p-FCM

Regulating Printed Food Contact Materials

- Problem definition
- Elements for legislation
- Way forward

5 May 2017

OVERVIEW

State of play

The problem of regulating printed FCM

Two models

- **The traditional approach (Plastics Regulation)**
- **Designated bodies**

Initial scope

Way forward

State of Play

Summer 2016 German notification on printed-FCM

- **Commitment confirmed in autumn**

Preparatory work has started

- **internal procedures + options**
- **first consultation with industry on present rules**
- **decision to cover printed FCM – not printing inks**

Ready by mid 2018

Rationale

- **Health concerns – German notification + JRC study**
- **EU measure more effective in protecting health**

Scope of the p-FCM project

Objective:

- **to protect against constituents of printing inks**

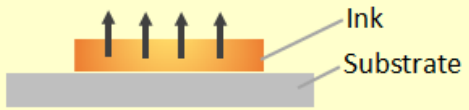
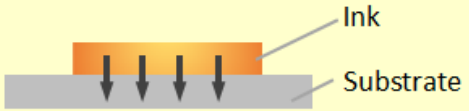
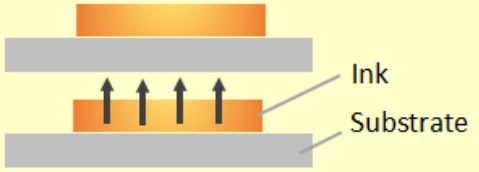
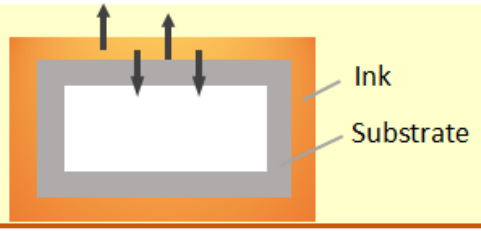
Printing is applied on substrates

- **substrates are covered with respect to the applied inks**
- **verification of compliance on substrate**

Other matters regarding scope addressed later

- **different printing techniques (e.g. thermal paper)**
- **dyes, colorants**
- **processing aids for printing (e.g. mineral oil)**

Printed FCM

What is migration?		
1	**Direct Migration** Direct migration from print to the food, in situations where the food is in direct contact with the print	
2	**Through Migration** Penetration through the substrate to the reverse side of the print	
3	**Set-off Migration** Set-off from the print to the reverse side while being stored in a pile or reel	
4	**Gas Phase migration** Volatilisation and condensation of components after heating	

Example from EUPIA GMP guideline

The problem of regulating p-FCM

Point of Compliance:

- **(small) Food Business Operators**

Complex supply chain

- **communication**

Number of substances

Combination with other materials

- **(recycled) paper and board**

Missing rules for verification of compliance

- **equivalent to Article 17, 18, Annex III and V of R 10/2011**
- **no known analytical methods – CoE to start on inventory**
- **technically challenging**

Ensure transparent risk assessment

I: Compliance at the FBO

Example: A small bakery

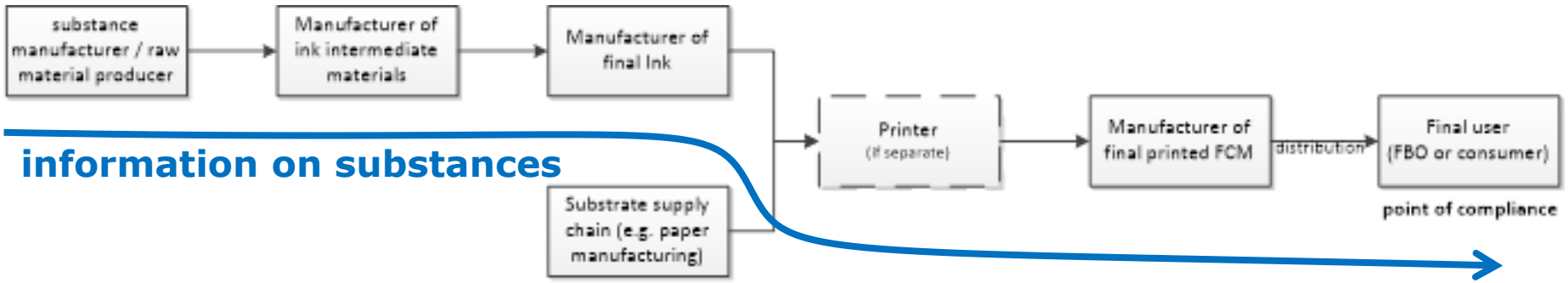
- **the baker prints logos on bags and other paper FCM**
- **the baker *designs* the bags, and has them printed**
- **printing ink on outside and possibly inside of packaging**

The bakery is the point of compliance

- **usage conditions known: food, time, temperature**
- **competent Authorities may control the bakery**

How should a baker comply to a Regulation on printing inks?

