Biocidal Products Committee (BPC)

Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on

Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying

ECHA/BPC/430/2024

Adopted

29 May 2024

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Opinion of the Biocidal Products Committee

on questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying

In accordance with Article 75(1)(g) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying.

This document presents the opinion adopted by the BPC.

Process for the adoption of the opinion

A request[1] by the Commission was received by ECHA on 28 April 2023. The mandate and call for rapporteurs was discussed in BPC-47 in June 2023.

SECR acted as a rapporteur for section 1 (questions 1 to 3) and presented the draft opinion on section 1 at the Human Health Working Group meeting on 19 March 2024 (WG-I-2024) and at the BPC-51 meeting 29 May 2024. Following the adoption of this part of the opinion at BPC-51 the opinion was amended according to the outcome of the discussion.

The (co-)rapporteurs for section 2 (question 4 to 6) presented the draft opinion on section 2 to the Working Group – Human Health meeting of xxx-xxx-xxx and the BPC-xx meeting of xx-xxx-xxx. Following the adoption of the opinion at BPC-xx the opinion was amended according to the outcome of the discussion.

[1] Article 75(1)(g) mandate: https://echa.europa.eu/documents/10162/3443005/mandate_opinion_request_coarse+spraying_en.pdf/168b23b7-1557-f1f0-133a-2c11f32b401d?t=1695984479765

Adoption of the opinion

Rapporteur: ECHA for questions 1 to 3

The BPC opinion for sections 1 was adopted on 29 May 2024. This part of the BPC opinion was adopted by consensus. One BPC member abstain from voting.

Rapporteur: BE eCA for question 4 and partly question 6

The BPC opinion for section 2 was adopted on xxx. This part of the opinion was adopted by xxx.

Rapporteur: (tbc) for question 5 and partly question 6

The BPC opinion for section 2 was adopted on xxx. This part of the opinion was adopted by xxx.

The opinion[2] is published on the ECHA website at: https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/opinions-on-article-75-1-g.

[2] The opinion adopted on 29 May 2024 for Section 1 was published on the ECHA website with the same title under number ECHA/BPC/430/2024. That opinion is now replaced by this opinion.

Further details of the opinion and background

Contents

List of abbreviations and acronyms

ACH	Air Changes Per Hour
AEC	Acceptable Exposure Concentration
AfA	Applications for authorisation under REACH Authorisation process
AGW	Occupational exposure limits (incl. substance-specific ones) in Germany
APF	Assigned Protection Factor
AR	Assessment Report
ART	Advanced Reach Tool
AS	Active Substances
AUVA	Austrian Workers' Compensation Board
BHHEM	Biocides Human Health Exposure Methodology
BP	Biocidal Product
BPC	Biocidal Product Committee
BPF	Biocidal Product Family
BPR	Regulation (EU) No 528/2012, Biocidal Product Regulation
CAD	Chemical Agents Directive, Directive 98/24/EC
CEN	European Committee for Standardization
CEN TC	CEN Technical Committee
CG	Coordination Group set under BPR
CLP	Classification, Labelling and Packaging of dangerous chemicals
CLP Regulation	Regulation (EU) No. 1272/2008 on classification, labelling and packaging of hazardous substances and mixtures
CMRD	Carcinogens, mutagens or reprotoxic substances at work Directive, Directive 2004/37/EC
ConsExpo	Consumer Exposure Tool
eCA	Evaluating Competent Authority
ECETOC	European Centre for Ecotoxicology and toxicology of chemicals
ECETOC TR	Technical report of ECETOC
ECETOC TRA	Targeted Risk Assessment of ECETOC
ECHA	European Chemical Agency
EFSA	European Food Safety Authority
ESCom	eSDScom (the industry standard for sending safety data sheets, exposure scenarios and all relevant compliance info in the chemical supply chain) integrates formerly known as the EuPhraC, SDScom and (since version 5.4) ESCom tools.
EUH	CLP risk phrases carried through from the Dangerous Substance Directive 67/548/EEC and Dangerous Products Directive 1999/45/EC to CLP Regulation, that are not yet included in the Globally Harmonised System for Classification and Labelling of chemicals of the United Nations (UN GHS)
EU-OSHA	European Agency for Safety and Health at Work
FAO	Food and Agriculture Organization of the United Nations
FDIS	Final Draft International Standard
Forum	ECHA's Forum for Exchange of Information on Enforcement

iMS	Initiating Concerned Member State
GESTIS	Database for International limit values for chemical agents (Occupational exposure limits, OELs)
GI(T), GT	Gastrointestinal Tract
HH WG, WG TOX	BPC Working group on Human Health
HEAdhoc	BPC Ad hoc Working Group on Human Exposure
HEEG	Human Exposure Expert Group under Biocidal Product Directive 98/8/EC, BPD
MMAD	Median mass aerodynamic diameter
MSCAs	Member State Competent Authorities for biocides
MSs	Member States
LEV	Local Exhaust Ventilation
LOAEC	Low Observed Adverse Effect Concentration
NOAEC	No Observed Adverse Effect Concentration
OELs	Occupational Exposure Limits
OSH Framework directive	European Framework Directive on Safety and Health at Work, Directive 89/391 EEC
OSH National authorities	National authorities on occupational safety at work
PPE	Personal Protective Equipment
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and restriction of chemicals under Regulation (EU) No. 1907/2006, REACH Regulation
RJPSST	Portuguese Legal Regime for the Promotion of Safety and Health and Work
RPE	Respiratory Protective Equipment
RMM	Risk Management Measures
rMS	Reference Member State
RT	Respiratory Tract
SCBP	Standing Committee on Biocidal Products, Standing Committee
SDS, (M)SDS	(Material) Safety Data Sheet
SLIC CHEMEX	Working group of Senior Labour Inspectors Committee for Chemical Safety and health issues at workplace
SPC	Summary of the Products Characteristics
SUCAM	System for selection, use, care and maintenance of advanced garments and ensembles of garments that provide protection against heat and flame, with integrated smart textiles and smart non-textile elements for enhanced health, safety and survival capabilities that are compliant with the European legislation
TAB	Technical Agreements on Biocides
STOT-RE	Specific Target Organ Toxicity after Repeated Exposure
TNsG	Technical Notes for guidance on implementation of Biocidal Products Directive 98/8/EC (BPD)
VMD	Volume Median Diameter

VOCs	Volatile Organic Compounds
UA	Union authorisation
UK HSE	Health and Safety Executive of United Kingdom
WHO	World Health Organisation
WG	Working Group
WINGIS	Hazardous Substances Information System of German statutory accident insurance association for the construction sector (BG BAU) (known as GISBAU)

1. Request for the opinion and background

The Article 75(1)(g) mandate[1] provides the following:

"(1) During the 76th, 77th and 78th meetings of the Standing Committee on Biocidal Products that took place from June to October 2022, the Commission presented a draft Implementing Regulation for the authorisation of the biocidal product family 'active chlorine-based products BPF – CID Lines' (the BPF) containing active chlorine released from sodium hypochlorite as active substance for uses in PT 2, 3, 4 and 5[3]. The BPF contains products classified as skin corrosive 'H314 – Causes severe skin burns and eye damage' due to the presence of sodium and/or potassium hydroxide[4] in the composition of the mixture. The proposal was based on the opinion of ECHA's Biocidal Product Committee (BPC) adopted on 19 August 2022.

(2) During the peer review of the assessment conducted for the BPF in ECHA's BPC, and to address concerns from France and Germany about the risks for professional users from applying such products by coarse spraying, consensus was reached at an ad hoc follow-up meeting of the ECHA Human Health Working Group of 22 June 2021 to request the evaluating Competent Authority (eCA) of Belgium to perform a local qualitative risk assessment for the relevant uses.

(3) The eCA of Belgium presented the outcome of its local qualitative risk assessment in the revised product assessment report (PAR) for discussion at BPC in October 2021 together with a proposal for personal protective equipment (PPE) and respiratory protective equipment (RPE) to be worn by the operators in order to mitigate the identified risks. In accordance with the ECHA BPR guidance Vol III, part B+C ('the ECHA BPR guidance'), table 27, the wearing of protective equipment could allow for deviations from the maximum frequency and duration of potential exposure if found acceptable by expert judgment. The BPC then adopted its opinion and recommended to authorise the BPF.

(4) After the 76th Standing Committee meeting in June 2022[5], the French authorities informed the Commission that they cannot support the authorisation of corrosive products applied by coarse spraying. They considered that a local qualitative risk assessment is not acceptable because the requirements of the ECHA BPR guidance for professional would not be met (e.g. that the time of exposure of the operator would be largely exceeded compared to the recommendations of the guidance[6]) and because of the irreversible damage resulting from the exposure to corrosive particles. They also criticised the types of PPE and RPE recommended by the eCA. According to the French authorities, it is expected that, given the high exposure of the operator to corrosive particles during coarse spraying applications, no adequate means of protection could be recommended to reach in practice no exposure as recommended by the BPR guidance[7].

(5) The French authorities also argued that similar products to be applied by coarse spraying for which France is the eCA (the biocidal product families 'Sodium hypochlorite – general and water disinfection' and 'Sodium hypochlorite – general disinfection') were not recommended for authorisation by the experts of the BPC Human Health Working Group (HHWG) in June 2022[8]. At BPC 44 in September 2022, the BPC confirmed the position of the HHWG and adopted opinions not recommending authorisation of the relevant products. The opinions were then submitted to the Commission on 29 March 2023.

(6) In December 2022, ECHA confirmed, based on information provided by both the Belgian and French authorities that there is no significant difference in the classification and uses of the products applied by coarse spraying in both applications.

