

Webinar on 30 April 2020

NMP RESTRICTION AND THE GUIDELINE

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NMP (1-methyl 2-pyrrolidone) Restriction

From proposal to adoption

- The Netherlands submitted a **restriction proposal** in August **2013**
 - **EU wide DNEL** (Derived No-Effect Level) **was chosen as the way to control the risks at the workplace**
- **ECHA's Committees:**
 - Risk Assessment Committee (RAC) **set DNELs for inhalation and skin**
 - Committee for Socio-economic Analysis (SEAC) considered the proposal's **cost-effectiveness**

NMP Restriction

From proposal to adoption

- **REACH Committee** voted on the **draft NMP restriction** in Oct. **2017** and it was **adopted** in Apr. **2018**
 - Several Member States requested the European Commission to **develop guidance** to assist users of NMP to comply with the restriction based on DNEL values
 - ECHA was given the task to prepare a **practical** and **easy to understand** guideline to **facilitate the compliance** with the restriction and the understanding of the relationship between the OEL (Occupational Exposure Limit) and DNEL

The restriction

Main points in relation to the guideline

- **NMP restriction was published in Apr. 2018**

Entry 71 of Annex XVII to REACH:

1. From **9 May 2020 harmonised DNELs** of 14.4 mg/m³ for inhalation and 4.8 mg/kg/day for dermal exposure apply
2. NMP users need to work under operational conditions with **appropriate risk management measures in place to ensure their exposure is below the DNELs**
3. For the process of **coating wires** the obligations apply from **9 May 2024**

Conditions of restriction: <https://echa.europa.eu/documents/10162/e7598958-ee7-1661-0636-02778b427efc>

NMP Guideline Development

- **Started in summer 2018**
- **In close cooperation with industry & authorities**

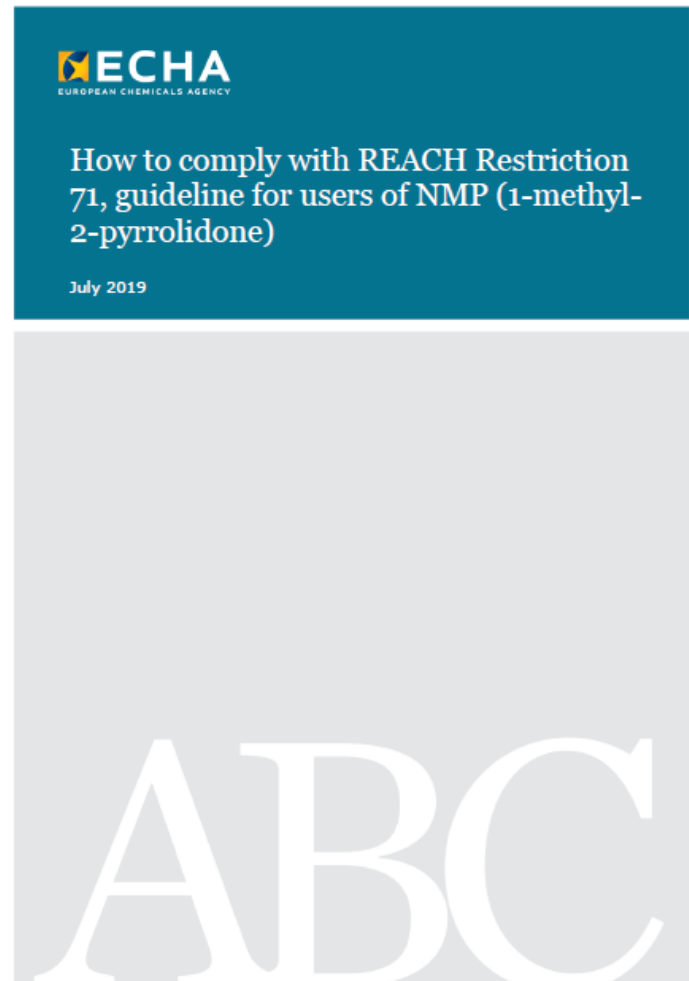
Petrochemicals Europe acted as the main industry partner but users also actively contributed:

*e.g. battery, fibres,
pharmaceutical, semiconductors
& wire coating sectors*

Authorities

REACH & OSH

Commission Services: *DG Grow, DG
Env & DG Empl*



NMP Guideline Development

STEP 1: Information gathering

a) Online survey tailored to REACH role of the respondent in Oct. 2018
Over 40 organisations contributed including NMP manufacturers, users and authorities

Information was collected on current NMP uses, good risk management practices & monitoring of workers' exposure

b) Stakeholder roundtable in Nov. 2018

- 17 industry & authority representatives with experience in NMP
- Discussed what should be included into the guideline