II: Complex supply chain



Final FCM needs to comply

- **legal certainty must be ensured**

Throughout supply chain communication on

- **composition**
- **conditions of use**

Complicated by

- **confidential information, liability disclaimers**
- **lacking standards and sheer complexity**

III: very large Number of Substances

Positive listing of suitable substances:

- **important tool under Regulation 1935/2004**

How many?

- **Germany list >700 substances**
- **Switzerland has inventory of ~5000 substances**
- **10 ppb limit, NIAS, …**

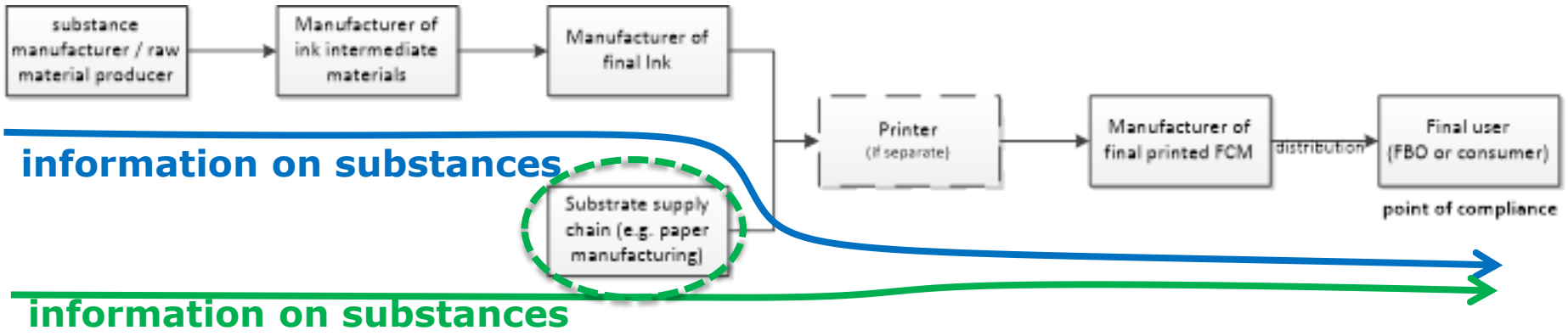
Mandatory procedure for positive listing

- **Regulation 1935/2004: EFSA shall evaluate each substance**
- **historical rate plastics is 25/yr**
- **significant allocation of resources, long term management**

Efficiency in doubt

- **Evaluation of substances for manufacturing**
- **Compliance in final material**

IV: presence of substrate



Substances in Final FCM from

- **printing inks**
- **substrate(s): plastic, paper + board, adhesives + coatings**

Paper and board particularly complex

- **natural material**
- **printing inks present after recycling**

Compliance problems further complicated

- **methods for combined materials**
- **further liability and legal certainty issues**

V: Missing rules for verification of compliance

Article 17, 18, Annex III, V of Regulation 10/2011

- **+complex guidance**

Common rules necessary for legal certainty

- **certainty for industry, as well as competent authorities**

Not easy to create

- **30 year unfinished project for plastics**
- **missing analytical methods** (10 ppb limit for many substances)
- **existing rules and guidance help to an extent**
- **migration modelling, partial overlap with plastics?**
- **CoE work?**

Documentary evidence also important for verification

- **migration modelling**

VI: Transparency of risk assessment

EFSA evaluates substances

- **Generally very transparent**

FCM manufacturers have a big role in risk assessment

- **generally under Article 3**
- **under R 10/2011 everything under Article 19, e.g. NIAS**

- **<u>ensuring that the final material is safe</u>**
  (modelling, conditions of use, foreseeable use, …)

in printed FCM this transparency needs to be ensured

- **enforceability and safety**

The problem of regulating p-FCM

Clarifications?

Discussion?

Coffee?

