

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



The Council of Europe



- ▶ Founded in 1949
- ▶ **Intergovernmental** organisation
- ▶ To promote democracy, **human rights** and the rule of law
- ▶ Headquartered in **Strasbourg**
- ▶ **46** Member States
- ▶ More than 700 million citizens

EDQM in brief

- Founded in **1964**
- **Partial agreement** (39 members and the European Union, 33 observers)
- **Contributes to the availability of and access to good quality and safe medicines and health products**
- **Our vision:** together for better health, for all
- **Our mission:** to contribute to public health protection by engaging with an international community of experts and stakeholders

EDQM's global outreach



European Committee for Food Contact Materials and Articles , CD-P-MCA

- ★ **Steering committee** that issues:

- ★ recommendations to be adopted by CoE Committee of Ministers
- ★ guidelines for specific materials, as annexes to Resolution CM/Res(2020)9

- ★ **36** out of 39 member States have designated their **representatives**

- ★ Participation of the **EC, JRC, EFSA**

- ★ **Observers** from Georgia, Singapore, and Taiwan Food and Drug Agency (TFDA)

- ★ **EDQM** coordinates the CD-P-MCA work programme and is an **observer to:**

- ★ EC WG FCM
- ★ EFSA FCM Network
- ★ JRC Taskforce on kitchenware testing

Update on CD-P-MCA activities

11th meeting of EFSA network for Food Contact Materials
22nd - 24th October 2024

Work programme 2024-27

★ **Metals and alloys**



★ **Compliance documentation** - upcoming publication of the new guide

★ **Cork** - review of technical documents, under consultation until 11 October

★ **Coatings** - review of technical documents (2025)

★ **Enamels** - preparation of a new guidance document (2025)

★ **Paper & Board** - amendments to the 1st edition in preparation

★ **Printing inks, resins for adsorption and ion exchange** - upcoming review of technical documents

Declaration of compliance and supporting documentation

- ★ The **declaration of compliance** (DoC) is to be **shared with customers** and may be **mandatory under national rules**.
- ★ **Appropriate supporting documentation** demonstrating compliance - from which a DoC may be derived - may contain confidential information to be kept **in-house** and must be made available to official enforcement authorities, at their request.
- ★ The Guide aims to help **business operators** (BO) generate and/or compile documentation, while offering control **authorities** an overview of all suitable proof of compliance.

