



Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

How long does it take to translate changes into legislation or guidance?

Lilia Medvedev

Federal Institute for Occupational Safety and Health

Federal Office for Chemicals (BfC)

How long does it take – it depends...

- **It depends on**
 - the **type of the legal act** to be adopted
 - the **procedure for adopting** the legal act
 - the **complexity of the content** of the legal act
- **Example:** How long did it take to translate changes into **Annex II to REACH** and the **Guidance on the compilation of safety data sheets?**

Different types of EU legal acts

- **Primary Union law** is set by the **Member States**
 - The Lisbon Treaty
 - Treaty on the Functioning of the European Union
- **Secondary Union law** is adopted by the **EU institutions** on the basis of the Treaties.
 - **Legislative acts** (regulations, directives) follow the ordinary or special legislative procedures
 - **Non-legislative acts** (delegated and implementing acts) follow specific rules

Ordinary procedure for legislative acts



Non-legislative acts: Delegated acts

- The **Commission** adopts delegated acts
- Purpose: to **supplement** or **amend non-essential elements**
- Procedure:
 - Mandatory **consultation** by the Commission **of Member States' experts** in preparation of draft delegate act
 - Public consultations: 4 weeks
 - Council and Parliament can object within 2 months
- e.g. Commission Delegated Regulation (EU) 2020/1677 with 2nd amendment of Annex VIII to CLP

Non-legislative acts: Implementing acts

- **The Commission** (or, in exceptional cases, the Council) adopts implementing acts
- Purpose: providing **further detail** to ensure **uniform application of EU laws** in the Member States
- **Committee procedure** (in EU jargon: **comitology**)
- Two types of procedures for implementing acts according to Regulation (EU) No 182/2011 (“Comitology Regulation”)
 - **examination procedure**
 - **advisory procedure**

Implementing acts: comitology

- However, **the regulatory procedure with scrutiny** still applies in cases, in which the basic act has not yet been aligned to the Lisbon Treaty, e.g. amendments to the Annexes to **REACH**.
- **Article 131 REACH, Amendments to the Annexes**
“The Annexes may be amended in accordance with the procedure referred to in Article 133(4).”
- **Article 133 REACH, Committee procedure**
“(4) Where reference is made to this paragraph, Article 5a(1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.”

Commission Regulation 2020/878

L 203/28

EN

Official Journal of the European Union

26.6.2020

COMMISSION REGULATION (EU) 2020/878

of 18 June 2020

amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ⁽¹⁾, and in particular Article 131 thereof,

- (9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

Why was the amendment necessary?

GHS

6th GHS revision:

- Re-arranged set of **phys-chem properties**

- 'desensitised explosives'

7th GHS revision: **bulk transport**

CLP

- UFI

- Specific concentration limits, multiplying factors and acute toxicity

REACH

Nanofoms amending Annexes I, III, VI - XII

Commission Regulation
amending Annex II to
REACH

Amendment of Annex II to REACH

REACH Committee

September 2018 Commission introduces the draft initial discussion	April 2019 comments discussion	September 2019 Language versions of Annex II available for comment	November 2019 Vote: unanimous positive
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Parliament

not opposed within
3 months from
date of referral

Council

CARACAL

November 2018 - January 2019
commenting round

Public

September 2019-
October 2019
Publication on the
Better Regulation
Portal

June 2020 Publication in
Official Journal

L 203/28 EN Official Journal of the European Union 26.6.2020

COMMISSION REGULATION (EU) 2020/878
of 18 June 2020
amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council
concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
(Text with EEA relevance)

Guidance on the compilation of safety data sheets, Version 4.0

Partner Expert Group (PEG)

March 2020
Nomination of PEG

April 2020 – May 2020
Commenting round
of the first draft

July 2020
Cross check
comments

Forum*

December 2020
Publication on
ECHA's website

CARACAL

September 2020-
October 2020
parallel consultation

 **ECHA**
EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on the
compilation of
safety data sheets

Version 4.0
December 2020

*The Forum for Exchange of Information on Enforcement (Forum)

Thank you for your kind attention!

Lilia Medvedev

Federal Institute for Occupational Safety and Health

Federal Office for Chemicals

Friedrich-Henkel-Weg 1-25

D-44149 Dortmund

Medvedev.lilia@baua.bund.de

www.baua.de