Solutions to Regulating p-FCM

2 serious options

- **several option have been considered internally**

Traditional structure of Regulation 10/2011

- **presently considered problematic**

New Approach based on designated bodies

- **selected for further development**

Solution I, the traditional model

Scope + definitions

Rules on composition

- **general rules**
- **positive list** — several decades work
- **(list of) limits** — procedure not clear, significant work
- **specific provisions on materials**

Rules on documentation

- **declaration of Compliance**
- **supporting documentation**

significant work
problems hard to resolve

Rules on verification of compliance — resources not available

Solution II: using designated bodies

Essentially a new approach to compliance

Shift in responsibilities to designated bodies

Rule base directing the work

- **legislation, standards, guidance, internal rules**

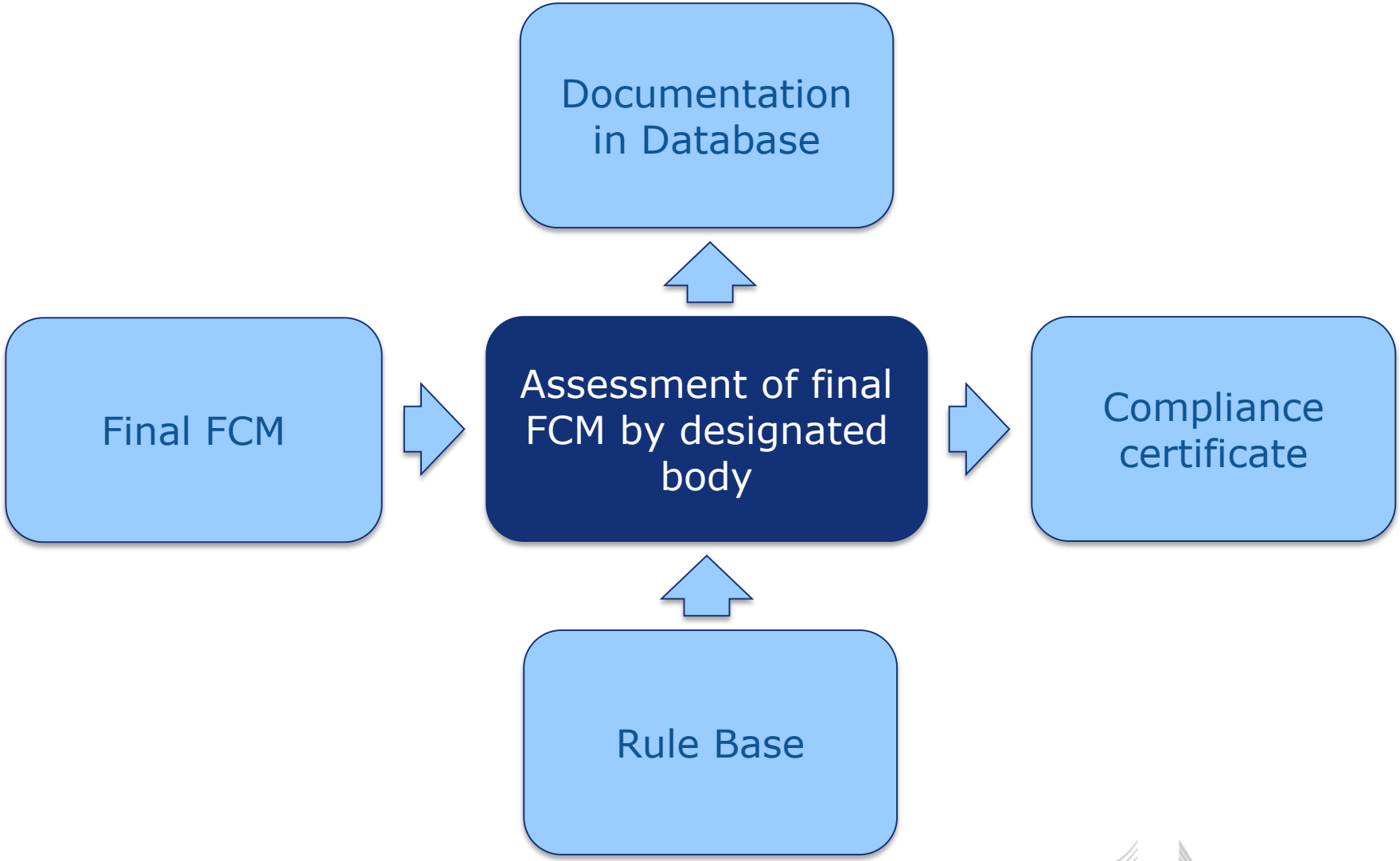
Central database

- **to facilitate exchange of information in supply chain**
- **accessible by public authorities**

