

# The European Commission's science and knowledge service

Joint Research Centre

## Developments in EU FCM Regulations

Eddo Hoekstra, Bastiaan  
Schupp



European  
Commission

# The European Union: 500 million people – 28 countries



Member States of the European Union



Candidate countries and potential candidates



## **The European Parliament**

- **voice of the people**

Antonio Tajani, President of the European Parliament



## **The European Council and the Council**

- **voice of the Member States**

Donald Tusk, President of the European Council



## **The European Commission**

- **promoting the common interest**

Jean-Claude Juncker, President of the European Commission

# The EU institutions



European Council (summit)

European Parliament

Council of Ministers  
(The Council)

European Commission

Court of  
Justice

Court of  
Auditors

Economic and Social  
Committee

Committee of the  
Regions

European Investment Bank

Agencies

European Central Bank

# How EU laws are made



Citizens, interest groups, experts: discuss, consult



Commission: makes formal proposal



Parliament and Council of Ministers: decide jointly



National or local authorities: implement

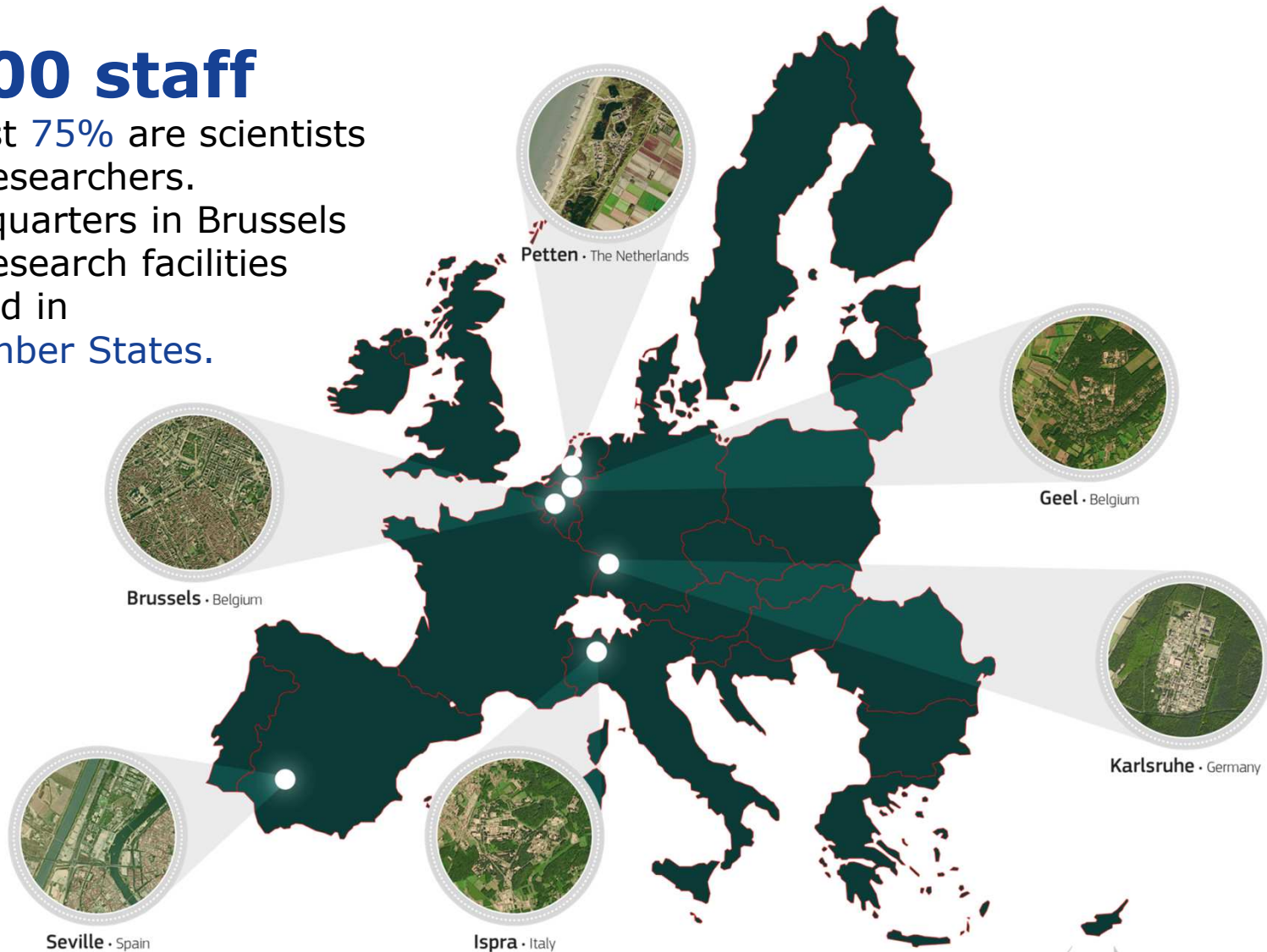


Commission and Court of Justice: monitor implementation

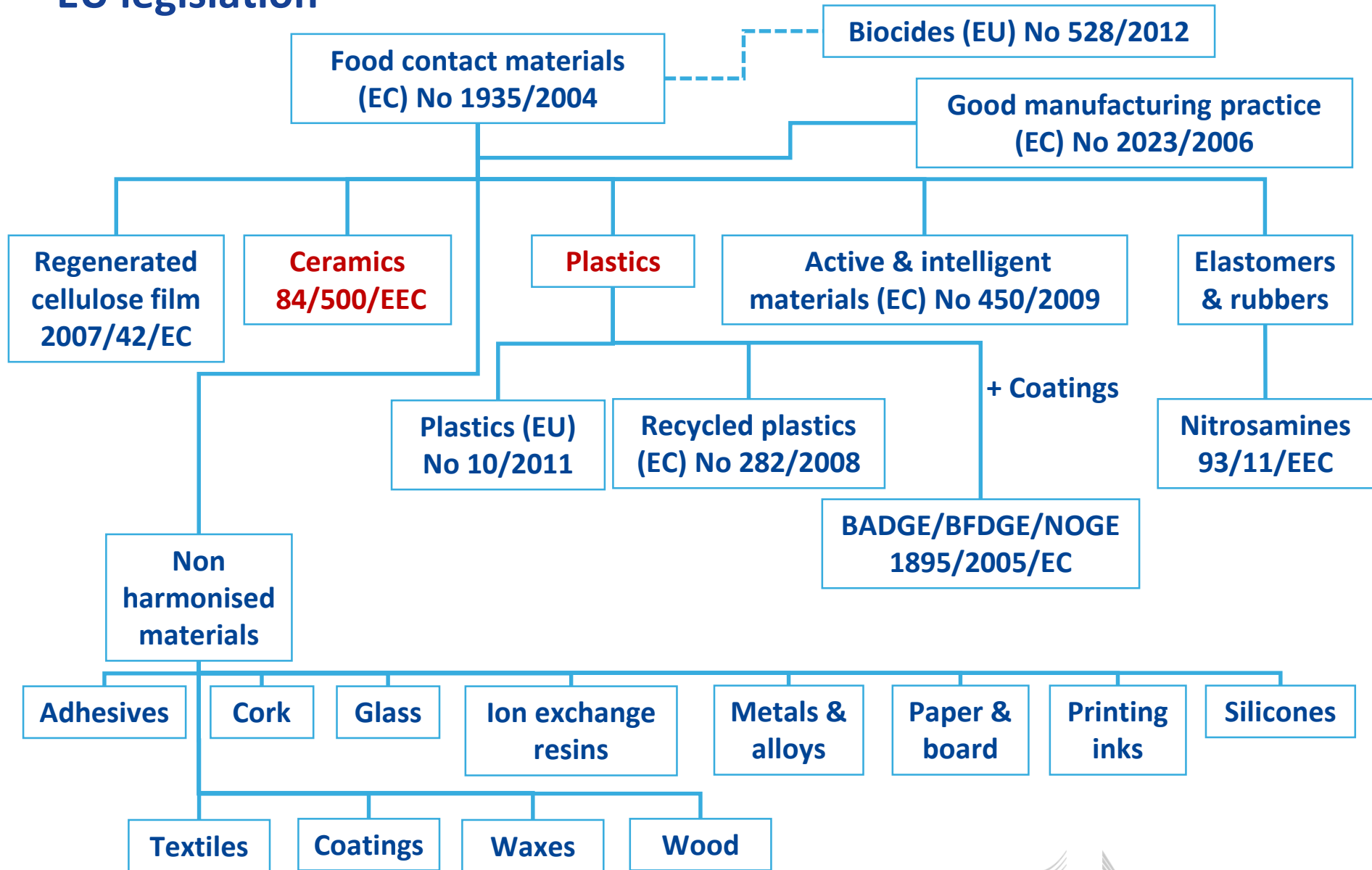
# The Joint Research Centre at a glance

## 3000 staff

Almost 75% are scientists and researchers.  
Headquarters in Brussels and research facilities located in 5 Member States.