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[3] Case number BC-MY047028-07
[4] See uses 1.1, 7.1, 8.1, 9.1 10.1 in PT2; uses 7.2, 8.2 in PT3 and uses 7.3, 8.3, 9.3 and 10.2 in PT4.
[5] France already submitted a minority opinion at the BPC stage.
[6] Table 27 of the BPR guidance, column 2 - Exposure Frequency and duration of potential exposure: few minutes per day or less.
[7] Table 27 of the BPR guidance, column 3 - Degree of potential exposure under best practice conditions: high level of containment, practically no exposure; no splashes, no hand to eye transfer, no (liquid or solid) aerosol formation e.g. exposure below or similar to brief contact with technical RMM and PPE, as touching of contaminated surfaces.
[8] Case numbers BC-HQ045419-21 (Sodium hypochlorite – general and water disinfection) and BC-LK045398-25 (sodium hypochlorite – general disinfection).

(7) Based on the information available at the 78th meeting of the Standing Committee on Biocidal Products of December 2022, it was thus not possible for the Commission and the Member States to decide whether the relevant uses of the family active chlorine-based products BPF – CID Lines could be authorised with the protective equipment recommended in one case by the BPC, or if such use should not be authorised. It was agreed to clarify this issue with a request to ECHA pursuant to Article 75(1)(g).

(8) On 3 February 2023, ECHA and the Commission received further information from the applicant for the BPF 'active chlorine-based products BPF – CID Lines' claiming that the diluted product sprayed by coarse spraying should not be classified as skin corrosive. The current classification of the diluted product was based on an extreme pH of the concentrate (worst case) in the absence of test data submitted in the application. ECHA confirmed that the applicant already submitted data via R4BP on 16 August 2021 but that the information was submitted too late in the opinion-forming process to be considered by the eCA, the HHWG or the BPC.

(9) Taking into account the background information mentioned above, ECHA is required to provide response to the following questions:

General questions

1. *Clarify if proposing the wearing of protective equipment (PPE, RPE) for the use by coarse spraying of corrosive products is in line with the ECHA BPR guidance (in particular the four indicators of Table 27), or whether such approach is not possible for coarse spraying of corrosive products;*

2. *If this approach is compliant with the ECHA BPR guidance:*

    a. Clarify for which product classification and working conditions, these conclusions could apply;

    b. Clarify if any additional risk mitigations measures are needed in addition to the use of adequate protective equipment to reduce the exposure of the operators to in practice zero exposure (e.g. directional spraying, recommended pressure spraying, room ventilation, room volume, detection of ambient air chlorine concentration during application, limiting further the time of spraying…).

3. *Taking into account the answers that will be provided by ECHA to questions 1 and 2, consider whether a review/clarification of the existing ECHA BPR guidance is necessary.*

Specific questions related to the product family 'active chlorine-based products BPF - CID Lines' (eCA Belgium)

4. *Taking into account the information provided on 3 February 2023 by the applicant for authorisation of the product family 'active chlorine-based products BPF - CID Lines', and the answers that will be provided by ECHA to questions 1 and 2 of this mandate:*

    a. clarify whether the diluted products applied by coarse spraying still needs to be classified as skin corrosive 'H314 – Causes severe skin burns and eye damage';

    b. clarify which personal protective equipment is necessary for the use by coarse spraying of this product, for which meta-SPCs and justify;

    c. provide an updated versions of the SPC, as necessary, in particular as regards to any additional risk mitigation measure to reduce the exposure of the operators to in practice zero exposure.

Specific questions related to the product families 'Sodium hypochlorite – general and water disinfection' and 'Sodium hypochlorite – general disinfection' (eCA France)

5. *Taking into account the answers that will be provided by ECHA to questions 1, 2 and 3 of this mandate, review its previous opinions on those two families, as necessary (i.e. if the wearing of PPE and RPE can or cannot be recommended for the application of products classified as corrosive by coarse spraying with appropriate risk mitigation measures).*

Consistency question:

6. *If different recommendations in risk mitigation measures of the product family 'active chlorine-based products BPF - CID Lines' on one side, and on the product families 'Sodium*

hypochlorite – general and water disinfection' and 'Sodium hypochlorite – general disinfection' on the other side, are eventually proposed, explain the differences between the three families and the intended methods of use that justify different measures.

In addressing those questions, ECHA should consider and take into account the following elements:

i. All data submitted in the respective application dossiers for Union authorisation and applicable guidance referenced in footnotes 1 to 6;

ii. The open issue documents and the minutes of the Human Health Working group and its Ad-Hoc follow-up meetings where this issue was discussed for the three applications;

iii. Any relevant information already provided by the applicants (in particular additional data submitted by the applicant for the product family 'active chlorine-based products – CID Lines' on 16 August 2021 and any further information already available to this applicant since then but not yet submitted to ECHA), the eCAs following the HH WG discussions and during the BPC commenting period;

iv. Any information available to ECHA, and information that ECHA may obtain from OSHA or CEN working group experts[9] on the resistance of protective equipment to corrosive particles applied by coarse spraying;

v. Any information that ECHA can find internally from its activities on Occupational Exposure Limits (OELs);

vi. For a general appreciation of RPE, ECHA may consider the technical information referred to in guidance developed by other authorities including those in third countries[10].

vii. Any relevant EN standards for the means of protection of workers."

Considering the interlinks between the different questions of the mandate, and considering that an agreement needs to be achieved first on the general questions before tackling the case-specific questions, the opinion is split in two main sections:

- Section 1: addressing questions 1 – 3 or in other words the "general questions". A discussion in the HH Working Group is foreseen for WG-I-2024 with possible adoption in BPC-51 (BPC-II-2024).

- Section 2: addressing questions 4 to 6 which are linked to the specific Union Authorisation cases. A discussion in the HH Working Group and BPC will take place following the BPC agreement on the general questions Qs 1-3.

[9] *See for example CEN Technical Bodies - CEN/TC 162 (cencenelec.eu)*
[10] *See Respiratory protective equipment at work: A practical guide HSG53 (hse.gov.uk)*

2. General questions (questions 1 to 3)

2.1. Summary of information supporting the assessment

2.1.1. General considerations and methodology applied

2.1.1.1. Consultation of Forum, EU-OSHA, OSH national focal points and SLIC-CHEMEX

In order to answer the general questions of this mandate, ECHA developed a questionnaire and launched a consultation to collect information on the acceptability of coarse spraying of corrosive products by national authorities. ECHA sought to collect information about any guidance, best practices, publications or OELs[11] available in the Member States about the coarse spraying of corrosive products by professionals and the associated exposure controls/personal protection. The following fora/members were consulted:

- Forum
- EU-OSHA
- OSH National authorities
- SLIC CHEMEX

An overview of the input received from EU-OSHA and five Member States can be found in the confidential Annex I.

2.1.1.2. Consultation of CEN Technical bodies

In parallel, ECHA developed a questionnaire and launched a consultation in order to gather specific input from Technical bodies of the CEN and its working groups on the resistance of protective equipment to corrosive products applied by coarse spraying and specific EN standards which would be applicable for such applications. The following CEN Technical bodies were consulted:

- CEN Technical Committee (CEN TC) 162
- CEN TC 462

An overview of the input received can be found in the confidential Annex I. Input was received from CEN TC 162 Working group (WG) 3 "Protective clothing against chemicals, infective agents and radioactive contamination".

2.1.1.3. Human Health Working group and BPC discussions

2.1.1.3.1. Human Health WG-II-2021

Case-specific discussion

In the context of the Union Authorisation case evaluated by BE CA (eCA), referred to in this mandate, the acceptability of professional spray use of corrosive products had been questioned and followed by discussions in the HH WG and in an ad hoc follow-up arrangement. See confidential Final minutes[12] and Annex II for relevant extract.

[11] Occupational exposure limits - ECHA (europa.eu)

[12] WGII2021_TOX_Minutes_Final *(Restricted access to MSCAs only)*: https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/68db5a5f-054f-49f2-a4b1-7a6a53db41f8/WGII2021_TOX_7-4_CID_LIN_Active_chlorine_BPF_PT2-5_Minutes_FINAL.docx

2.1.1.3.2. BPC-40

The above-mentioned case specific HH WG discussions have been finalised within the opinion adoption proceedings by BPC at its 40th plenary meeting. See public Final case minutes[13] under point 8.3.

2.1.1.3.3. Human Health WG-II-2022

Case-specific discussion

A discussion on the acceptability of the compression spraying of corrosive products by professionals took place at the HH WG-II-2022 in the context of the two FR eCA's Union Authorisations in scope of this mandate[8]. See confidential Final minutes[14][15] and Annex II for relevant extract.

2.1.1.3.4. Human Health WG-II-2023

Local risk assessment

A discussion at the 2nd meeting of the HH WG in 2023 (HH WG-II-2023) took place on local risk assessment in the context of the ECHA Guidance Vol III Parts B+C revision. Preliminary input from the members was collected on local risk assessment and the acceptability of the coarse spraying of corrosive products. See confidential Final minutes[15] and Annex II for relevant extract.

Case-specific discussion

A discussion on the acceptability of coarse spraying of corrosive products by professionals took place at the HH WG-II-2023 in the context of one Union Authorisation. See confidential Final minutes[16] and Annex II for relevant extract.

EN standards

A discussion took place at the HH WG-II-2023 regarding the requirement to assign an EN standard (or equivalent) when prescribing personal protective equipment (see confidential Final minutes[17] and Annex II for relevant extract).

2.1.1.3.5. Human Health WG-IV-2023

EN standards

An e-consultation[18] on EN standards and follow-up discussion took place at the HH WG-IV 2023 (see confidential Conclusions[19] and Draft minutes[20] in Annex II for relevant extracts).