Governance committee

- **Commission, Member States, Designated bodies, Stakeholders**

Designated body: compliance work



Designated body

Designated by Member States after accreditation

- **Commercial laboratories**
- **Other consultants**

Independent from FCM manufactures

- **impartiality and confidentiality**

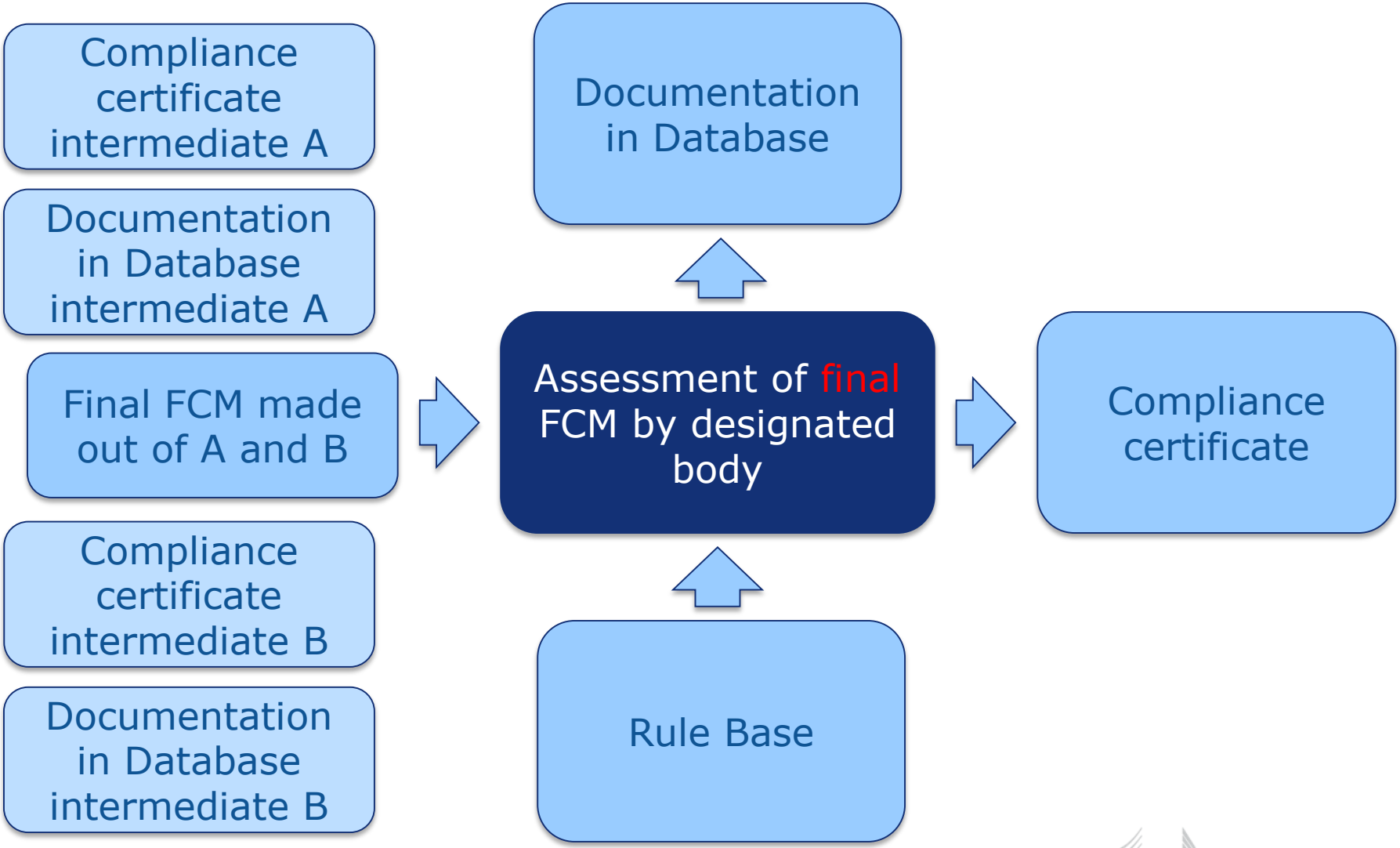
Responsible for certifying compliance work