Principles

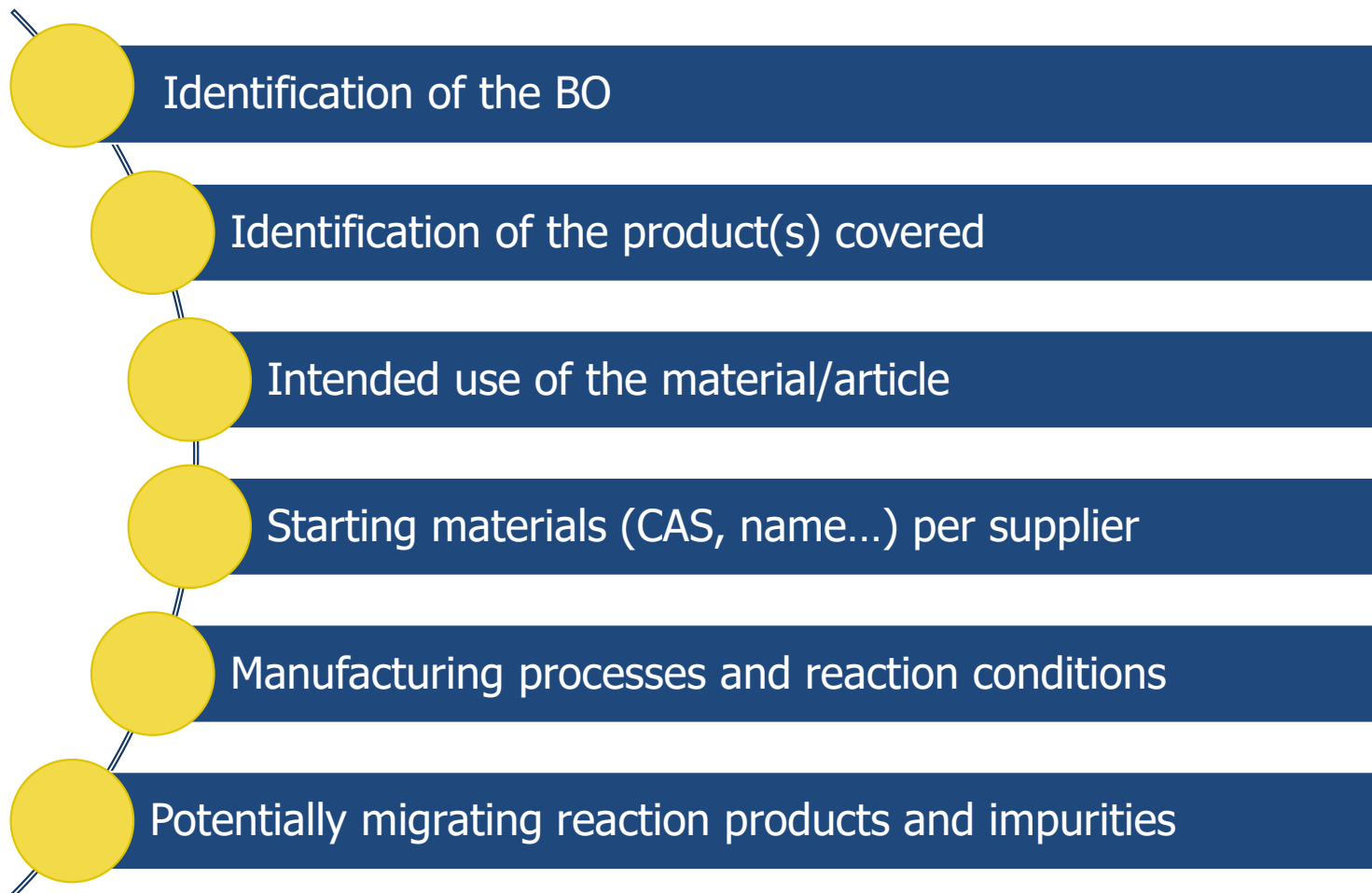
★ The guide emphasises the **shared responsibility** along the production chain, from the starting substances.

