# Hazardous substances and the New Medical Devices Regulation

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**Brussels**

**3 December 2019**

# Revision of the EU Medical Devices Legislation

Directive 90/385/EEC on active implantable medical devices
Directive 93/42/EEC on medical devices

Regulation on medical devices

Directive 98/79/EC on *in vitro* diagnostic medical devices

Regulation on *in vitro* diagnostic medical devices

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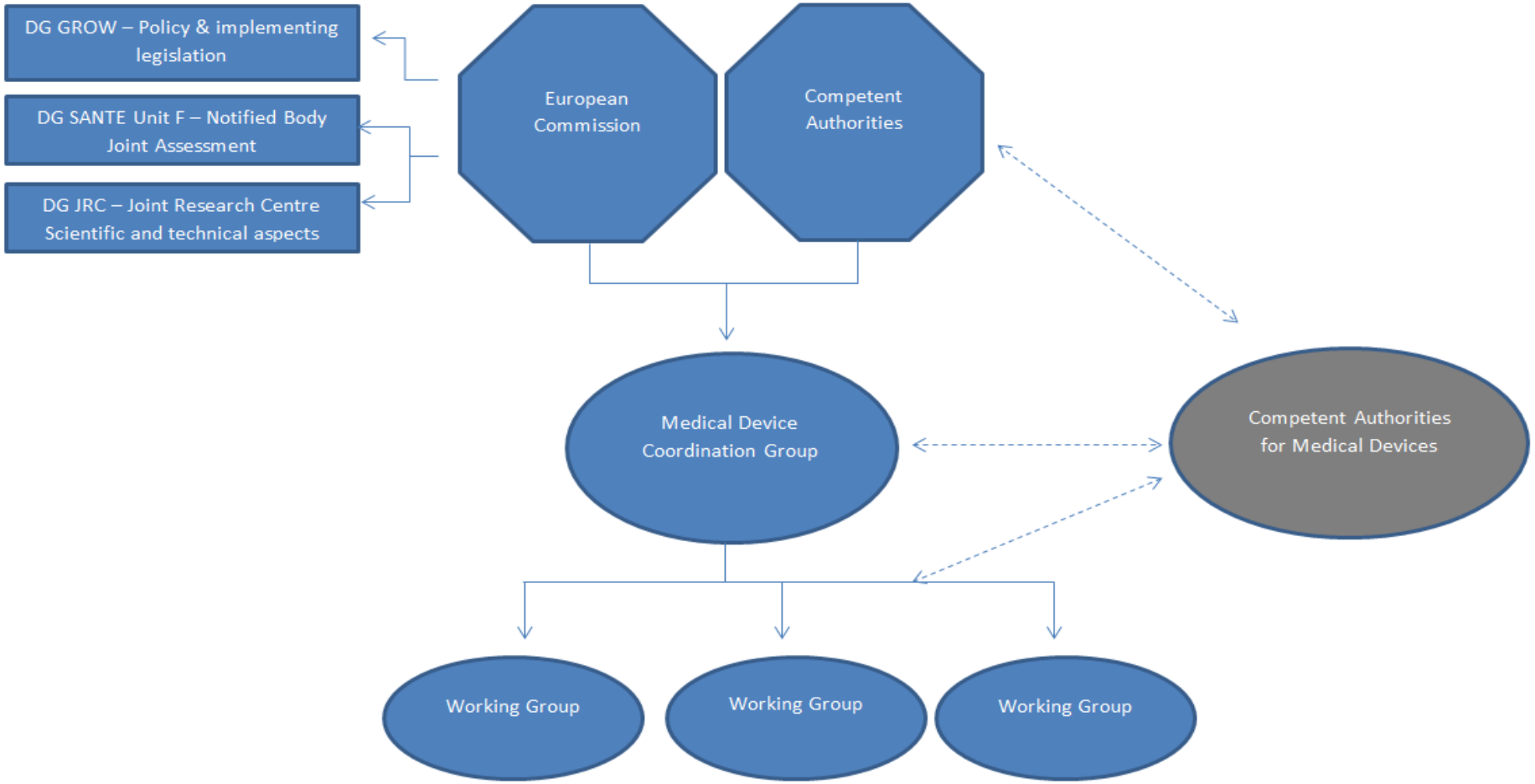
# Transitional period