- **at each stage of manufacturing**
- **they can also carry out the compliance work**
- **possibly some self-certification (FBO's, retail, distribution)**

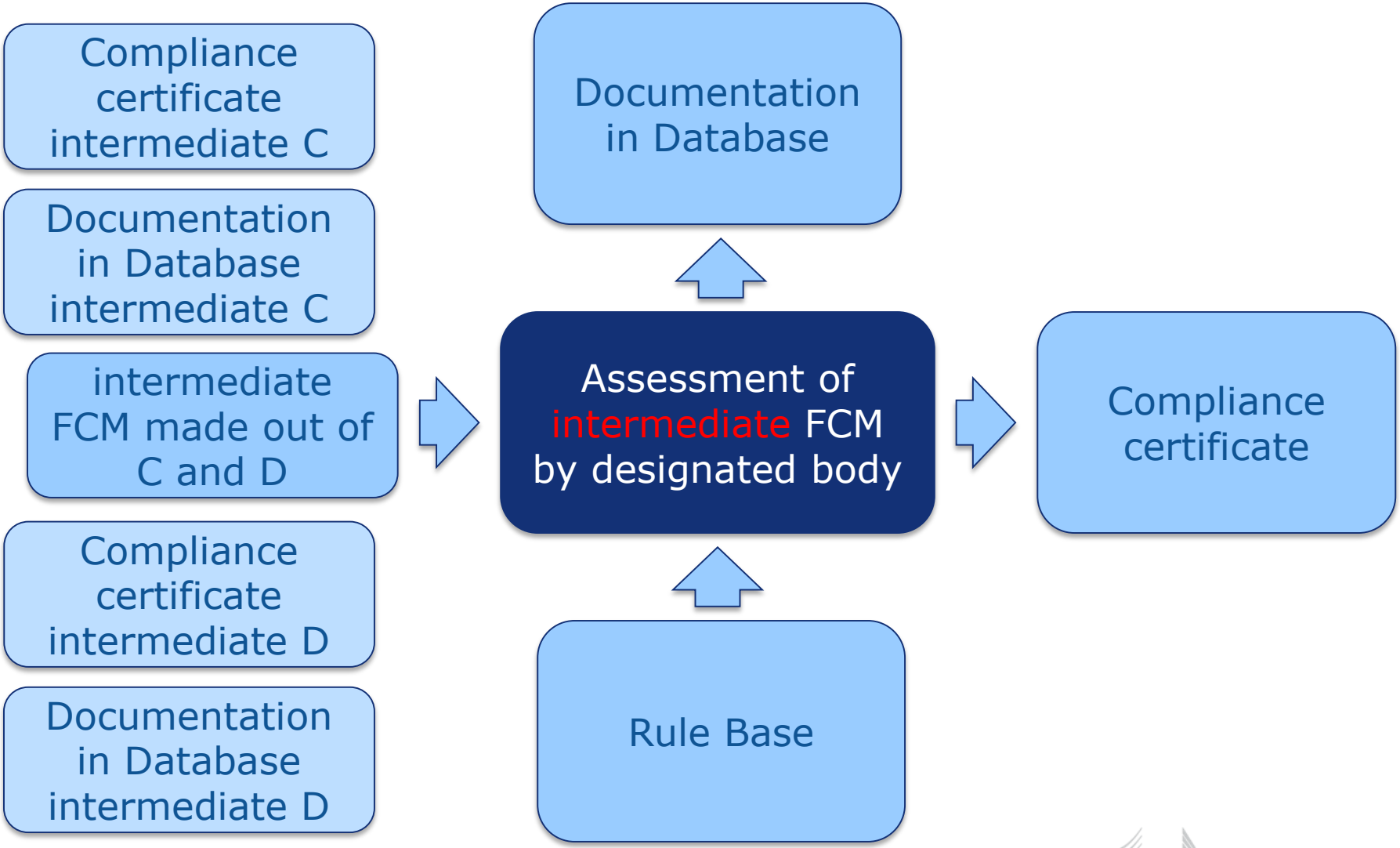
Certification is the only added burden

- **the other work should be carried out already**

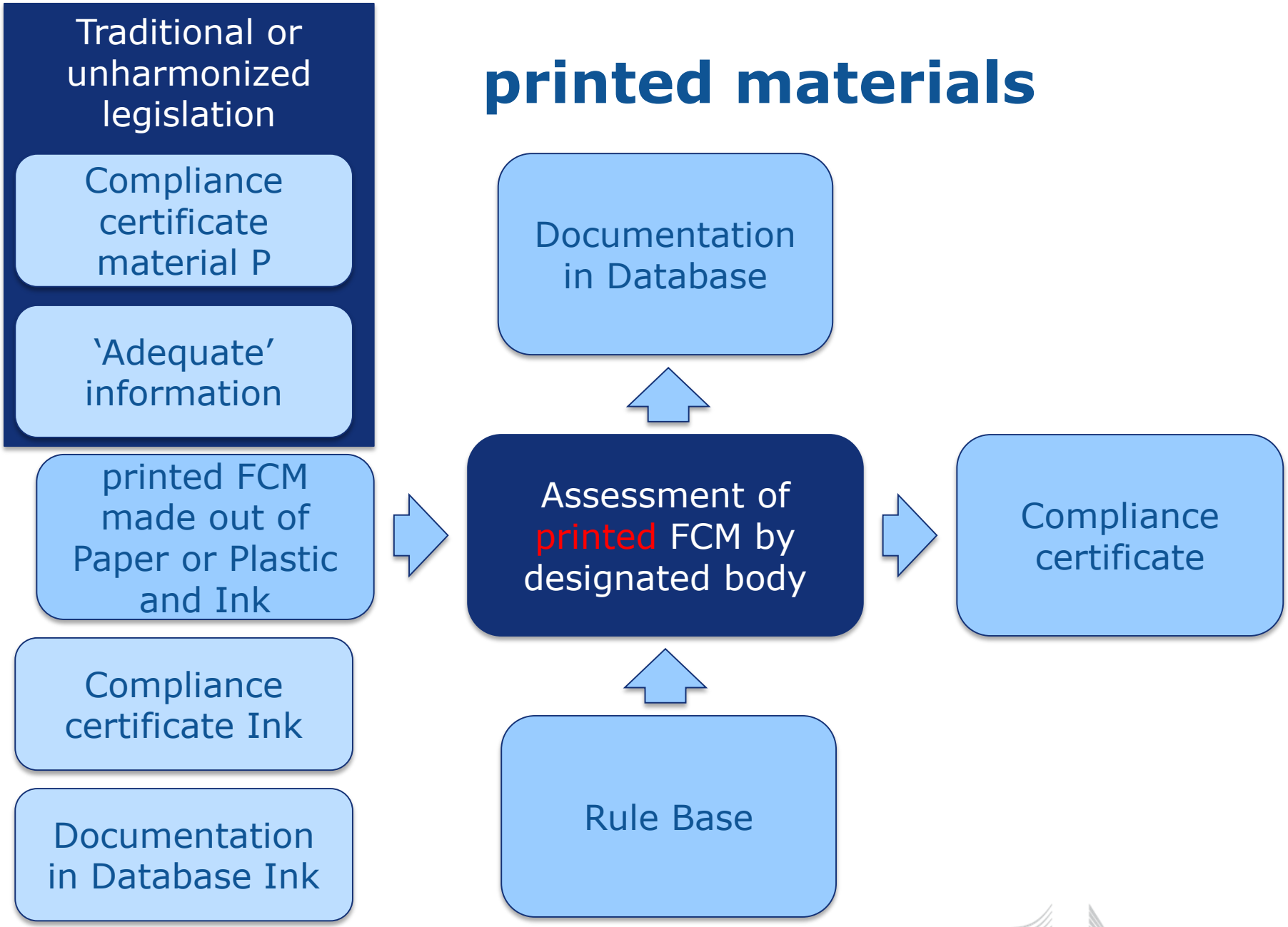
intermediate materials I



Intermediate material II



printed materials



Activities of a designated body

Identification of (migrating) substances

Migration testing

Toxicology

- **Testing (where not available)**
- **Interpretation (partially a new regulated activity)**

Evaluation of applicable rules

Decision on safety

- **(partially a new regulated activity)**

Certification, documentation, control parameters

Actual activities subject to point in supply chain

Rule Base

Legislation sets out main obligations

- **procedures, functioning of the system**
- **hazard/exposure based rules, e.g. CMR, nano, …**
- **rules concerning risk assessment**
- **rules based on contact mode**

Standards

- **technical + analytical procedures**

Guidance

- **where rules are available, but too much technical detail for legislation, flexibility is needed, or change expected**