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[13] BPC-40 final minutes: https://echa.europa.eu/documents/10162/2166591/bpc_40_minutes_en.pdf/0e1c8d2b-ba6f-8199-b5d9-709bd4221fbe?t=1652245021089

[14] WGII2022_TOX_Minutes_Final *(Restricted access to MSCAs only)*: https://interact-toolbox-docviewer.echa.europa.eu/wopihost-generic-module/OWA?fileID=090236e18807dc16&application=Meetings

[15] WGII2023_TOX_8-1_Local_risk_assessment_Minutes_Final.docx *(Restricted access to MSCAs only)*: https://interact-toolbox-docviewer.echa.europa.eu/wopihost-generic-module/OWA?fileID=090236e1896efa40&application=Meetings

[16] Final minutes - WGII2023_TOX_7-1 *(Restricted access to MSCAs only)*: https://interact-toolbox-docviewer.echa.europa.eu/wopihost-generic-module/OWA?fileID=090236e1896ef500&application=Meetings

[17] WGII2023_TOX_Minutes_Final *(Restricted access to MSCAs only)*: https://interact-toolbox-docviewer.echa.europa.eu/wopihost-generic-module/OWA?fileID=090236e1896ef4fc&application=Meetings

[18] WGIV2023TOX_9-1_EN_standards *(Restricted access to MSCAs only)*: https://interact-toolbox-docviewer.echa.europa.eu/wopihost-generic-module/OWA?fileID=090236e189ac3095&application=Meetings

[19] WGIV2023_TOX_9-1_EN_standards_Conclusions *(Restricted access to MSCAs only)*: https://interact-toolbox-docviewer.echa.europa.eu/wopihost-generic-module/OWA?fileID=090236e189b7e3ec&application=Meetings

[20] WGIV2023_TOX_Minutes_draft *(Restricted access to MSCAs only)*: https://interact-toolbox-collaboration.echa.europa.eu/wopihost-module/OWA?doc=41543ebc-869c-ff69-29cc-e941fe81e943

2.1.2. Standing committee discussions

The issue in scope of this mandate were discussed in the SCBP-77 (see public Final minutes[21]) and SCBP-78 (see public Final minutes[22] and respective confidential meeting document B.05[23] in Annex II).

2.1.3. Coordination Group (CG) discussion

A discussion[24] on the coarse spraying of corrosive products took place at the CG in the context of a disagreement on Mutual recognition in accordance with Article 35(2) of the BPR. See confidential Annex II for relevant documents.

2.1.4. Other input from MSs

Upon request at the BPC-47 in June 2023 (see point 9.2 of the confidential BPC-47 minutes[25]), ECHA also received some input from MSs on a bilateral basis (see section 2.4.6).

2.2. Types of spraying

In the consultations described in 2.1.1.1, regarding the types of spraying, the following guidance was referred to:

- The Portuguese Code of conduct for applicants of phytopharmaceuticals (Appendix A to Annex I, parts G, H and I) provides further useful details on where and how the spraying solution and "drift" are produced and applied, including the factors contributing to the spray entrainment and ways to control them, what type of spraying equipment may be used for the purpose (e.g. sprayers, baits, nebulizers, dusters, irrigators, fumigators, granule distributors) and the parameters to be considered when selecting the most appropriate equipment.

- The EFSA Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products (2014, updated in 2022)[26] includes useful references to spraying devices, but focuses more on the spraying drift formation and estimating the expected exposure.

2.2.1. "Coarse" spraying

The mandate refers "corrosive particles during the use of biocidal products by coarse spraying". The following clarifications are needed:

- The word "particles" is understood to refer to liquid spray droplets and not solid particles.
- The term "coarse spraying" is not defined in the BPR guidance but should be understood as referring to relatively large droplet sizes generated by the method used.

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[21] SCBP-77 minutes: https://health.ec.europa.eu/events/77th-meeting-standing-committee-biocidal-products-2022-10-06_en?prefLang=pl
[22] SCBP-78 minutes: https://health.ec.europa.eu/events/78th-meeting-standing-committee-biocidal-products-2022-12-08_en
[23] Document SCBP78-Doc.B.05 in CIRCABC *(Restricted access to MSCAs only)*: https://circabc.europa.eu/ui/group/8b6b0199-c74b-43bd-a9dd-79bdcae3b825/library/9acebdac-633f-48ab-bdfe-01f713bace4b/details
[24] Referral: https://interact-toolbox-collaboration.echa.europa.eu/collaboration-frontend/collaborations/754707
[25] BPC-M-47-2023_final_confidential_minutes: https://interactportal.echa.europa.eu/meetings?title=BPC-48-1&agendaPointUniqueId=AP-b3cdecf3-6300-44cd-9b4c-a19758b31e0d
[26] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2022.7032#:~:text=The%20EFSA%20Guidance%20on%20the,approach%20to%20exposure%20assessment%20remains

The *Technical Notes for guidance*[27] (TNsG Part 2[28], 2002 p. 246) on ECHA website informs that "spray, coarse" has aerosol droplet sizes of a diameter > 400 µm:

- *Droplet size*

Pest control products can be sprayed using a ready-to-use aerosol can or a plant sprayer. The droplet size is an important parameter when estimating the exposure. Smaller drops fall at a lower speed and stay in the air for longer. The large droplets will quickly disappear from the air after being formed. As an indication: the falling time of droplets with a diameter of 100 µm from a height of 3 meters is calculated at 11 sec, and for droplets of 10 µm it is calculated at 17 min (Biocides Steering Group, 1998). If a larger droplet is sprayed, part of the aerosol cloud will consist of finer droplets which stay in the air for longer, as a result of edge effects around the nozzle and the 'bounce back' effect due to spraying onto a surface. There is hardly any measurement data available for the droplet size.

"Assessment of human exposure to biocides" from the Biocides Steering Group (1998) gives a WHO classification with regard to the droplet size of sprays (table 5).

Table 5 Classification of aerosol droplets

Droplet diameter [µm] a)	Classification
< 15	mist
< 25	aerosol, fine
25-50	aerosol, coarse
51-100	mist
101-200	spray, fine
210-400	spray, medium
>400	spray, coarse

a): the median diameter; half of the particles are larger, half are smaller

The TNsG, Part 2 (p. 291) further specifies that:

> "*Sprays for a surface application (such as targeted spot, crack and crevice and general surface sprays) produce a coarser droplet, designed to end up on the sprayed surface.* ***Part of the aerosol cloud will actually consist of finer droplets which stay in the air for longer and can be inhaled****. No references were found with relation to the percentage of the aerosol cloud that become airborne. The default value will initially be set at 15%.*
>
> *Sprays for air space spraying applications are meant to produce a very fine mist which stays in the air for a longer period of time. The value of this parameter can therefore be set at 100% for air space spray applications: all of the active ingredient is present in the air after spraying."*

Information from "PES" (Pesticide Environment Stewardship[29]) provides information on droplet size categories, indicating that coarse spraying has an approximate Volume Median Diameter[30] range of 326-400 µm.

In the context of this mandate, "coarse spraying" is understood to:

- refer to the spraying of average droplet sizes above 325 µm with a liquid biocide solution or dispersion.

- lead to exposure in all directions (a wide dispersive use) and aerosol formation (as noted in the TNsG reference above).

The above interpretations will be subject to discussion in a wider scope when preparing

[27] Technical Notes for guidance on implementation of Biocidal Products Directive 98/8/EC (BPD): https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/biocidal-products-directive

[28] Technical Notes for guidance on Human exposure to Biocidal Products – Guidance on exposure estimation (June 2002), Part 2: https://echa.europa.eu/documents/10162/983772/bpd_guid_tnsg+human+exposure+2002_en.pdf/af2020f7-6cd2-471a-8cf2-efd1a0500fa8

[29] Understanding Droplet Size – Pesticide Environmental Stewardship (pesticidestewardship.org)

[30] The Volume Median Diameter (VMD) refers to the midpoint droplet size (median), where half of the volume of spray is in droplets smaller, and half of the volume is in droplets larger than the median. A VMD (DV0.5) of 400, for example, indicates that half of the volume is in droplet sizes smaller than 400 microns, and half the volume is in droplet sizes larger than 400 microns.

further guidance; please refer to chapter 2.6 further clarifying the topics for guidance development.

2.2.2. "Coarse spraying" vs. "compression spraying"

At the request of the Commission (see point (9) in SCBP77-Doc.B.06 in confidential Annex II), a table summarising the uses by coarse spraying included in the 3 union authorisations (UA) in scope of this mandate was performed by ECHA in collaboration with the eCAs FR and BE. This table was shared in SCBP-78 (see *SCBP78-Doc.B.05_ACI CID Lines_update* in confidential Annex II) and includes information on the uses of the products applied by coarse spraying in these UA applications, such as duration, type of spraying and the pressure applied. It should be noted as well that ART modelling was used in these exposure assessments with volatile substances. Based on information provided by the FR and BE eCAs, it was concluded that there are no significant differences in the uses of the products applied by coarse spraying in these UA applications.

While the mandate and BE UA application refers to "coarse spraying", the terms "coarse spraying" and "compression spraying" are both used in the FR UA application, which may lead to confusion. Both terms were also used and referred to in different documents, discussions and fora (e.g. HH WG-II-2023 minutes/RCOMs, Standing Committee, CG).

As discussed above and in the SCBP-78 document, the "coarse spraying" uses in scope of this mandate are very similar, and these assessments refer e.g. to HEAdhoc Recommendations No. 6[31] and 3[32].

HEAdhoc Recommendation No. 6 proposes an exposure scenario for the professional hard surface disinfection by coarse spraying. Spraying Model 1 is proposed as the exposure model for low pressure spraying (1 to 3 bar) of non-volatile substances, with exposure duration of 120 minutes.