★ The **safety**

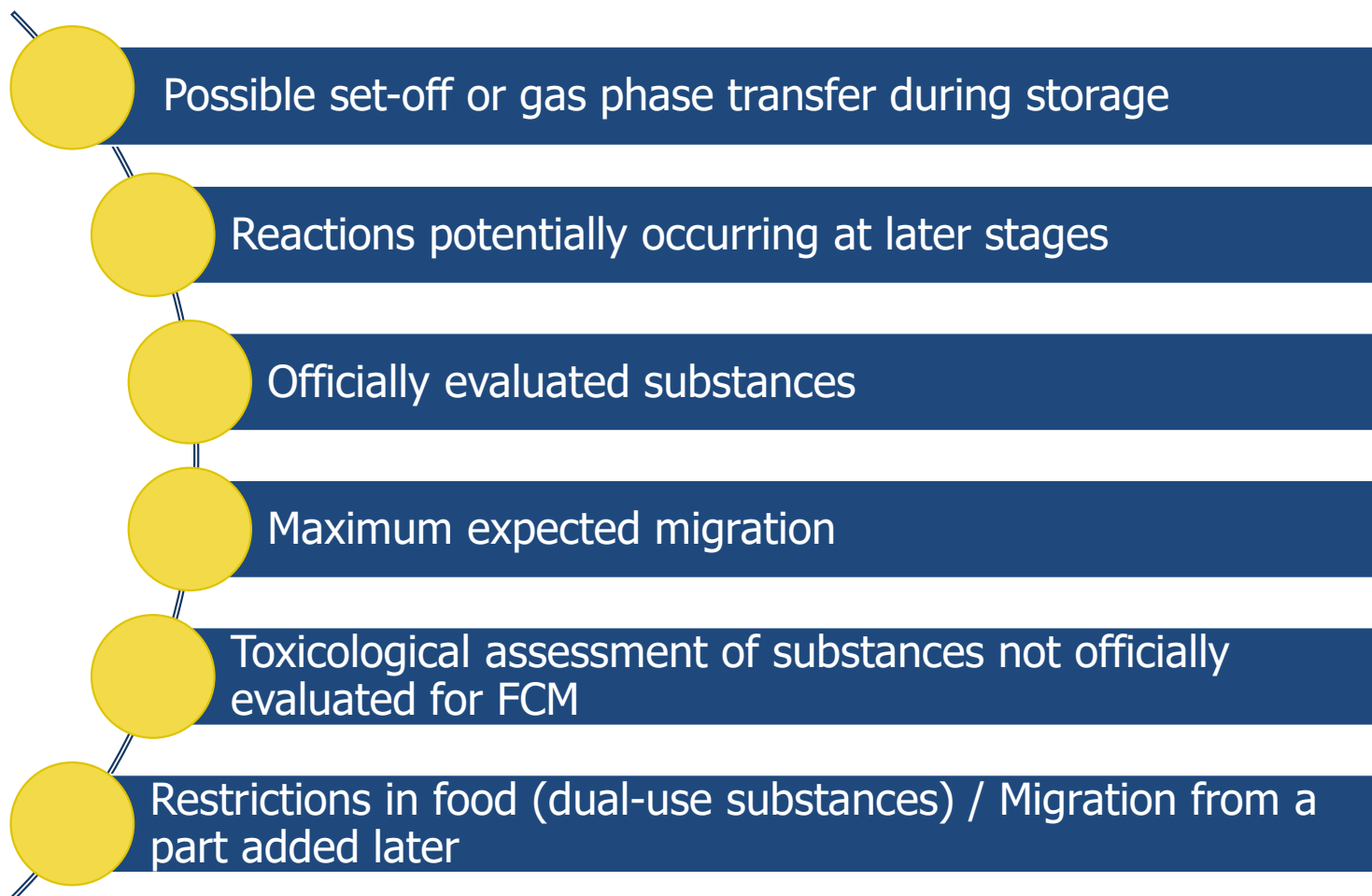
- ★ of substances or components not listed in national or European repertories as evaluated officially,
- ★ reaction products (including oligomers and degradation products),
- ★ and impurities

must be evaluated *"in accordance with internationally recognised scientific principles on risk assessment, and, where appropriate, with guidance"* (Resolution CM/Res(2020)9, Guiding Principles, Section 4).