Internal rules made by designated bodies

- **only if no other rules apply to a specific case**
- **can be ad-hoc**
- **mandatory documentation of rules/reasoning**
- **possibly notification to EFSA**

Evaluation of toxicology/suitability

Evaluation by designated bodies: conservative

- **Low exposure**
- **well established toxicological tests**
- **criteria in general rules on basis of EFSA opinion**
- **further guidance to be established for this purpose**

If substance fails to meet conservative criteria

- **e.g. in case of higher exposure or a specific concern**
- **EFSA evaluation → authorisation → positive listing**

Conservativeness needs to strike a balance

- **EFSA evaluation capacity is limited**
- **The system thus facilitates prioritisation**

Access to information

Dossier information stored in central database

Competent authorities + EFSA: access to all information

- **dossiers + internal rules used by designated bodies**

Designated bodies can access relevant dossiers

- **info on the intermediates stored by designated bodies**

FCM manufacturers + FBOs can access basic info

- **parameters for control and identification**
- **not to detailed, confidential, info on composition**

(Optional public access to selected information)

- **e.g. basic information on the materials, producers, designated bodies**
- **e.g. other information designated by manufactures**
- **risk however that it is misleading, because partial**

Control of the system by CA's

Accreditation and Designation

- **To ensure sufficient quality of the bodies**

Control of assessment dossiers

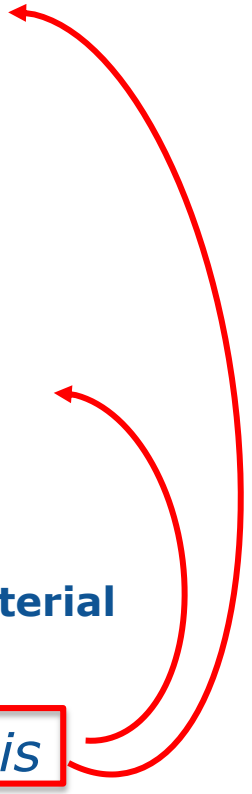
- **To verify adequateness of the work of the bodies**
- **To verify whether it is in compliance with rule base**
- **To monitor reasoning on risk (internal rules)**
- **To understand control parameters**
- **CA can overrule DB's**

Market controls on basis of control parameters

- **i.e. traditional FCM controls according to OFFC**
- **control parameters in compliance certificate**
- **defined by designated body as part of certification**
- **parameters to identify a material as the certified material**
- **relevant quality parameters, e.g. SMLs**

Control of dossiers and OFFC controls on risk basis

- **not all dossiers/material**



Governance

Governance Committee

- **expert group similar to this group**
- **established by the Regulation**
- **Member States, EFSA**
- **representation of designated bodies, industry, FBO's**