						• Ventilation: 2.5/hour
3.	PT2[2]	Professional hard surfaces disinfection (floors, walls, ceilings) by	Liquid	Spraying Model 1 Spraying Model 1 can be used for low pressure spraying (spray pressures from 1 to 3	Indicative dermal exposure – Hand: 181 mg/min (without protective gloves) 10.7 mg/min (inside gloves)	For inhalation exposure see *footnote 1*. For professional use (volume knapsack 15L) time is 6 hours exposure duration. The data originates from a HSE study, UK. The model

No	PT	Exposure scenario	Aggregation state of the product (solid/liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
		coarse spraying		bar). For volatile compounds the assessment of vapour in addition is necessary.	– Body: 92 mg/min Indicative inhalation exposure to non-volatile compounds: 104 mg/m³ Exposure duration 120 minutes. Area of disinfection is necessary for the assessment of volatile compounds.	UK-POEM model, mandatory within European crop pesticide regulation, provides information on the times and volumes used for exposure assessment of knapsack spraying. During the HEAdhoc-1-2016 meeting, the spraying time of 120 minutes was proposed, in line with the spraying time for insecticides. 181 mg/min = max of range 10.7 mg/min = 75th % value and 104 mg/m³= median (50th % value) When air concentrations are used to compare to toxicological value choose no median but higher percentiles. However, the use of the 75th percentile (130 mg/m³) is not described in the TNsG 2002 User Guidance - Version 1.
4	PT2	Professional hard	Liquid	– Trigger spray consumer	Indicative dermal exposure	This scenario was included after discussion

HEAdhoc Recommendation No. 3 refers to Spraying model 1 being the classical model used for professional low pressure spray applications. The task is described as:

> *"Mixing and loading liquids and powders in compression sprayers or dusting applicators and applying at 1 to 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards."*

[31] HEAdhoc Recommendation No. 6: https://echa.europa.eu/documents/10162/1154636/recom6_methods_models_en.pdf/3399feed-8731-4a5b-b37f-0be2853b2f4c?t=1591272532625

[32] HEAdhoc Recommendation No. 3: https://echa.europa.eu/documents/10162/1154636/recom3_spraying_model_low_pressure_pt18_en.pdf/544ff551-8664-449d-ba17-b575c189ff4b?t=1415211477989

Compression sprayer working under low pressure is understood as a spraying device achieving a "coarse spray", i.e. average droplet sizes above 325 µm.

The above interpretations will be subject to discussion in a wider scope when preparing further guidance; please refer to chapter 2.6 further clarifying the topics for guidance development.

2.3. Hierarchy of control

2.3.1. General principles

For occupational risk management, the general measures necessary for safety and health protection of workers (article 6 of Directive 89/391/EC), the reduce-to-a-minimum principle (article 6 of CAD) and the hierarchy of RMM prescribed in the CAD must be followed. This includes in particular:

- avoiding risks;
- evaluating the risks which cannot be avoided;
- combating the risks at source;
- giving collective protective measures priority over individual protective measures;
- develop a coherent risk prevention policy;
- replacing dangerous by non-dangerous or the less dangerous;
- giving appropriate instructions to workers.

The OSH Directive 89/391/EEC also clearly specifies that the employers have the duty to ensure the health and safety of workers in every aspect related to their work, in particular sensitive risk groups must be protected against the dangers that specifically affect them.

The recommended RMMs for the occupational setting should enable and support the employer to meet the goals of occupational safety and health protection. Manufacturers, importers and downstream users should therefore consider measures needed for controlling risk in the order of the following hierarchy of the general workflow:

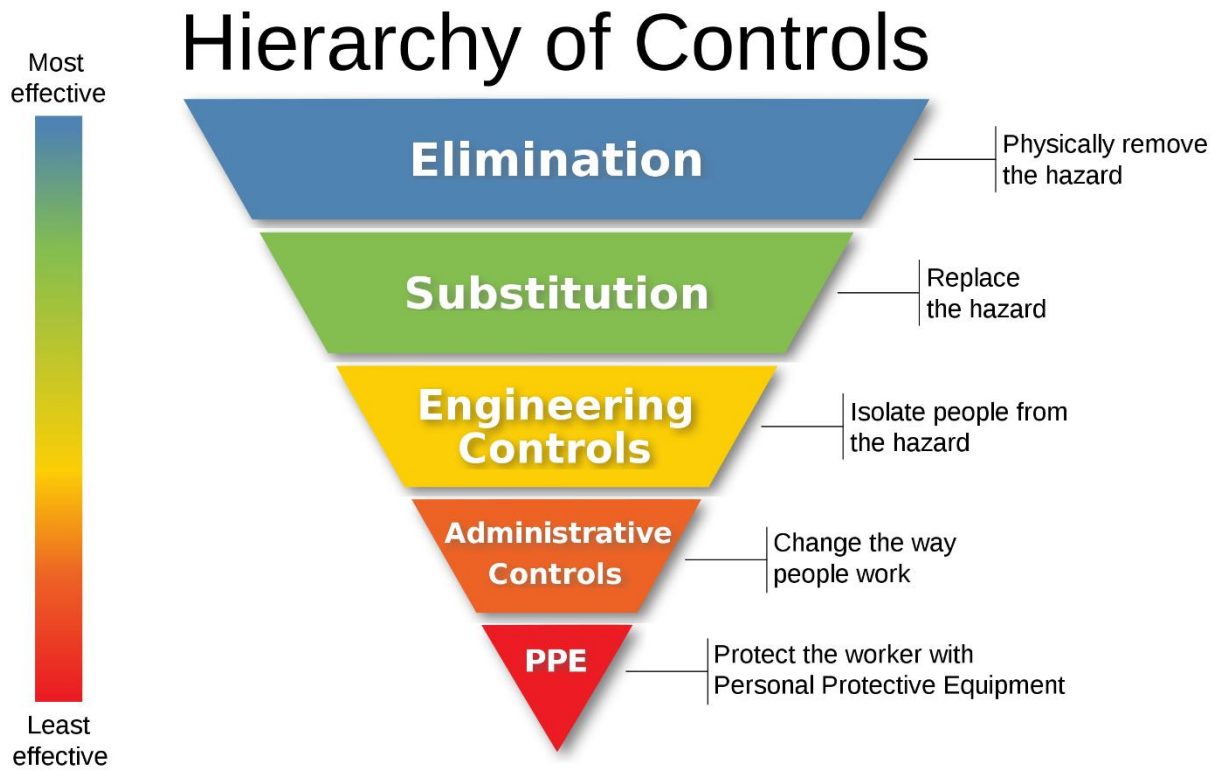
- Eliminate risks by limiting the use of the substance in market or modification of process, by using intrinsically safe equipment[33] or by automation;
- Reduce risk by limiting the concentration of a substance, and/or change form of physical state, and/or apply closed processes, and/or install effective local exhaust ventilation;
- General area ventilation and other workplace related measures (like segregation of dirty departments, safe storage, fire/explosion protection and prevention, eyebaths/showers);
- Other collective RMMs[34] aimed at protecting the population of workers, e.g., organisational measures limiting the number of exposed workers or the duration of exposure;
- Personal protective equipment (respiration, skin, eyes) where exposure cannot be prevented by other means.

Apart from substance or process specific risk management measures, good industrial hygiene practice forms the basis to minimise exposure of workers during and after normal operations. Personal hygiene procedures (e.g. washing hands after handling of substances, changing contaminated cloths) and organisational settings (e.g. separation between exposure areas and non-exposure areas) should be supported by regular

[33] For more details, see Directive 2014/34/EU: https://eur-lex.europa.eu/eli/dir/2014/34/oj

[34] Collective RMM = a measure to eliminate workplace risks at source, through technical or organisational means or by providing protection on a collective basis, like providing scaffolding instead of harnesses, that have priority over protective measures applying to individual employees (see collective protective measure | Safety and health at work EU-OSHA)

training/instruction of workers and consequent supervision. Application of PPE should be based on acceptance and a high level of comfort to achieve effective implementation (REACH Guidance R.13 Risk management measures and operational conditions[35], version 1.2, October 2012).



Infographic by NIOSH.

Control methods at the top of graphic are potentially more effective and protective than those at the bottom. Following this hierarchy normally leads to the implementation of inherently safer systems, where the risk of illness or injury has been substantially reduced.

This approach has been already enforced under the REACH Authorisation process that is very similar to the product authorisation processes under BPR. The REACH AfA (application for authorisation) Guidance[36] notes that the applicants are responsible to provide sufficient information on RMMs (including PPEs with relevant EN standards) in their applications and gives clear advice how to do it.

Further elaboration of technical measures/engineering controls that reduce dispersion, adapted from Hierarchy of controls applied to dangerous substances - OSHwiki | European Agency for Safety and Health at Work (europa.eu)

When measures at the source cannot sufficiently reduce the release of substances, technical measures that reduce further dispersion and consequently exposure of workers should additionally be considered. Local exhaust ventilation (LEV), which extracts the substances as close to the source as possible, should always be the first option to consider. Usually, it is much more effective than general (room) ventilation. However, daily checks of its proper functioning - by the worker, as well as periodic maintenance – to be organised by the employer – are crucial to the effectivity of these measures.

BPR, Annex VI, paragraph 62 refers to the same principles, as explained above, i.e. that:

> "*The evaluating body shall, where appropriate, conclude that criterion (iii) under point (b) of Article 19(1) can only be complied with by application of prevention and protection measures including the* ***design of work processes, engineering controls, use of adequate***

[35] https://echa.europa.eu/documents/10162/17224/information_requirements_r13_en.pdf
[36] How to apply for authorisation_v1_corrected (europa.eu)

> ***equipment and materials**, **application of collective protection measures** and, where exposure cannot be prevented by other means, **application of individual protection measures** including the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles, in order to reduce exposure for professional operators."*

It must be noted that it is the core responsibility of the applicants to provide sufficient information in their biocidal applications about the manufacturing/formulation processes, the operational conditions set, the concerned worker groups and all measures undertaken by manufacturers/producers, following the 'Hierarchy of control' considerations, while ensuring the elimination or minimisation of risks for human health when applying appropriate technical, operational or other measures (incl. use of PPE). All these have to be taken into consideration during the risk characterisation of concerned hazardous biocidal active substance and products, together with the conclusions of their hazard and exposure assessment when deciding on the risk acceptability for the claimed biocidal uses.

In line with Commission Implementing Decision (EU) 2022/835[37], "*where the applicant for authorisation identifies **technical or organisational measures** and the authorising authority agrees **that** such measures achieve a level of **exposure reduction** equivalent to or higher than the reduction achieved by wearing the protective equipment referred to in the first paragraph, or the authorising authority itself identifies such measures leading to an equivalent or higher level of exposure reduction than the reduction achieved by wearing the protective equipment referred to in the first paragraph, **those measures shall be used instead of that personal protective equipment** and shall be specified in the authorisation and on the label of the biocidal product. In that case the obligation to include the condition regarding the use of the biocidal product laid down in the first paragraph shall not apply.*"

The applicants should describe the possibilities for substitution with less hazardous options or for implementation of technical measures, such as automation and operational RMMs for controlling the risks at the workplace, before exploring the need for PPE.