NMP Guideline Development

STEP 2: Consultation on draft documents

1. Consultation of 1st draft in Jan. 2019

- Over 200 written comments from 70 organisations

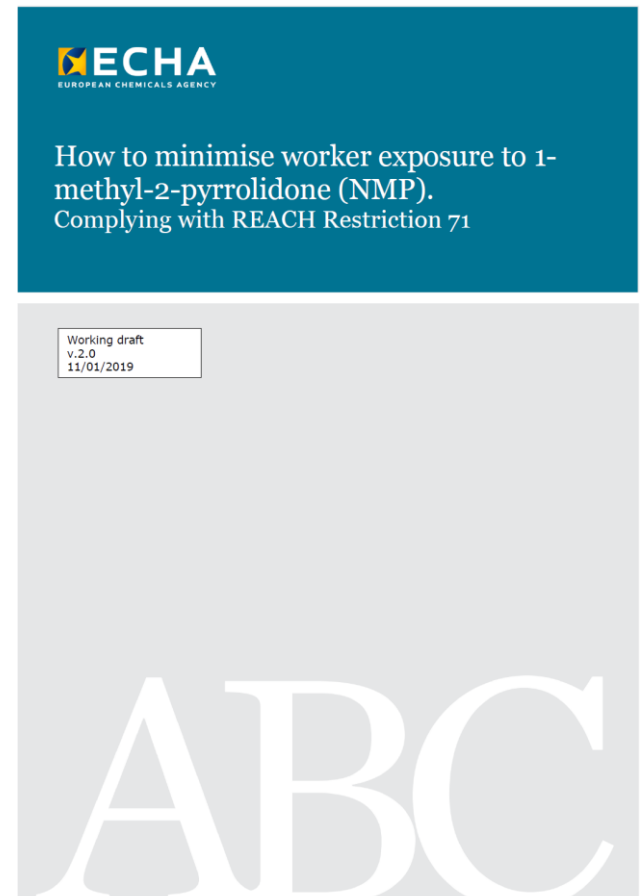
2. Stakeholder roundtable on 12 Feb.

- 18 experts provided feedback on how the 1st draft could be improved
- Companies committed to harvest additional good practice examples

3. Consultation of 2nd draft in Mar.-Apr.

- **REACH authorities:** *CARACAL* and *the Forum*
- **OSH authorities:** *DG Empl's Working Party on Chemicals* and *SLIC's CHEMEX*
- **Roundtable participants**

28 organisations contributed by providing over 250 comments



NMP Guideline Development

STEP 3: Endorsement

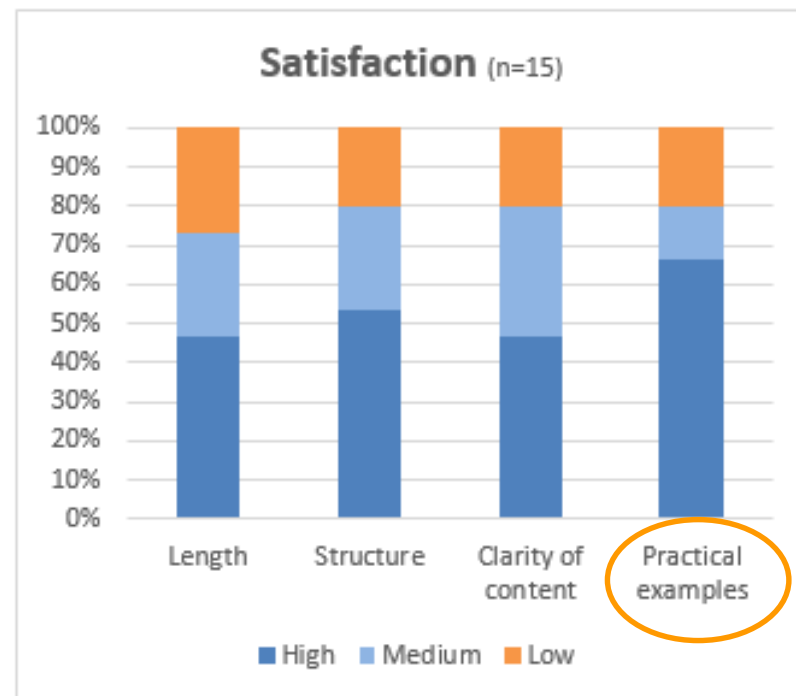
CARACAL in Jun. 2019

- Considered the **measures proposed reasonable** and endorsed the final version
- NMP Guideline **complements national guidelines** where such exist
- **Guideline chapters:**
 1. Introduction of NMP, **the aim of the guideline**, what is the restriction and what is a DNEL
 2. **What you need to do** to adequately control exposure: how to use exposure scenarios and check if your uses are covered
 3. **Examples of good practice** to control exposure to NMP: examples and handling recommendations provided by companies
 4. **Checking compliance** and monitoring
 5. Why and **when to communicate with** your **supplier**

NMP Guideline Development

STEP 4: Publishing & feedback

- **Published in Jul. 2019**
- **Translations** into 22 EU languages on ECHA's website
- **Feedback** collected from users of the guideline with an **online form**
 - 15 responses, 8 countries (CZ, CY, DK, DE, IT, PL, PT & UK)
 - Including companies, industry association & authorities



ECHA is grateful to all who contributed

All participated in a very open and forthcoming manner

The approach used was considered a good way to involve all interested parties

Industry and authority participation was critical for the success

Thank you!

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