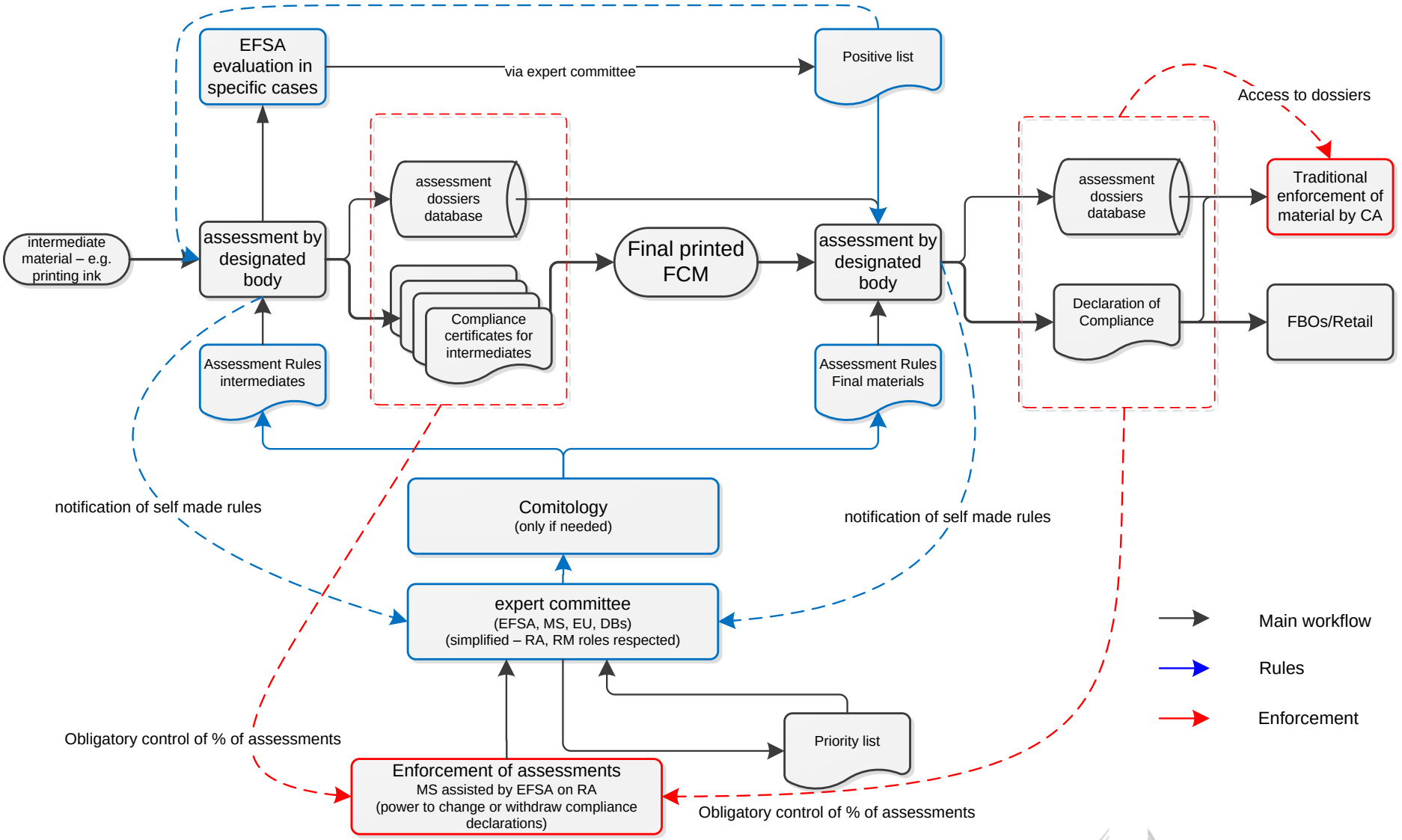
Tasks

- **determine where further/formal rules are needed**
- **discuss specific dossiers**

Typical agenda

- **prioritisation of new cases → public list of issues**
- **management of technical task forces**
- **discussion of on-going cases**
- **preparation of new rules**

overview



Key changes with respect to traditional approach

Rules for supporting documentation formalised

- **Use of central database to facilitate access**

Risk assessment further formalised

- **not left to business operators, but to designated bodies**

No detailed compliance rules

- **designated body's certification means it is compliant**

Positive listing only in case of problematic use

- **prioritisation of evaluation**

Formal role for governance committee

- **detailed risk management & procedural matters**

Expected Shifts in burden

Official controls

- **Lower burden per control, better documentation, more to the point**
- **imports follow the same rules**

Central Authorities

- **New burden, designation of bodies and checking of their work**

FCM manufacturers

- **obligatory use of designated bodies**
- **more taylored rules, shorter time to market**

FBO

- **improved information**

long term benefits

Formalised approach to assessment and documentation

- **increased transparency & better access**
- **more efficient use of (scientific) resources**

Detailed technical/scientific work decentralised

- **Authorities focus at norm-setting**

Prioritization of EFSA risk assessments

- **risk assessments become exception → only those cases that really require it**

Flexibility and speed for businesses

- **clarity in the supply chain**

Same approach perhaps also for other FCM

- **now only printed FCM**

Possible drafting complications

Legal basis

- **role of EFSA and official controls**

Need to

- **establish a database**
- **designate bodies**

Establish general rules

Legal certainty on certification

- **competent authorities may not accept**

Way forward

Hiring of contractor to

- **identify labs/consultants that could act as designated bodies**
- **establish main procedures**
- **establish database architecture**

Decision to take new approach or fall back on traditional approach

Drafting of Regulation

Transition period following adoption

- **Designate bodies**
- **Establish database**

Conclusion

Drafting difficulties for p-FCM

- **complex technical rules on verification of compliance**
- **solution for information exchange in supply chain**

Two potential approaches

- **Traditional: does not solve drafting problems**
- **Designated bodies: does solve these problems**

Commission not yet committed to any approach

- **we raised your awareness on potential new approach**