# Other relevant compliance timelines

- 26 November 2021/2023 (or 24 months after Eudamed becomes available): Registration of devices (including UDI)
- 26 May 2021-2023-2025(MD)/2023-2025-2027 (IVD): UDI labelling
- 26 May 2024: Maximum period of validity of certificates issued under current Directives
- 26 May 2025: Making available of devices placed on the market pursuant to current Directives
- 26 May 2027: Coordinated procedure for clinical investigations

# The European governance map for MD

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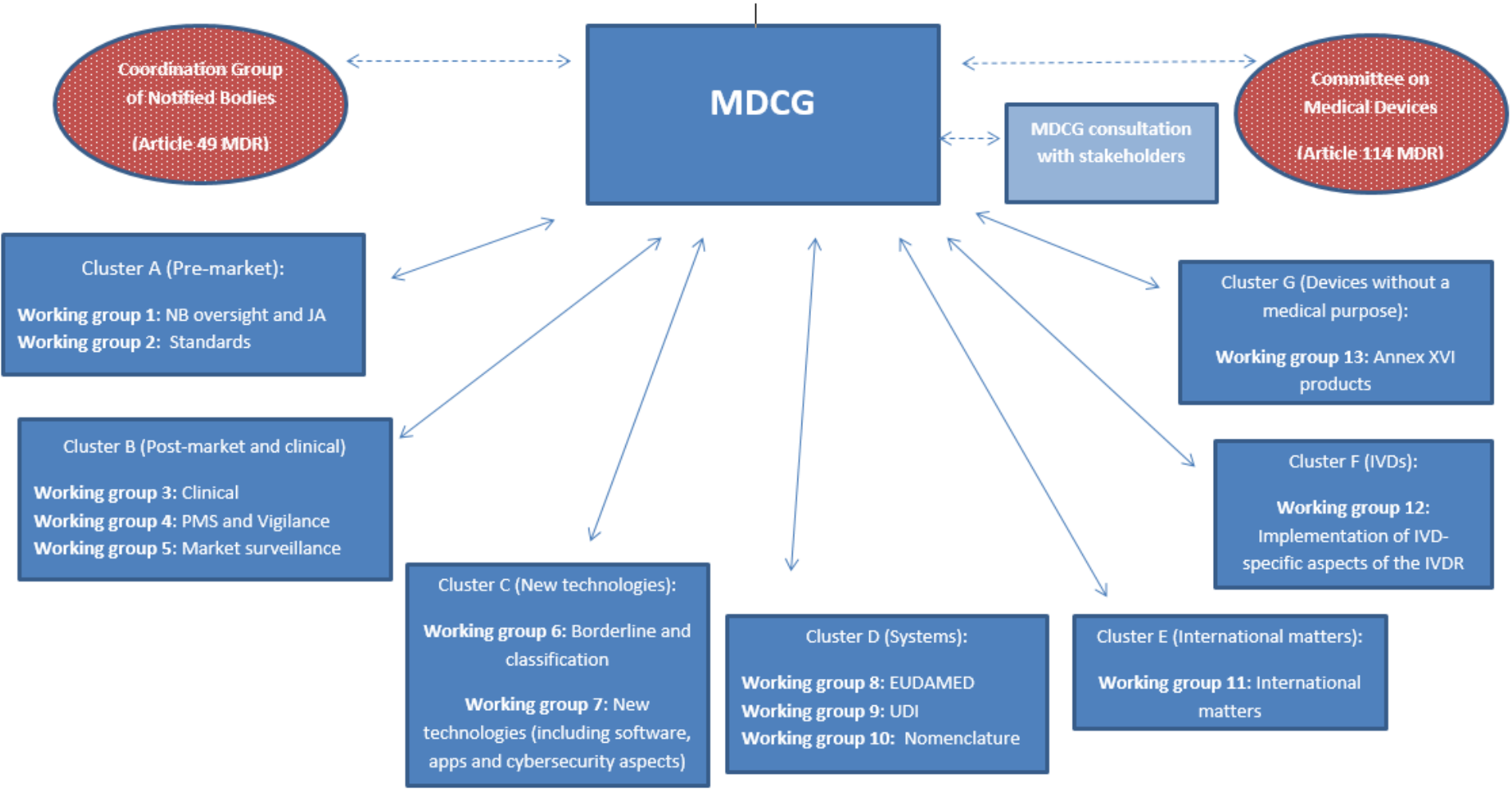
# MDCG: Organisational structure

