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

Technical guide on documentation supporting compliance and safety of FCM

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What is «supporting documentation»?

- any (written) information that is used by a business operator (BO) to demonstrate compliance of food contact materials (FCM)
- this includes particularly information on:
  - the substances used, the processes applied, and the reactions/ treatments performed
  - the safety of released substances (IAS and NIAS),
  - the conditions and results of release testing, toxicological test descriptions
  - the data and the reasoning used for the conclusion
- this information originates from:
  - suppliers (information on starting materials) in the form of declarations of compliances (DoCs) and accompanying documents
  - analysis of supplier information and new information generated in-house during the manufacturing process
- Based on this information, the BO issues a DoC and accompanying documents, which in turn are included in the supporting documentation of its customers.

Regulatory background on supporting documentation

- Resolution CM/Res(2020)9 - Guiding Principles for food contact materials foresees a DoC for all FCM and requests "supporting documentation"
- in the European FCM regulation, a DoC is mandatory for all FCM covered by specific measures - e.g. plastics (Art. 5 and 16 of the Framework Regulation (EC) No 1935/2004)
- the GMP Regulation requires "appropriate documentation" for all FCM (Art. 7 of (EC) No 2023/2006)
- DoC and "supporting documentation" for plastic FCM (Art. 15 and 16 of (EU) No 10/2011)
- in the "Union Guidance on Regulation (EU) No 10/2011" limited information on "supporting documentation" can be found

What are the aims of the Technical Guide (TG)?

- Support BOs to demonstrate compliance of their products
  - by providing a list of the potentially relevant checkpoints
  - by helping to provide the evidence and rationale that support compliance for these checkpoints
- Support enforcement authorities in the verification of compliance
  - by providing a template with a clear structure for supporting documentation
- Safer FCM on the market
  - by strengthening compliance work along the entire production chain and emphasising the responsibility of each stakeholder

Structure of the TG

1. **Introduction** with a focus on compliance work in the production chain
2. **Scope and Definitions**
3. **Checklist for the supporting documentation** list of all information that may be required for compliance work
4. **Data requirements for risk assessment of migrating substances**
5. **Authority access to compliance and safety documentation** information on data from sources upstream sources or third parties
6. **Further reading** (references)
7. **Annexes** editable checklist and workflow diagram

Key messages of the TG

- **Focus on the importance of cooperation within the production chain for compliance work**

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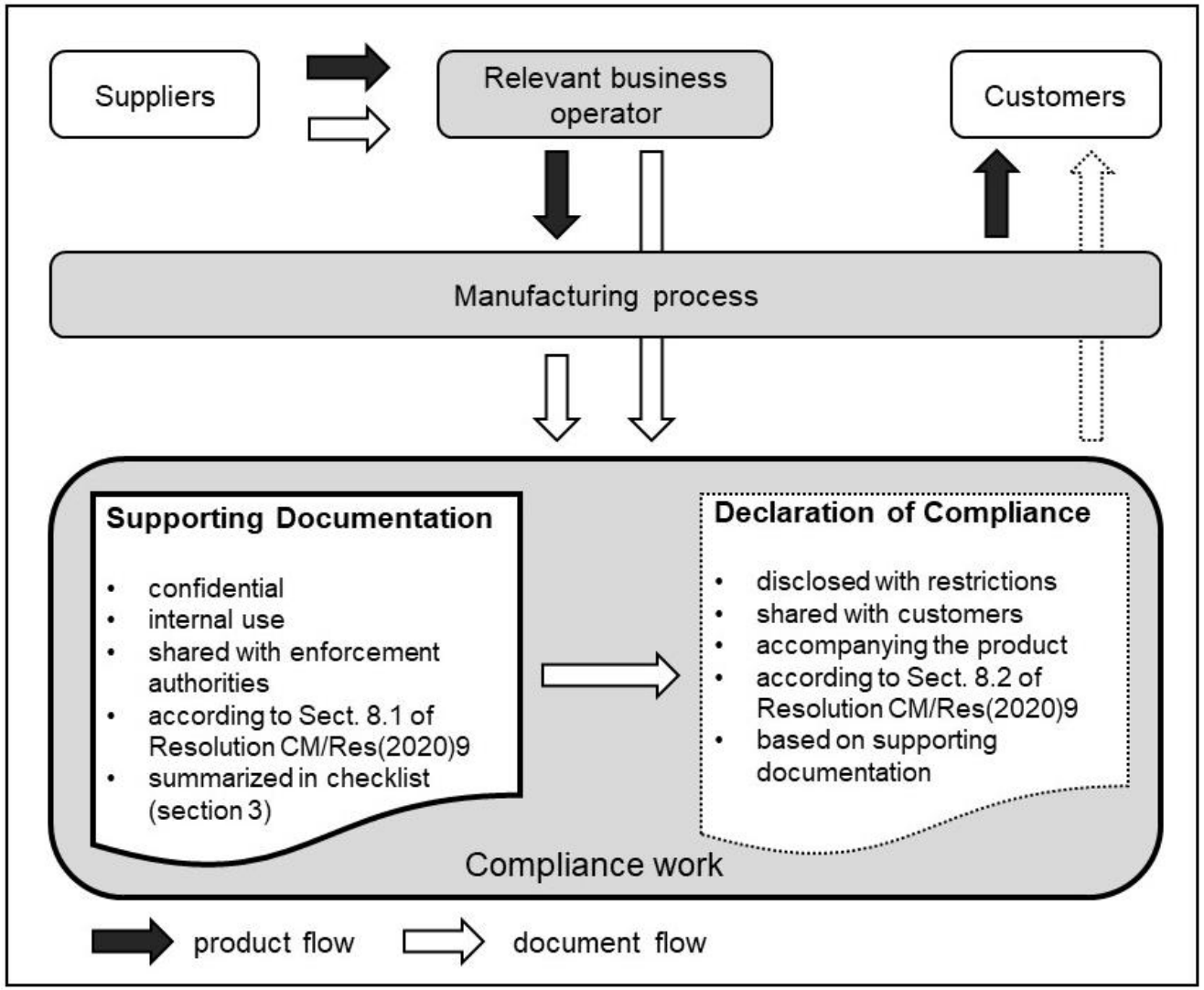
- **DoC and the supporting documentation as part of the compliance work**