When a range of multiple diverse uses is proposed for authorisation, the worst-case(s) have to be identified and assessed first by the applicant. It is the eCA's task then to evaluate the hierarchy of control information and RMMs/PPEs proposed, while concluding on the acceptability of identified risks from biocidal uses at workplace during the evaluation of the biocide application. Where necessary, the eCA may request additional information to clarify the appropriateness and the efficiency of recommended RMMs.

When an authorisation on a biocidal application is granted, it may include terms and conditions that have to be followed by all users, including employers and employees at the workplace. The national enforcement authorities have the responsibility to check if authorised biocidal products are used according to the relevant legislation (BPR, CLP, OSH, etc.).

This approach is of particular importance also when assessing the acceptability of any occupational risks and potential exposure reduction/elimination measures in coarse spraying applications with corrosive products.

2.3.1.1. Local exhaust ventilation

Designing effective LEV is a specialist activity. If the design, installation, maintenance or the operation of LEV is improper, its effectiveness will be reduced. It is advisable to consult a specialist supplier in order to ensure its effectiveness. Generally, well-designed and correctly operated LEV systems may be capable of reducing exposure by 80-99%. A general recommendation is to place the inlet of the system as close to the source as possible. For LEV hoods a maximum distance equal to the diameter of the hood is often used as a rule of thumb. Other recommendations are to avoid long or bended ducts, and to take account of potentially turbulent air flows. Advantage should be taken of the direction and kinetic energy of the emitted substances. In many cases it will be necessary to (partially) enclose

[37] Implementing decision - 2022/835 - EN - EUR-Lex (europa.eu)

the process to increase the effectiveness of the LEV.

2.3.1.2. General ventilation

Although LEV generally is the preferred option, it is never 100% effective. Therefore, additional general ventilation is sometimes needed (depending on the outcome of the risk assessment) to prevent the uncaptured pollutants from building up to harmful concentrations. In scenarios where many small diffuse sources are present, general ventilation may even be the preferred option.

Natural ventilation, i.e. opening doors or windows, is normally not considered sufficient because it is less feasible e.g. during the night and winter, and it is difficult to estimate its efficiency. As for LEV, the design, installation and maintenance of general ventilation is a specialised task. Careful consideration is needed regarding the location of air inlets and outlets, to prevent short circuits where fresh air that is brought in is extracted again close to the inlet, without diluting the pollutants. In addition, the required air flow (in m^3/hour) or the number of air changes per hour should be determined. The geometry of the room, any objects that might disturb airflows and interfering air flows should all be considered. The possibilities for recirculation, in relation to filtering options and energy demand for heating, are often considered. In most cases, recirculation is not allowed when carcinogenic substances are present. It is advisable to consult a specialised supplier of ventilation systems to ensure its effectiveness.

2.3.2. Organisational measures

Organisational measures have generally not been very strictly defined and may include several types of measures. Here, a distinction is made between spatial measures, influencing the locations of worker and hazardous substances and the distance between the two, and temporal measures, determining the period of time in which emission of substances occurs relative to the period of time that workers are present or exposed.

2.3.2.1. Spatial measures

Spatial measures aim at increasing the distance between the worker and the substances emitted, or in ideal cases at full separation (segregation) of the worker from the source of the substances. Full separation may be achieved by access restrictions to certain areas. Access to areas where biocidal products have recently been sprayed may be temporarily restricted. This prevents secondary exposure to vapours or mists by inhalation. Access to work in confined spaces, e.g. to carry out maintenance in tanks, should be strictly limited to those who are properly instructed and protected. Finally, a less radical type of separation in general is the use of long-stemmed brushes, rollers, or mixing equipment. This type of equipment increases the distance from the source and may have some effect on both inhalation and dermal exposure, although the magnitude of the effect remains unclear.

For coarse spraying applications, the use of long(er) spray lance would be an appropriate spatial measure.

2.3.2.2. Temporal measures

Temporal measures may reduce the duration of the exposure for individual workers. Task rotation is a well-known example.

Thoughtful work planning may reduce workers' exposure. For example, spraying of biocidal products could be carried out when other workers are not present.

2.3.3. PPEs/RPEs

2.3.3.1. General principles

The following paragraph is adapted from REACH R.14 Occupational Exposure Assessment, version 3, June 2016[38] pages 25-26.

PPE is used when residual exposure cannot be avoided after application of other means. Thus, exposure scenarios that rely on PPE as a primary risk management option should be avoided whenever possible. Selection and use of personal protective equipment will always need to be seen within the context of national OHS legislation where the full range of risks need to be considered.

For example, the employer may need to consider the additional physiological burden introduced by the use of PPE, such as heat stress, or impact on the hands due to long wearing of PPE, if appropriate breaks are not taken. It is the responsibility of the employer to ensure such risks are avoided. This may be particularly relevant to exposures for extended periods, for example when wearing of impervious gloves national legislation requires that breaks are taken to avoid the effect of wet working (e.g. time for continuous wearing of the gloves may need to be limited e.g. 2 hours, 4 hours depending on the case).

For the risk characterisation, the RCR should be calculated including the reduction factor achieved by the use of the PPE. The reduction factors applied should be transparently reported in the AR. Justification should be provided when PPE is specified within exposure scenarios as the primary method to achieve acceptable exposures. The use of RPE should usually be a temporary measure, during short time intervals, until other technical measures are provided to ensure safe use. RPE should be proposed for use well within its designed performance. This may mean an exposure assessment that indicates an RPE performance of 90% (by default). However, equipment providing 95% or better performance may be preferred (based on good practice advice) to meet the requirements of other legislation, especially in cases where the exposures are close to the limit values.

PPE to protect against dermal exposure will often be needed due to the very variable and unpredictable nature of dermal exposure. The outcome of the quantitative assessment alone should not be the only information used to propose suitable and adequate gloves, chemical resistant footwear and other chemical protective clothing such as coveralls. Glove effectiveness is determined by the management systems in place to ensure the prescribed level of performance. The required level of management is described by the eSDSCom phrases (https://phrases.esdscom.eu/) which are generally included in the exposure scenarios. Gloves alone will not provide protection when other parts of the body are exposed. It is an absolute requirement that the barrier properties of the glove material are known to be adequate to ensure the substance does not migrate through the material of the glove during the proposed use. It is important that gloves are sufficiently described in the IUCLID dossier, the AR and SPC so that there is assurance that suppliers of substances and formulations, can effectively communicate (in section 8 of the Safety Data Sheet) the correct information to downstream users. Important information on gloves relates to those materials that are effective and over what duration they are effective. It is also useful to provide information on common glove materials that are known not to be effective as a barrier. Note: Glove manufacturers' literature may provide indicative information, but the best information derives from specific testing against the specific substance. Such information will also help producers of mixtures to select appropriate gloves for their products. Information such as "*suitable chemical resistant gloves tested according to EN 374*" alone does not give sufficiently concrete information to ensure the correct information is available to control the risk adequately down the supply chain (REACH R.14 Occupational Exposure Assessment, version 3, June 2016[38]).

[38] Guidance on Information Requirements and Chemical Safety Assessment Part R.14: Occupational exposure Assessment - Draft (Public) Version 3.0 - June 2016: https://echa.europa.eu/documents/10162/2324909/r_14_caracal_en.pdf/18442141-4b1a-41cb-b2eb-c619aae9fcb5?t=1467622667011

Where potential eye exposure cannot be eliminated through technical/ organisational measures, then eye appropriate eye protection shall be selected, such as a face shield or chemical goggles.

In the consultations described in section 2.1.1.1 a number of useful references were included. The Appendix A to Annex I covers several Portuguese guidance documents (in EN and PT languages) on exposure control against chemical agents, on selection of PPE, RPE and protective gloves, on safe use of phytopharmaceuticals where a good description of the EU and PT legal framework and its implementation, as well as listing of the appropriate/available EN standards for each of them.

For example, part G of the Code of conduct for applicants of phytopharmaceuticals (Rf. Appendix A to Annex I) clearly notes for the product users that "*The Safety Data Sheets and the label of the products in question provide clear instructions on the PPE to be used as well as the conditions under which the product must be applied. In general, it is also necessary to observe a re-entry interval into the facilities or treated field and also implement safety measures in the vicinity of the treated area to protect people unfamiliar with the treatment and animals. Clearly visible warnings must be placed around the entire area to be treated, alerting you to the imminent application, identifying the product, the duration of the treatment and the length of waiting time before being able to re-enter the treated area. Strictly respect the labelling instructions and instructions in the product's Safety Data Sheet.*"

The Technical manual for safety in the use of plant protection products further specifies the minimum PPE recommended, how to choose most suitable protective suits, masks, gloves, rubber boots, visors, goggles, hats, etc. (including references to the relevant EN standards) and how to maintain/clean the PPE after product applications.

The UK HSE practical guide[39] on respiratory protective equipment at work also provides good overview of the RPE types, selection, use and maintenance, as well as some examples on selecting adequate and suitable RPE in a few case studies (see Appendix V of the guide).

See also in Appendix B to Annex I provided links to other useful PPE guidelines.

The risk mitigation measures in the SPC should contain the information that the employer must provide company-specific instruction on the safe handling and operation of the respiratory protective equipment.

When RMMs for biocidal applications include the use of PPE for controlling occupational risks, employers must ensure that their employees are properly trained on the correct use of the PPE and its maintenance.

2.3.3.2. EN standards

There are a wide range of EN standards[40] referring to the type/specification or testing of PPE. Numerous examples are taken from the EU OSH-wiki.

For example, Annex III of the Portuguese Guide on PPE selection (see it in Appendix A to Annex I) provides a good overview on the standardisation at International/EU and national level - its purpose, framework, principles and standard preparation processes.

Appendix B to Annex I provide some useful links to several CEN standards.