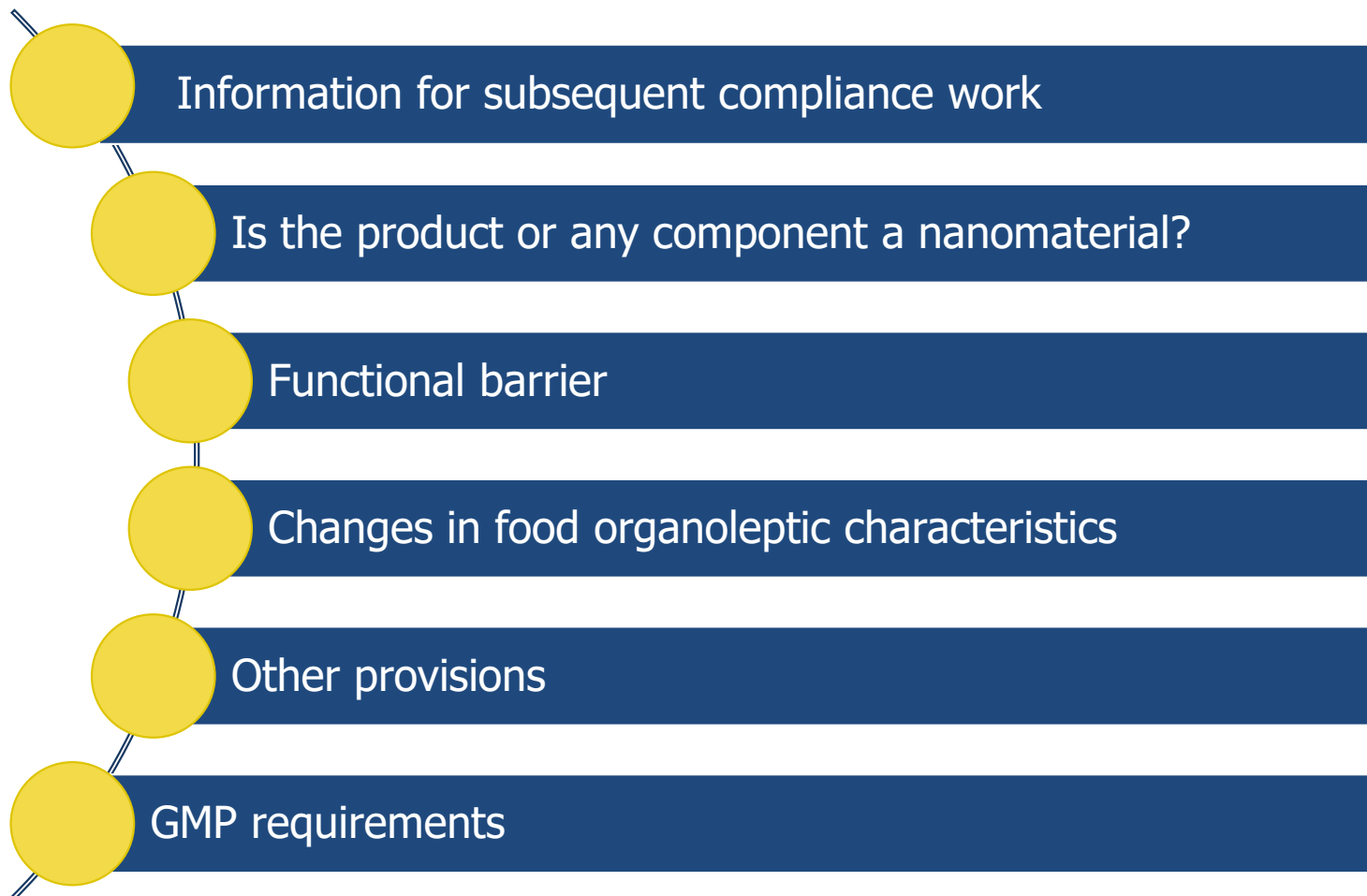
Checklist for supporting documentation



Checklist for supporting documentation



Checklist for supporting documentation



Coatings technical guide in preparation

Main contents

- ★ Council of Europe Resolution CM/Res (2020) 9
- ★ Scope
- ★ Definitions
- ★ General requirements
- ★ Specific requirements
- ★ Compliance testing
- ★ List of national provisions, standards or guidance



Cork technical guide in preparation

Main contents

- ★ Council of Europe Resolution CM/Res (2020) 9
- ★ Scope
- ★ Definitions
- ★ Specific requirements
- ★ Compliance testing
- ★ Test conditions and methods of analysis
- ★ Officially evaluated substances used in the manufacture of cork FCM and articles



Enamelled FCM technical guide in preparation

Main contents

- ★ Council of Europe Resolution CM/Res (2020) 9
- ★ Introduction – substances and their functionality
- ★ Legal status and link with the EU
- ★ Scope
- ★ Labelling
- ★ Safety review and recommendations for elements
- ★ Release testing method: simulants and test conditions



Paper and board technical guide (amendments to the 1st edition in preparation)

Main contents

- ★ Council of Europe Resolution CM/Res (2020) 9
- ★ Scope
- ★ Definitions
- ★ General requirements
- ★ Specific requirements
- ★ Compliance testing
- ★ Detection of recycled material
- ★ Supporting documentation and declaration of compliance
- ★ National regulations or recommendations
- ★ Specific migration limits (SML) for some constituents or contaminants
- ★ Standard methods for testing compliance



Events

★ **Symposium on FCM**, co-organised by EDQM and AESAN* and hosted by the latter, 18-19th September

Main conclusions:

- Need for further harmonisation
- Analytical challenges
- Hurdles to official control and enforcement

★ **Next Plenary Session**

10th CD-P-MCA will be held in Strasbourg on 3-4th June 2025

* Spanish Agency for Food Safety and Nutrition

Questions?



Thank you for your attention



Stay connected with the EDQM

EDQM Newsletter: <https://go.edqm.eu/Newsletter>
LinkedIn: <https://www.linkedin.com/company/edqm/>
X: @edqm_news
Facebook: @EDQMCouncilofEurope