# EU legislation



# Developments in EU FCM regulations

- **6<sup>th</sup> amendment of Plastic Regulation (EU) No 10/2011**
- **Commission Recommendation (EU) 2017/84 of 16 January 2017 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food**
- **7<sup>th</sup> amendment of Plastic regulation (EU) No 10/2011 upcoming**
- **Regulation on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials**
- **Evaluation of 40 years of FCM legislation**
- **Study on information transfer in supply chain**
- **Printed FCM**
- **Recycling**



# Mineral Oils (MOH)

## Recommendation

- **Member States should monitor the presence of MOH in food and FCM during 2017-2018.**
  - active involvement of food business operators and manufacturers, processors and distributors of FCM and other interested parties
  - animal fat, bread and rolls, fine bakery ware, breakfast cereals, confectionery (including chocolate) and cocoa, fish meat, fish products (canned fish), grains for human consumption, ices and desserts, oilseeds, pasta, products derived from cereals, pulses, sausages, tree nuts, vegetable oils
- **Following guidance of EURL to ensure uniform application of this recommendation and in order to generate reliable and comparable results of the monitoring**
- **Member States should perform food sampling in accordance with the provisions laid down in Commission Regulation (EC) No 333/2007**
- **Sampling should include a proportionate number of pre-packaged foods**
  - focus on commodities that are closer to the end of the minimum date of durability
- **The samples should be analysed as marketed**

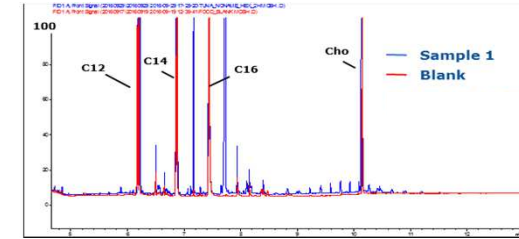
# Mineral Oils

## Food

- Member States should carry out further investigations in the food business establishments in order to determine the possible source in food

## Pre-packed food

- MOH should be determined both in the food and in the FCM if that is the suspected source of detected MOH
  - Particular attention should be paid to the differences between MOSH and MOAH
- Sources of MOH related to storage or processing, should be investigated if relevant
  - Focus on relatively warm conditions
- If MOH detected, collection of data on the FCM
  - e.g. type and composition of the packaging material, presence of functional barrier, shelf life of the packaged food
  - carry out further investigations in the establishments of the manufacturers, processors and distributors of food contact materials



## Reporting to EFSA

# Bisphenol A

- **In plastics (10/2011) and varnishes and coatings**
- **Current specific migration limit (SML) of 0.6 mg/kg of food**
  - Possible lower limit on basis of EFSA opinion
- **Plastics:**
  - No use as additive
  - Use as monomer or other starting material
  - Not to be used for the manufacture of polycarbonate infant feeding bottles
- **In order to verify compliance with the SML, the rules laid down in, Article 18(1), (2), (3), (6) and (7), Annex III and Chapters 1, 2 and 4 of Annex V to Regulation (EU) No 10/2011 shall apply.**
- **Test results shall be expressed in accordance with the rules laid down in Article 17(1) to (3) of Regulation (EU) No 10/2011.**
- **business operators shall ensure that varnished or coated materials and articles are accompanied by a written declaration of compliance**
- **Supporting documentation shall be available**

# FCM EVALUATION

# FCM Evaluation



## *Ex-post evaluation*

- **FCM legislation is 40 years** (Directive 76/893/EEC)
- **Is it effective, efficient and sustainable?**
- **Focus at level of Framework Regulation**

## *Objectives:*

- **To understand whether EU procedures are adequate**
- **To prepare possible further harmonisation**

### *Article 2*

Materials and articles must be manufactured in compliance with good manufacturing practice, so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could :

- endanger human health,
- bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.

### *Article 3*

The Council shall, under the procedure provided for in Article 100 of the Treaty, adopt by means of Directives special provisions applicable to certain groups of materials and articles (specific Directives).

Such specific Directives may include :

- (a) if possible and if necessary, a list of the substances the use of which is authorized to the exclusion of all others ;
- (b) purity standards for such substances ;
- (c) special conditions of use for these substances and/or the materials and articles in which they are used ;

# Why evaluate?



*40 years old legislation, never evaluated*

*Does it function correctly?*

- **Non-harmonised**
- **Risk Assessment**
- **Information exchange in supply chain**
- **Difficulties with implementation and drafting of new legislation → e.g. how to risk assess 8000 substances**

*Very little concrete evidence available*

- **JRC study provides clear evidence on non-harmonised**
- **Otherwise it is difficult to substantiate perceived problems**





*Use of compliance information in the supply chain*

# **STUDY**





## **Study:** information transfer in supply chain

*Transfer of information on composition important for safety*

- **e.g. to facilitate testing**

*Does this mechanism function?*

- **Declarations of Compliance + Supporting documentation**
- **our feeling is that the functioning of this mechanism could be improved**
- **efficiency of restrictions; safety of plastic materials**

*Why?*

- **to understand the functioning of the plastics Regulation**
- **to inform future harmonised measures**







*A new harmonised measure*

# **PRINTED FCM**



# Printed FCM



## ***New harmonised measure on printed FCM by mid 2018***

### *Prioritisation – health concerns*

- **German notification, scientific study (napkins)**

### *Initial Scope*

- **printed food contact materials**  
**= printing inks + food contact materials that are printed**