EN standards for respiratory protective devices:

[39] https://www.hse.gov.uk/pubns/priced/hsg53.pdf
[40] European Standards (EN standards): an expression of requirements for products, processes or services to meet the requirement of fitness for a particular purpose.

EN 136:1998	Respiratory protective devices. Full face masks. Requirements, testing, marking
EN 137:2006	Respiratory protective devices. Self-contained open-circuit compressed air breathing apparatus with full face mask. Requirements, testing, marking
EN 138:1994	Respiratory protective devices. Specification for fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece assembly
EN 140:1998	Respiratory protective devices - Half masks and quarter masks - Requirements, testing, marking
EN 142:2002	Respiratory protective devices - Mouthpiece assemblies - Requirements, testing, marking
EN 143:2000	Respiratory protective devices - Particle filters - Requirements, testing, marking
EN 144-1:2000	Respiratory protective devices — Gas cylinder valves
EN 145:1997	Respiratory protective devices - Self-contained closed-circuit breathing apparatus compressed oxygen or compressed oxygen-nitrogen type - Requirements, testing, marking
EN 148-1:1999	Respiratory protective devices — Threads for facepieces
EN 149:2001 + A1:2009	Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
EN 402:2003	Respiratory protective devices - Lung governed demand self-contained open-circuit compressed air breathing apparatus with full face mask or mouthpiece assembly for escape - Requirements, testing, marking
EN 403:2004	Respiratory protective devices for self-rescue - Filtering devices with hood for escape from fire - Requirements, testing, marking
EN 404:2005	Respiratory protective devices for self-rescue - Filter self-rescuer from carbon monoxide with mouthpiece assembly
EN 405:2001 + A1:2009	Respiratory protective devices - Valved filtering half masks to protect against gases or gases and particles - Requirements, testing, marking
EN 1146:2005	Respiratory protective devices - Self-contained open-circuit compressed air breathing apparatus incorporating a hood for escape - Requirements, testing, marking
EN 1827:1999 + A1:2009	Respiratory protective devices - Half masks without inhalation valves and with separable filters to protect against gases or gases and particles or particles only - Requirements, testing, marking
EN 12021:2014	Respiratory equipment — Compressed gases for breathing apparatus
EN 12083:1998	Respiratory protective devices - Filters with breathing hoses, (Non-mask mounted filters) - Particle filters, gas filters, and combined filters - Requirements, testing, marking
EN 12941:1998	Respiratory protective devices - Powered filtering devices incorporating a helmet or a hood - Requirements, testing, marking
EN 12942:1998	Respiratory protective devices - Power assisted filtering devices incorporating full face masks, half masks or quarter masks - Requirements, testing, marking
EN 13794:2002	Respiratory protective devices - Self-contained closed-circuit breathing apparatus for escape - Requirements, testing, marking
EN 13949:2003	Respiratory equipment — Open-circuit self- contained diving apparatus for use with com- pressed Nitrox and oxygen — Requirements, testing, marking
EN 14387:2004 + A1:2008	Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking
EN 14435:2004	Respiratory protective devices - Self-contained open-circuit compressed air breathing apparatus with half mask designed to be used with positive pressure only - Requirements, testing, marking

EN 14529:2005	Respiratory protective devices — Self-contained open-circuit compressed air breathing apparatus with half mask designed to include a positive pressure lung governed demand valve for escape purposes only
EN 14593:2005	Respiratory protective devices - Compressed air line breathing apparatus with demand valve
EN14594:2005	Respiratory protective devices - Continuous flow compressed air line breathing apparatus - Requirements, testing, marking

EN standards for protective gloves:

EN ISO 374-1	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
EN ISO 374-2	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
EN ISO 374-3	Protective gloves against dangerous chemicals and micro-organisms – Part 3: Determination of resistance to permeation by chemists
EN ISO 374-4	Protective gloves against dangerous chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
EN 16523	Determination of material resistance to permeation by chemicals - Part 2: Permeation by potentially hazardous gaseous chemicals under conditions of continuous contact
EN ISO 21420:2020 updated the previous EN420:2003	Protective Gloves – General requirements and test methods Buying Guide: Buying the Right EN 420 Gloves EN 420 Waterproof Safety Gloves EN 420 Cut-Resistant Safety Gloves EN 420 Thermal Safety Gloves EN 420 High Dexterity Safety Gloves EN 420 Heat-Resistant Safety Gloves

EN standards for protective coverall:

EN ISO 13688	Protective clothing. General requirements
EN 943	Protective clothing against dangerous solid, liquid and gaseous chemicals, including liquid and solid aerosols Performance requirements for Type 1 (gas-tight) chemical protective suits
EN 14605	Protective clothing against liquid chemicals – performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])
EN ISO 13982	Protective clothing for use against solid particulates
EN 13034	Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)
EN ISO 27065	Protective clothing - Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers

EN standards for eye protection against chemicals:

EN ISO 16321	Eye and face protection for occupational use
EN 166	Personal eye protection

EN standards for chemical protective footwear:

EN ISO 13832	Footwear protection against chemicals

EN standards for Air Quality Analysis of workplace atmospheres:

EN 481	Workplace atmospheres. Defining the size of fractions for measuring particles suspended in the air.
EN 482	Workplace atmospheres - General performance requirements procedures for measuring chemical agents (particles, gases and vapours).
EN 689	Workplace atmospheres. Guide to appreciating the exhibition by inhalation to chemical agents by comparison with limit values and strategy measurement (particles, gases and vapours)
EN 1076	Exposure in the workplace. Procedures for measuring gases and vapours using sampling pumps. Requirements and methods of test (gases and vapours).
ISO 7708	Air quality — Particle size fraction definitions for health-related sampling
ISO 13137	Workplace atmospheres — Pumps for personal sampling of chemical and biological agents — Requirements and test methods
ISO 15767	Workplace atmospheres — Controlling and characterizing uncertainty in weighing collected aerosols

It should be noted as well that there are national standards in place, e.g. the below Portuguese ones:

NP 2266 – Occupational health and safety. Air collections for analysis of solid and liquid particles in workplaces. Filtration method.

NP 1796 – Occupational Health and Safety. Professional exposure limit values to chemical agents.

2.4. Question 1 of mandate

Clarify if proposing the wearing of protective equipment (PPE, RPE) for the use by coarse spraying of corrosive products is in line with the ECHA BPR guidance (in particular the four indicators of Table 27), or whether such approach is not possible for coarse spraying of corrosive products;

2.4.1. BPR Guidance Vol III Parts B+C

Section 4.3.2.5 of the BPR guidance Volume III Parts B+C[41] provides guidance for the qualitative risk characterisation for local effects, e.g.:

- *Acceptability or non-acceptability of the risks (supporting arguments) is determined on the basis of qualitative arguments, as suggested in Section (iii) below and Table 25.*

- *Concluding qualitatively on the acceptability of risk: Guidance to decide on the acceptability of exposure for each of the hazard categories is given in Section (iv) below and in Table 26 for the general public and Table 27 for professionals. The guidance takes into account:*

    - *(1) frequency and duration of potential exposure,*

    - *(2) potential degree of exposure,*

    - *(3) necessary operational conditions and other RMMs,*

    - *(4) necessary PPE. For each exposure scenario the minimum requirements for all 4 indicators of exposure should be met to support that the risk is acceptable.*

  Expert judgment is necessary when evaluating (a) if the RMMs and PPE given in the tables can be met in the specific exposure scenario and (b) if deviations from the frequency and duration of potential exposure and degree of exposure as well as deviations from the minimum RMMs and PPE required (including e.g. missing RMM/PPE, substitution by other means) may be acceptable. The conclusion on the acceptability of the risk should be accompanied by a narrative of the uncertainties in the data underpinning the conclusion."

Table 25 provides examples of qualitative arguments supporting acceptability or non-acceptability of risk.

[41] Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017: https://echa.europa.eu/documents/10162/2324906/biocides_guidance_human_health_ra_iii_part_bc_en.pdf/30d53d7d-9723-7db4-357a-ca68739f5094?t=1512979002065

Support for acceptable risk	Support for non-acceptable risk
For products or in use dilutions that are not classified the risk for local effects should always be considered as acceptable.	
+ reversible effect + adverse effect expected only after repeated, prolonged exposure (e.g. STOT-RE and EUH066)	- irreversible and/or severe effect[24] (e.g. Cat. 1 effect) - adverse effect occurring after a brief exposure
+ used with low frequency	- used with high frequency
+ used for short duration	- used for long duration
- low likelihood for exposure of critical initial sites of contact: skin, eye, RT, GI(T)	- high likelihood for exposure of critical initial sites of contact: skin, eye, RT, GI(T)
+ low exposure (approximate information) : - low amount used per event - low vapour pressure - low (liquid or solid) aerosol formation - high viscosity of product (aerosol formation and potential for splashes reduced) - high ventilation expected, e.g. due to outdoor use - no direct contact with skin, eye, GT expected - low exposure level compared to adverse effect concentration (LOAEC) or no adverse effect concentration (NOAEC) if available	- high exposure (approximate information) : • high amount used per event • high vapour pressure • high (liquid or solid) aerosol formation • low viscosity of product • low ventilation expected (e.g. indoor use) • direct contact with skin, eye, GT expected • high exposure level compared to adverse effect concentration (LOAEC) or NOAEC, if available
+ high degree of operational RMMs already in use or recommended and compliance expected • High level of containment • Easy maintenance • Minimization of manual phases • Local exhaust ventilation	- necessary operational RMMs not applicable, not feasible or compliance not expected
+ high degree of organisational RMMs already in use or recommended and compliance expected • Permit to work procedures • Trained workers • Intensive supervision of workers for proper use of RMM	- necessary organisational RMM not applicable
+ professionals using appropriate PPE	- general public cannot be expected to use PPE
+ Package design eliminating exposure	
+ child-proof closure	- potential children and infant exposure
+ proper instructions for use	
+ special formulation effects (such as encapsulation, coating, partitioning or adsorption of substances within the product, exposure reduction by particle size or aerosol/droplet size control, pellet formation and antagonistic co-formulant effects, see Appendix 4-3) reduce or eliminate exposure and/or expression of the hazard	- special formulation effects increase exposure and/or expression of the hazard

Table 27 provides guidance for concluding qualitatively on the acceptability of the exposure

for professional users. For corrosive products (Category 1B, C, H314), this provides (p. 257):

Frequency and duration of potential exposure: few minutes per day or less.