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# Implementation - achieved

(1) Governance and transitional provisions
- ✓ Setting up of Medical Device Coordination Group (MDCG) - as of 26/11/2017)
- ✓ Establishment of the new technical Expert Groups (MDCG subgroups) - as of 1st March 2019
- ✓ + 2 new subgroups: Annex XVI (May 2019) and Nomenclature (September 2019)

(2) Increasing monitoring and transparency in the planning of activities
- ✓ Rolling plan listing Commission's essential actions during the transitional period: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en
- ✓ New documents on completed and ongoing work of MDCG Subgroups https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

(3) Notified Bodies
- ✓ Infrastructure and codes for the designation procedure – as of 26 November 2017
- ✓ All applications managed by the Commission within the requested timelines
- ✓ Designation of 9 Notified Bodies completed (including 2 under IVDR)
- ✓ Estimated 20 designations to be completed in the course of Q1 2020

(4) Setting up of scientific structures (expert panels, expert laboratories, reference laboratories)
- ✓ Implementing Act establishing expert panels adopted on 10 September 2019
- ✓ Call for expression of interest for expert panels finalized on 24 November 2019 https://ec.europa.eu/growth/content/call-expression-interest-expert-panels-medical-devices-and-vitro-diagnostic-medical-devices_en

# Implementation - achieved

(5) Design and establishment of EUDAMED/UDI
- ✓ Plan for implementation of functional specifications completed in May 2018 and release of high-level functional specifications in March 2019
- ✓ Designation of UDI issuing entities on 6 June 2019 and many UDI guidelines and Q/A published; decision on nomenclature in March 2019

(6) IVD
- ✓ Publication of CTS on combined test adopted in July 2019

(7) Communication campaign
- ✓ New dedicated website and first updated library are live; Factsheets https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/getting-ready-new-regulations_en

(8) SCHEER's opinion on phthalates
- ✓ Published on 10 September 2019

(9) Guidelines (31) released on many crucial aspects
- ✓ Notified Bodies, UDI, Registration procedure and timelines (including legacy products), Application of Article 54(2), Incident reporting form, Implant card, PRRC, Qualification and classification of software, SSCP

(10) Corrigendum to the MDRs published in May 2019
- ✓ Important clarifications on sampling plans for auditing and employment of certain types of Notified Body staff

# Implementation – next steps

1) Continuing the designation of Notified Bodies

2) EUDAMED: go-live in 2022; possible release of voluntary actor registration module by May 2020

3) Standards: Mandate to European Standardisation Organisations

4) Common specifications on Annex XVI products

5) Common specifications on reprocessing

6) Establishment of expert panels and reference laboratories

7) Establishment of UDI system:
   Issuing of additional guidelines, implementation of nomenclature, establishment of UDI helpdesk

8) MDCG Guidance documents in crucial areas, notably on borderline and new classification rules, clinical evaluation, vigilance, medical software/apps

9) Second corrigendum (possible finalisation by end of the year)

10) Communication campaign

# Hazardous substances in medical devices

## Annex I General Safety and Performance Requirements

**Article 5 Placing on the market and putting into service**

"2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose."