### *Simplification*

- **information in the supply chain and compliance**
- **possibly over 5000 substances involved**



# Paper and Board



*Paper and Board is main printed FCM*

- **Testing for PI compliance on final material: paper and board**

*Issues?*

- **Lacks the barrier properties of plastic**
- **Lacks well defined testing approach**
- **Potential presence of PI in recycled paper & board**

*Hence, P&B cannot be ignored when considering PI*

- **The measure will be on Printed FCM (P-FCM)**

*NO new compositional rules for paper & board itself!*



# State of Play



*Clear commitment to develop the Regulation by mid-2018*

- **Legal basis: Article 5 of Regulation 1935/2004**

*Information phase before summer*

- **Gather information**
- **First information request send to EU stakeholder associations**

*Summer-Autumn*

- **Develop credible options for a Regulation**

*Winter 2017-2018*

- **Draft text**





*120 Decisions on*

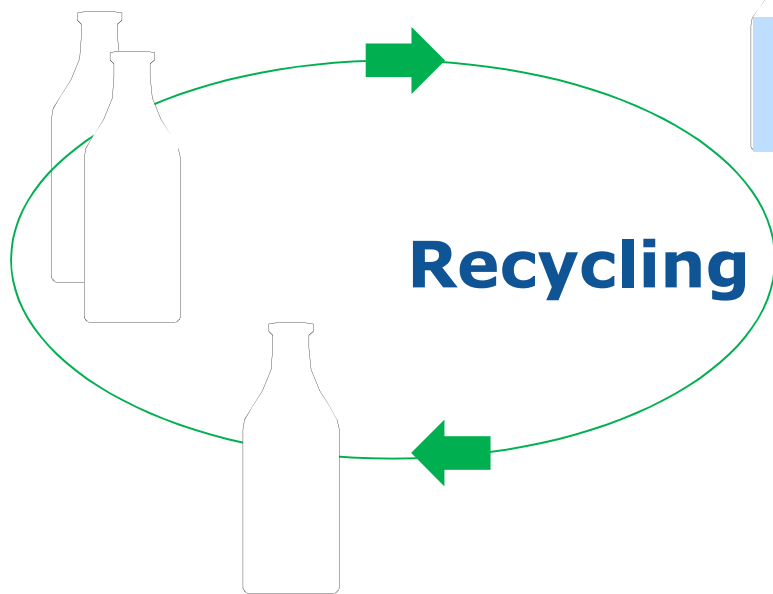
# **RECYCLING**



# Why Regulate recycled plastics?

## "virgin" Plastic

*Plastic compliant  
with **Reg. 10/2011***



⇒ plastic packaging  
waste

residues/contaminants

- previous use

(e.g. food, shampoo)

- "misuse" (e.g. paint,  
detergents)

- non-food use  
material

(non-authorized substances)



## *Plastic*

- **Regulation (EU) No 10/2011**
- **Specifies the permitted composition of the plastic**
- **When placed on the market migrants are known, risk assessed and controlled**
- **During control, the migration limits and documentation are verified**

## *Recycled Plastic*

- **Regulation (EC) No 282/2008**
- **During use plastic can be contaminated with unknown contaminants**
- **Only a recycling process that sufficiently decontaminates is permitted**
- **Control: is the process as authorised, and is it operated accordingly?**
- **No laboratory control is possible**

# Recycling Process



## *Restrictions on Input, Process, output:*

- **Input:** source of the plastic, washing, shape (d)
- **Process:** unit operations, critical steps, parameters (e)
- **Output:** max percentage, conditions of use (f, g)

## *In addition prescriptions on monitoring (h)*

(letters refer to Article 6(3) of Regulation (EC) No 282/2008)



# State of Play



*EFSA has published the Opinions*

- **Initial authorisation phase completed in 2015**
- **Evaluations are on-going, new processes**

*Authorisations are delayed for several reasons*

- **Drafting process is now finally advancing**

*Three main activities:*

- **Drafting of 120 individual Decisions**
- **Resolution of certain problems**
- **Drafting of Guidance and Compliance Monitoring Summary Sheet format**



# Controlling the process

European  
Commission

*Goal: recycled plastic safe for human health*

- **cleaning efficiency is met**

*Achieving compliant operation*

- **the technology is as in the application**
- **it is operated in accordance with the authorization**
- **i.e. parameters of critical process steps are respected**
- **monitoring**

*Auditing – verifying compliance*

- **controlling whether the technology complies**
- **controlling whether each batch is compliant**

*Documentation – being able to audit*

- **description of process**
- **traceability of batches**
- **based on monitoring**



# Stay in touch



EU Science Hub: [ec.europa.eu/jrc](https://ec.europa.eu/jrc)



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