Degree of potential exposure under best practice conditions: High level of containment, practically no exposure; no splashes, no hand to eye transfer, no (liquid or solid) aerosol formation e.g. exposure below or similar to brief contact with technical RMM and PPE, as touching of contaminated surfaces.

Relevant RMM:

Measures to ensure well controlled exposure, such as:

Technics

- *Containment as appropriate;*
- *Segregation of the emitting process;*
- *Effective contaminant extraction;*
- *Good standard of general ventilation;*
- *Minimisation of manual phases;*
- *Regular cleaning of equipment and work area;*
- *Avoidance of contact with contaminated tools and objects;*

Organisation

- *Minimise number of staff exposed;*
- *Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed;*
- *Training for staff on good practice;*
- *Good standard of personal hygiene.*

PPE:

- *Substance/task appropriate gloves;*
- *Skin coverage with appropriate barrier material based on potential for contact with the chemicals;*
- *Substance/task appropriate respirator;*
- *Optional face shield;*
- *Eye protection*

2.4.2. Human Health WG-II-2021

In the context of the BE eCA's Union authorisation case, HH WG discussed the acceptability of professional spray use of corrosive products with expected dermal and inhalation exposure. The detailed analysis on this case will take place in the context of question 4. However, the key elements raised during the WG and BPC discussion (see section 2.4.3) regarding local risk assessment are included here for completeness. See the extract from the final minutes of the discussion in the confidential Annex II.

The members also discussed:

- whether RPE should be required during spraying/foaming application and post-application tasks when warranted from qualitative risk assessment but when quantitative risk assessment is acceptable for inhalation exposure to aerosols,

- which APF for RPE would be most relevant for all spraying applications of products classified as Skin Corr. 1.

Several members considered that a "*qualitative risk assessment has to be done at least for all spraying/foaming applications*" with corrosive products, noting that "*this is of particular importance with regard to the exposure duration, degree of exposure and coarse spraying applications for corrosive products, where RPE assignment may be needed*". It was further underlined that the presented quantitative risk assessment had some deficiencies as it was based on a single substance assessment that neither covers the qualitative risk assessment nor the full mixture assessment and does not address the impact of other relevant corrosive co-formulants in a BPF composition (like potassium hydroxide and sodium hydroxide), so the remaining uncertainties in the conclusions of the quantitative risk have to be qualitatively addressed.

According to the minutes, the WG agreed that "*for Meta-SPCs[42] with spraying/foaming applications, a stepwise approach should be followed, where:*

- *qualitative risk assessment is performed first,*
- *then depending on its outcome, the eCA will propose appropriate RPE, as needed, to be further considered and agreed by BPC."*

In the discussion, members also raised the following arguments regarding these coarse spraying applications:

- *"RPE10 should be considered, accounting for the product corrosivity,*
- *the local inhalation and dermal risk assessment is not acceptable, as high level of containment is not expected, but there will be a long exposure duration,*
- *it is important to justify which protection factor is sufficient against corrosive effects when deciding on the RPE type,*
- *the exposure duration, the degree of exposure and product dilution, where relevant, should be taken into account in the qualitative risk assessment, in particular for long-term application times where inhalation exposure is difficult to be excluded,*
- *appropriate RPE should be indicated by the applicant, as specified in the guidance (Vol III, Part B+C)."*

2.4.3. BPC-40

Following the above HH WG-II-2021 conclusions, the eCA had prepared the qualitative risk assessment on the coarse spraying applications for the identified Meta-SPCs with corrosive products with the respective RMMs and provided it to BPC for review and agreement. It was discussed at the 40th BPC plenary meeting (BPC-40) where majority of the members agreed with the outcome of the assessment and the recommended RMMs.

One BPC member disagreed with the outcome of the qualitative risk assessment for coarse spraying, noting that "*for a corrosive product they consider that exposure should be zero*" and suggested "*discussion at the Working Group Human Health would be needed to discuss if further reduction of the exposure would be feasible with alternative measures*".

In response, "*The eCA explained that the measures proposed (full face mask with a P3 filter, gloves with the appropriate break through time in combination with the fact that it concerns directional spraying) were the outcome of the assessment and considered sufficient to mitigate the risks. … there is no cloud formation as the spraying is directional.*" See the public Final case minutes[43] under point 8.3.

The members adopted the opinion[44] by majority, favouring the coarse spraying applications with corrosive products for professional use only with the following RMMs specified in the opinion:

[42] Level 2 (also called meta-SPC) of information in the Summary of Product Characteristics (SPC) that describes the composition and permitted variations within subgroups of the biocidal product family.
[43] https://echa.europa.eu/documents/10162/2166591/bpc_40_minutes_en.pdf/0e1c8d2b-ba6f-8199-b5d9-709bd4221fbe?t=1652245021089
[44] https://echa.europa.eu/documents/10162/3443008/active_chlorine_bp_bpf_cid_lines_nv_final_bpc_opinion_en.pdf/4c7ab684-e333-9071-d805-39f7f7835c7c?t=1646803948187

– surface disinfection
"No adverse health effects are expected for professionals …, performing mixing and loading, surface disinfection and post-application tasks, when using PPE appropriate for handling corrosive mixtures (chemical resistant gloves, eye/face protection, protective clothing and closed footwear). For some spraying/foaming applications (…) this includes appropriate respiratory protection.
Professional bystanders are to use the same protective measures when exposed via inhalation.

- *(…)*
- *APF40 full face mask for coarse spraying/foaming meta SPCs …*

In order to reduce inhalatory exposure, additional risk mitigation measures (RMMs) to limit spraying/foaming applications to coarse droplet size are proposed:

- *(…)*
- *When Coarse spray/foam:* "In order to reduce inhalatory exposure product may only be applied by coarse spraying. + Please refer to device supplier for technical details."

Professionals – additional RMM for ventilation
*For some professional uses (*incl. coarse spraying*), an additional RMM for ventilation is suggested:* "Ensure adequate ventilation during the application.""

There was a minority position[45] noting the following:

- *"The coarse spraying application of corrosive products/dilutions is considered acceptable by the Committee as long as the operator is protected with appropriate Personal Protective Equipment (PPE) and Respiratory Protective Equipment (RPE).*
- *For products classified as corrosive, it is essential to ensure that the operator is not in contact at all with the product, but the coarse spraying is a method leading to a very high exposure of the operator.*

Therefore FR CA considers that the setting of the appropriate PPE/RPE is very important for the authorisation of this use. However, a list of possible PPE/RPE available has been added in the Product Assessment Report by the eCA after the Working Group in charge of Human Health (WG TOX) meeting and the acceptability/efficacy of the proposed PPE/RPE for authorising corrosive products have not been discussed within the WG TOX. In consequence, FR CA considers that the risk assessment for the operator applying corrosive biocidal products by coarse spraying cannot be concluded without a proper discussion by the experts of the WG TOX on the efficacy of the PPE/RPE leading to the absence of exposure of the operator to the corrosive biocidal products during application."

The Product Assessment Report concludes that "*RMM are achievable and PPE are realistic when used with daily frequency but very short exposure duration, under the following user conditions when applied by:*

Professionals expected to use PPE
Professionals expected to follow instructions for use
Professionals expected to maintain good standard of personal hygiene"

Moreover, the SPC for this case further specifies for the Meta-SPCs with corrosive products that for coarse spraying applications, the following RMMs should be in place in addition to the PPE/RPE to be worn by the professional users:

*"During application (**coarse spraying**, foaming, trigger spraying/foaming):*
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
The use of eye protection during handling of the product is mandatory.
A protective coverall (at least type 4, EN 14605) shall be worn.
Wear suitable protective footwear (EN 13832) when applying the product.
(…)

***During application by coarse spraying/foaming**:*
Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH3/TM3), or a full-face mask with particle filter P3 is required.

[45] https://echa.europa.eu/documents/10162/3443008/fr_minority_opinion_active_chlorine_bp_bpf_cid_lines_nv_en.pdf/d41c2f65-b00e-209c-424d-6ab0e844cfa1?t=1646805818874

***Coarse spray/foam**: In order to reduce inhalatory exposure product may only be applied by coarse spraying. (RMM N-219) + Please refer to device supplier for technical details.*

Ensure adequate ventilation during the application.

***After disinfection by coarse spraying or foaming**, the treated area can be re-entered only when an ambient air concentration of chlorine is ensured to be below 0,5 mg/m³. If no appropriate method to determine the chlorine air concentration after use is available, contact the supplier.*

After disinfection, treated surfaces should be thoroughly rinsed with water of drinking water quality.

No access of the general public during treatment and until surfaces are dried.

Keep away from pets/keep out of reach of pets."

In line with the outcome of the HH risk assessment, it is required that all professional users performing coarse spraying operations with concentrated corrosive products or other tasks linked to them (e.g. loading and mixing, cleaning and maintenance) are trained properly for the tasks they should do in line with the good practices and for the appropriate use and maintenance of the PPE during their work.

2.4.4. Human Health WG-II-2022

2.4.4.1. Case-specific discussion

A discussion on the acceptability of the compression spraying of corrosive products by professionals took place in the context of two Union authorisations in scope of this mandate[8]. See extracted point 7 of the Final minutes[46] in the confidential Annex II.

Detailed analysis on this case will take place in the context of question 5. However, the key elements raised during the WG discussion regarding local risk assessment are included here for completeness. See also the detailed information presented by the eCA for this point[47].

Briefly, the WG did not support authorising professional compression spraying/foaming for corrosive products. According to the minutes of the discussion, the following arguments were made:

"… while permeation might not be a problem, type 3/4 coveralls are not suitable as they do not protect the head. Since the substance is volatile, type 1A coveralls would be more appropriate since they are closed and combined with a filtering device.