**Annex I General Safety and Performance Requirements**

"1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be **safe and effective** and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that **any risks** which may be associated with their use constitute **acceptable risks when weighed against the benefits** to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged **state of the art**." [*emphasis added*]

# Hazardous substances in medical devices

## Annex I General Safety and Performance Requirements

**10.4.1. Design and manufacture of devices**

"Devices shall be designed and manufactured in such a way as to reduce **as far as possible** the risks posed by substances […]

Devices, or those parts thereof or those materials used therein that:

— are invasive and come into direct contact with the human body,

— (re)administer medicines, body liquids or other substances, including gases, to/from the body, or

— transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,

shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where **justified** pursuant to Section 10.4.2:

(a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B […]

(b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health […]"

# Hazardous substances in medical devices

## Annex I General Safety and Performance Requirements

**10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances**

The justification for the presence of such substances shall be based upon:

(a) an analysis and estimation of potential patient or user **exposure** […];

(b) an analysis of possible **alternative** substances, materials or designs, including[…];

(c) argumentation as to why possible substance and/or material substitutes, if available, or design changes, if feasible, are **inappropriate** in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly **vulnerable** to such substances and/or materials; and

(d) where applicable and available, the latest **relevant scientific committee guidelines** in accordance with Sections 10.4.3. and 10.4.4.

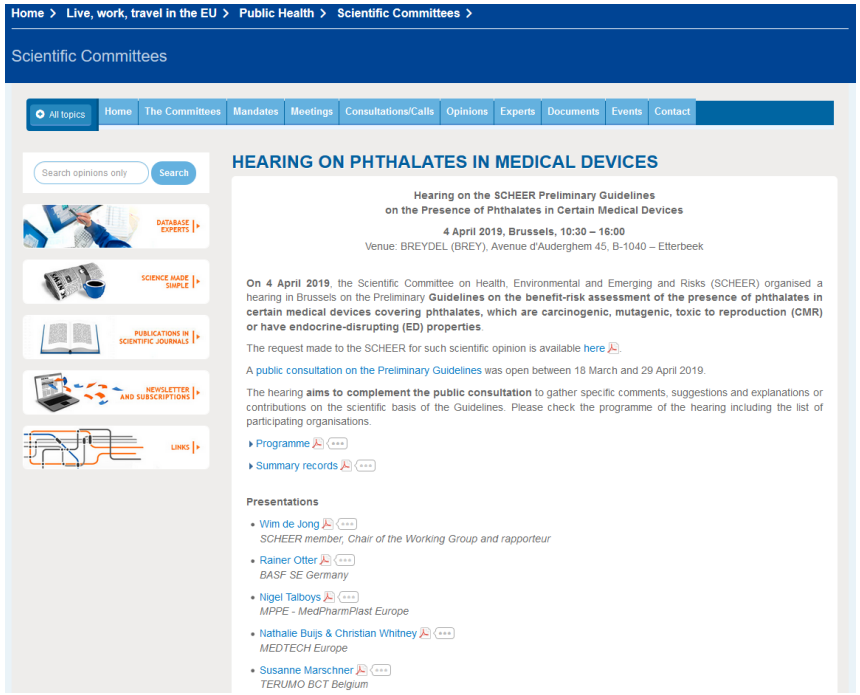
# Hazardous substances in medical devices