DoC and supporting documentation



Key messages of the TG

- Focus on the importance of cooperation within the production chain for compliance work
- DoC and the supporting documentation as part of the compliance work
- **Provision an easy-to-understand checklist for compiling the supporting documentation**

Annex 1 - Editable version of checklist

7. Annex 1 Checklist for supporting documentation

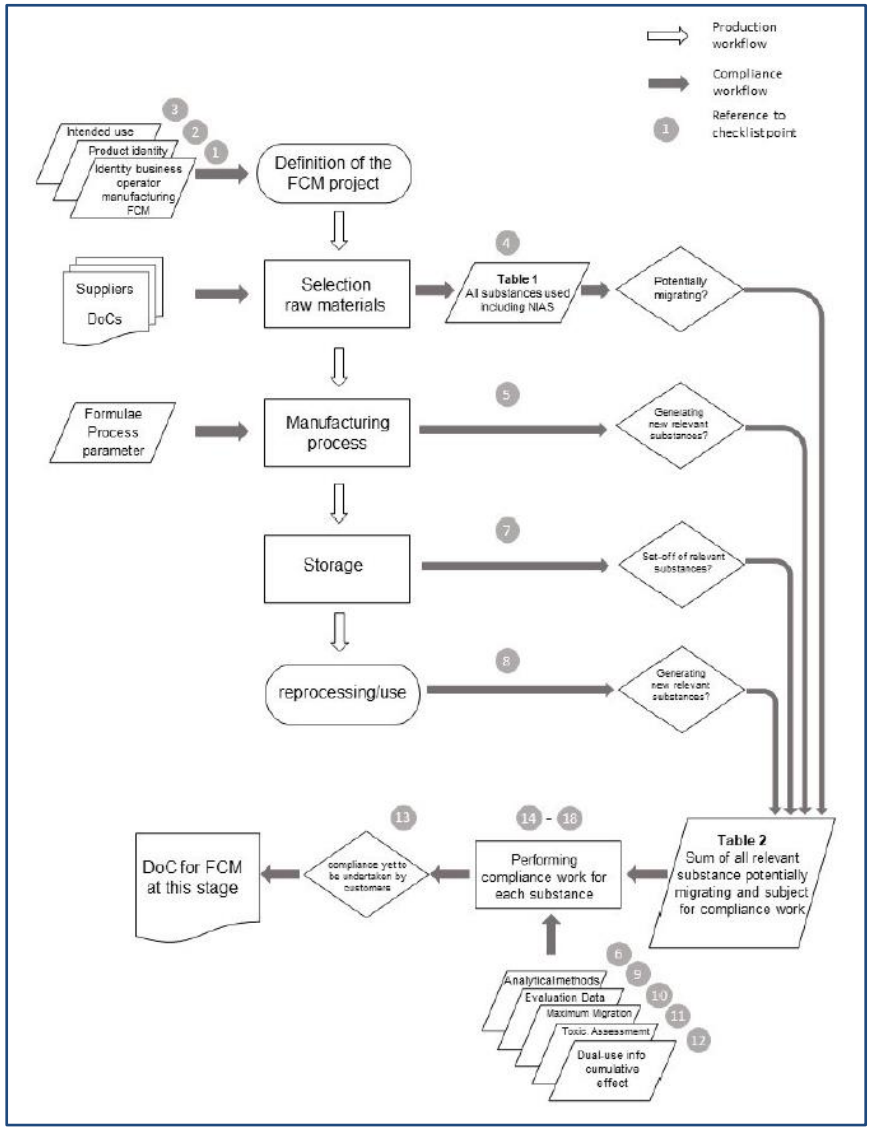
[file to be made available on publication]

*Please complete the in-house form below to the best of your knowledge and as applicable for **each product or family of products** covered by the supporting documentation. Insert additional documentation and separate files where needed, naming each file clearly (include the product name or description).*

1. Identity of business operator responsible for the product	
Company name	
Address	
Country	
Contact person	*(Name and email address)*

2. Product (or family of products) covered by the supporting documentation	
a. Identification/trade name(s)	*Including part number(s) of kitchenware, appliances, etc.*
b. General product description	*Such as the type of material and design and the principal intended use(s): for example, teats for baby bottles made of rubber or silicone, or stoppers for wine or juice bottles made of cork*
c. Justification for any omission of the compliance work	*If the compliance work was performed for one of several similar products, a justification describing the similarity is needed for a read-across of the compliance work. In case of uncertainty, the worst-case scenario should be considered*

Annex 2 - workflow diagram



Working Group «Compliance Documentation »

- around 20 participants with experts from **industry**, **enforcement authorities** and **regulatory bodies**
- WG was formed in early 2020
- meetings were held online
- 1-2 meetings per year
- **stakeholder consultation** in early 2024
- approval by CD-P-MCA delegates summer 2024
- **publication in Q4 2024** on the EDQM website (Freepub)

Acknowledgements

Many thanks to

- all the members of the working group, especially Koni Grob
- the former Chair and Co-Chair of the CD-P-MCA: Katharina Adler and Bianca Van de Ven
- the staff at EDQM, Susanne Bahrke, Teresa Carrilho, Marie-France Schlachter and Rita Davis

Thank you for your attention

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