposing wide-ranging restriction
 - New film out soon - “Dark Waters” – very powerful
- **More info: <https://chemtrust.org/pfas/>**



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PFAS in food packaging – new tests

Data from FIDRA, 11th Feb
2020
<https://www.pfasfree.org.uk>

Moulded fibre “labelled as
sugarcane or begasse”

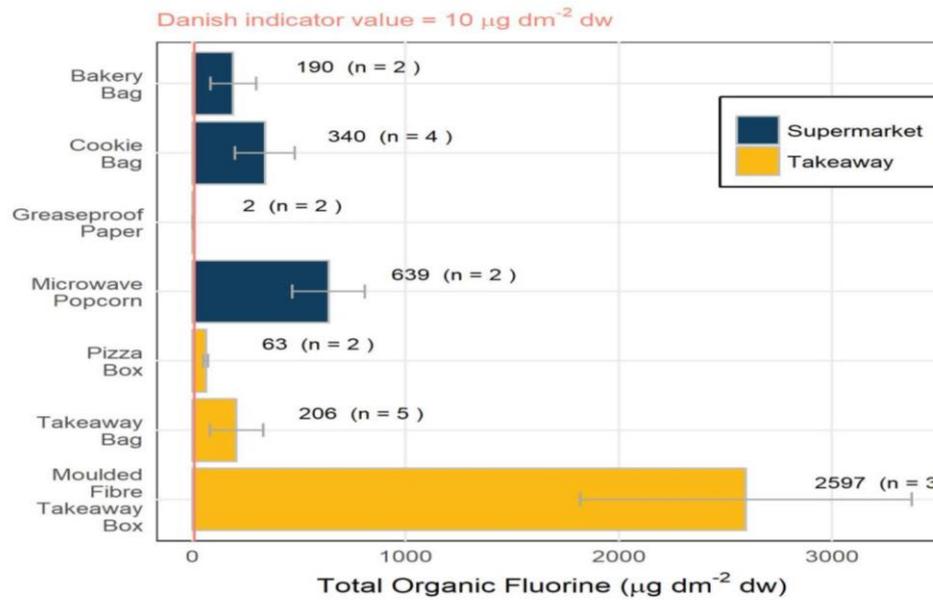


Figure 3. Results from Total Organic Fluorine (TOF) testing. Values indicate category mean and sample size. Bars represent mean concentrations \pm standard error of the mean. The value of $10 \mu\text{g dm}^{-2} \text{ dw}$ is designated by the Danish authorities as background contamination.



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Recast of Drinking Water Directive

- **Final text about to be agreed**
- **ECHA to compile & manage a list of chemicals**
 - First positive list (?1500) adopted by Commission in 2024
 - Will all be reviewed over 15 years (in three prioritised batches);
authorisations will be time limited
 - Procedures to add new chemicals, and for removal
- *“we can rely on our expertise in risk assessment, achieve efficiencies and ensure consistency across different pieces of chemicals legislation. Harmonising the assessment also ensures a level playing field for companies providing these materials across different European countries” – Bjorn Hansen, Exec Dir ECHA*
 - <https://echa.europa.eu/-/echa-starts-work-on-making-drinking-water-safer>



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A risk: Brexit

- **Up to now the UK has only implemented EU harmonised rules on chemicals in FCM**
 - Could have gone further, like Germany or Denmark, but they didn't
 - This has been useful for companies to place products on the market in the UK & then sell them across the EU using 'mutual recognition'
 - this will no longer be possible
- **What next?**
 - The UK has copied out existing EU law, but then who knows...
 - Will depend on EU trade deal 'level playing field' requirements, EU import controls and UK trade deals with other countries
 - A risk that the UK could deregulate – the level playing field is vital, but our ideal scenario is to keep the UK attached to the REACH system



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Pointers to a new approach

- **The new system needs to learn from what does work in the current system, what works in REACH and the other models that exist (e.g. drinking water contact chemicals)**
- **It should avoid bottlenecks and over-complex processes**
 - E.g. should an independent scientific committee have to review every chemical before it goes on a positive list?
 - Or should the positive list be a pool that is regularly reviewed in a prioritised way?
- **One idea – split the positive lists from the more complex scientific issues:**



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A thought starter (*not an agreed position*)

Managing FCM positive list

- Based in ECHA
- Similar to Drinking Water Contact model
- Covering **substances** in all materials

FCM scientific assessment

- Based in EFSA
 - plus JRC research assistance
- Dealing with scientific questions around FCM **materials & articles**
- E.g. NIAS, migration testing guidance, safety of final food contact articles



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Conclusions

- **The shift away from plastic is demonstrating the lack of a comprehensive EU approach**
- **We need a confirmation from the Commission that a new approach will be urgently developed**
- **There must be an open and transparent process to develop this new approach, with the aim of creating a protective and effective system**
- **It must be both enforceable & enforced – ensuring a level playing field & that the public are protected from the worst of sector, including imports.**
- **The EU should immediately start using REACH to its full potential e.g. through addressing FCM uses in Restrictions (e.g. phthalates), rather than excluding them.**