## Annex I General Safety and Performance Requirements

## Guidelines on phthalates

### 10.4.3. Guidelines on phthalates

### 10.4.4. Guidelines on other CMR and endocrine-disrupting substances





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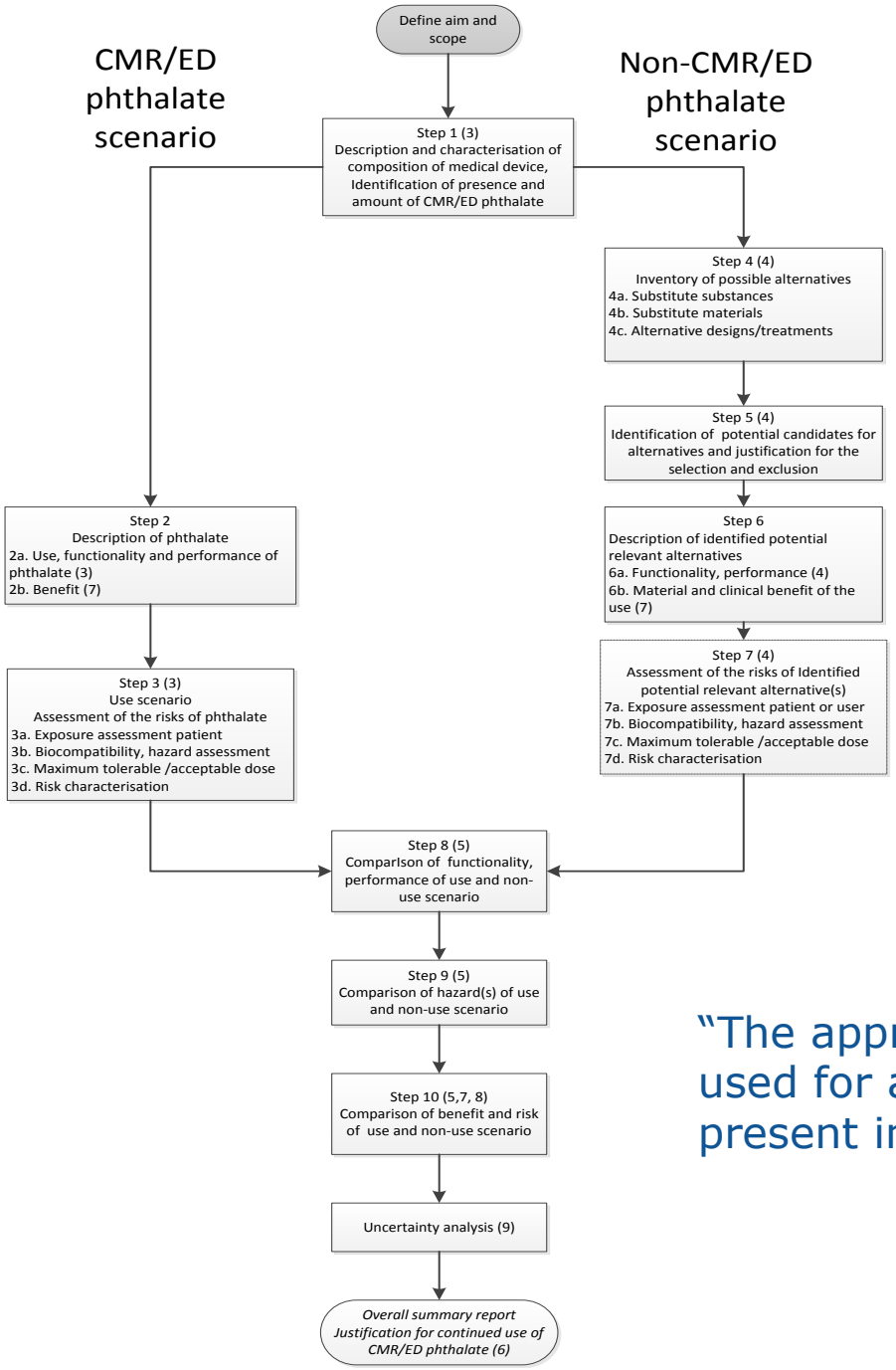
# Guidelines on phthalates in medical devices

**Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties**

https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scheer_consultation_08_en




"The approach of these Guidelines can also be used for a BRA of other CMR/ED substances present in medical devices." (p 10)

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# Thank you!