The applicant mentioned that:

- *the exposure in the food industry is short (10-20 minutes/day) and asked whether a RMM limiting the exposure duration would be acceptable to allow the use;*
- *a distinction should be made between spraying and foaming since foaming triggers are designed to reduce exposure (negligible formation of particles < 10 µm);*
- *the guidance mentions "containment" so application in a separate room could be a RMM to avoid exposure.*

The eCA clarified that manual compression spraying/foaming of corrosive products for professionals is not acceptable considering that:

- *the main concern relates to the pulverisation of corrosive products which leads to exposure in all directions;*
- *the guidance does not differentiate spraying from foaming, therefore the same PPE/RPEs should apply;*
- *"practically no exposure" cannot be achieved with PPEs;*
- *the exposure duration is longer than "a few minutes/day" (e.g. 120 minutes);*
- *exposure duration in the assessment should cover all uses in the dossier even if some uses have a shorter duration;*

[46] Final minutes – WGII2022_TOX_7-2 and 7-3 *(Restricted access to MSCAs only)*: https://interact-toolbox-docviewer.echa.europa.eu/wopihost-generic-module/OWA?fileID=090236e18807dc16&application=Meetings
[47] WGII2022_TOX_7-2_7-3j_UA_Sodium_hypochlorite_BPF_point7 *(Restricted access to MSCAs only)*: https://interact-toolbox-docviewer.echa.europa.eu/wopihost-generic-module/OWA?fileID=090236e1879f51b1&application=Meetings

- *it would be difficult to limit the duration as RMM since it is different for the different uses.*

The members agreed with the eCA that:

- *exposure is possible even with PPEs;*
- *a RMM based on limiting the exposure time to "a few minutes/day" would be difficult to handle in practice as it could lead to different interpretations (e.g. time from taking off the coverall?);*
- *the guidance is clear and the foreseen long exposure duration is not acceptable."*

2.4.5. Human Health WG-II-2023

2.4.5.1. Case-specific discussion

A discussion on the acceptability of coarse spraying of corrosive products by professionals took place in the context of one Union authorisation. See point 3 of the extracted Final minutes[48] in confidential Annex II.

Briefly, for this specific case it was concluded that the coarse spraying application by professional users is not acceptable as the applicant was asked to provide additional RMMs for risk mitigation, but these were not provided. It was noted that coarse spraying for professional users can therefore not be authorised in this case because the products are corrosive, and exposure cannot be excluded. It was further noted that the applicant was asked to provide additional RMMs for risk mitigation, but these were not provided.

During the discussion, it was emphasised that the support for non-authorisation of this specific coarse spraying professional application does not mean that it would not be possible to authorise professional coarse spraying of corrosive products in general.

2.4.5.2. Local risk assessment

An e-consultation with the HH WG was launched on 30 March 2023 to identify needs to revise specifically the guidance regarding local risk assessment. The relevant CAs of Belgium and France were separately notified of this, flagging the need to consider the cases where they acted as the eCA.

In addition to numerous written proposals, several topics were further discussed at WG-II-2023[15].

Frequency and duration

Regarding frequency and duration of exposure, the conclusion was:

> *It should be clarified that the frequency and duration given in Tables 26 and 27 are not definite values. The relation between the above Tables and Table 25 needs to be clarified. In general, more arguments "supporting acceptability" in Table 25 might allow more deviations from the indicative values, however also considering the hazard category.*

In the discussion, question was raised on how theses duration and/or frequency values should be considered when PPE are worn. It was noted that the assessments do not always follow the duration and/or frequency values indicated in the guidance and that the column "frequency" in Table 27 could be confusing. These values were initially included to differentiate between high and low hazard, to give an indication on how much exposure could be accepted, but establishing definite values may not be possible as there is no solid basis for numerical values. The frequency and duration values in Table 27 should thus not be considered as strict or binding values, but it would be better to include in the guidance indications on what would justify deviating from them. For example, when many arguments "supporting acceptability" in Table 25 are applicable, this might allow more deviations from

[48] Final minutes - WGII2023_TOX_7-1 (*restricted access to MSCAs only*): https://interact-toolbox-docviewer.echa.europa.eu/wopihost-generic-module/OWA?fileID=090236e1896ef500&application=Meetings

the indicative values, however also considering the hazard category.

See confidential Final minutes[15] and Annex II for relevant extract.

Coarse spraying of corrosive products

A discussion took place to clarify if in principle coarse spraying of corrosive products by professionals should be possible or whether it should (always) be unacceptable. To conclude, the majority of the members supported the possibility of accepting such a use:

> *The majority of the members agreed that coarse spraying of corrosive products can be acceptable for professionals in some conditions. These conditions/indicators are to be specified.*

It was further noted that the substances are very reactive/short-lived (so the corrosive properties may disappear) and that many products are classified based on pH due to lack of data.

In addition to this conclusion, the minutes (in confidential Annex II) reflect the discussions that took place and can be used to indicate which types of changes are needed in the guidance. The following suggestions were made to support acceptability:

(i) Specific PPEs and proper training for the professionals

It should be ensured that no corrosive products come through at the connection points between gloves, sleeves, hood and head. For corrosive products, the highest probability to be exposed is when opening or removing the PPE and via the openings. This requires special training. If it is possible to distinguish appropriately trained professionals as a subgroup of professionals, the risk could be acceptable. It however remains open how this could be ensured.

It was also noted that there is no agreed and harmonised definition for a "trained professional".

(ii) Automatic spray equipment

Corrosivity is a high hazard category that provokes irreversible effects. The guidance foresees a high level of containment with no splashes/aerosol exposure, but coarse spraying leads to aerosol formation and a high level of exposure in different directions. Small droplets are generated, leading to inhalation exposure when spraying upwards. The use of an automatic spray equipment allowing the operator to leave the room during the treatment may lead to an acceptable use.

(iii) Principles of the hierarchy of controls

In line with the principle of hierarchy of controls, it would first be necessary to consider alternatives (substitution of corrosive products), technical measures/RMMs that can be put in place, and only as a last resort prescribe RPEs/PPEs and assess their feasibility. In addition to training, technical RMMs should be considered such as ventilation of the room, distance between the spraying machine and the user and the type of spraying device and pressure applied.

Noting the possibilities mentioned in the discussion, several members considered that the acceptability of the use would always be a case-by-case decision, with some combinations of parameters in Table 27 allowing acceptability.

One member however considered coarse spraying of corrosive products always unacceptable, as it would not be possible to set up conditions that would ensure that the application is done in a safe manner.

See confidential Final minutes[15] and Annex II for relevant extract. See also the discussion described under 2.6.1.

2.4.6. Other MSs input

Following the discussion and request for information at the BPC in June 2023, Germany (BAuA) informed SECR that according to them, PPE (coveralls, RPE, gloves, boots) can adequately protect against coarse spraying of corrosive products. Impermeable coveralls specially designed for spray applications (Types 3 or 4) shall be used and workers shall be trained in the use of these PPE, especially for taping of the connections between gloves/boots and the coverall and removing the coveralls after use. If exposure of the head region cannot be excluded, adequate protection of the face must be ensured e.g. by a full-face mask.

2.4.7. CG discussion

A discussion[49] on the coarse spraying of corrosive products took place at the CG in August 2023 in the context of a disagreement on Mutual recognition in accordance with Article 35(2) of BPR.

Briefly, the rMS/eCA informed that:

- The in-use dilutions are corrosive (H314) and only used by professionals.
- Several PPE and RMM are proposed to ensure exposure is negligible and reference was made to the Technical Agreements for Biocides (TAB)[50]: systemic dermal and oral exposure is not required for exposure to corrosive concentrations as exposure will be negligible as appropriate PPE and RMM will always be required for corrosive concentrations, resulting in no direct contact with the corrosive substance.
- Proposed PPE:
    - "*Wear protective chemical resistant gloves, coverall and boots (at least type X, EN XXXXX) which is impermeable for the biocidal product when handling the pure product, during application and post-application rinsing (glove and coverall material to be specified by the authorisation holder within the product information)*".
    - The gaps between sleeves/gloves and boots/trousers must be sealed with tape to prevent any dermal exposure.
    - Face shield (covered by RPE): in combination with the respiratory protection a full-face mask with appropriate RPE would be necessary.
- During the referral phase, it was questioned whether the proposed PPE would be sufficient as according to the HEEG opinion 9, a coverall does not totally protect from exposure. The rMS however noted that HEEG opinion 9 refers to default protection factors applicable to all chemicals rather than specific for corrosive products.
- For this specific BP, an impermeable coverall – EN 14605 type 4, is proposed which has a breakthrough time of >120 min (i.e. the application duration). An additional requirement of the coverall is to meet the EN 468 norm, which guarantees resistance to penetration by sprays.
- HEEG opinion no. 9 also states that: "*the degree of protection afforded by protective clothing and gloves will be dependent on the behaviour of the operator in correctly fitting, removing and maintaining the protective clothing/gloves."* The rMS noted that this will be overcome by the RMM that the professional user should be trained prior to using the product.
- Proposed RMMs:
    - During disinfection, the stables should be ventilated at is maximum capacity.
    - The application is restricted to floors only: with use of a spraying lance, the professional user is in general not exposed, only the footwear can be wet.
    - The professional user should be trained before conducting spray application.
- Reference was made to the safe history of use of the product.
- Reference was also made to discussion at the HH WG-II-2023[15] meeting where it was

[49] Referral: https://interact-toolbox-collaboration.echa.europa.eu/collaboration-frontend/collaborations/754707
[50] https://webgate.ec.europa.eu/s-circabc/w/browse/a999a9c7-801d-4b7d-a92f-979f7438ed8d https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/a999a9c7-801d-4b7d-a92f-979f7438ed8d/TOX-TAB-09_08_2021_corr.pdf (download url)

noted that the duration and frequency given in Table 27 of the BPR guidance should be considered case-by-case and where several members indicated that the coarse spraying of corrosive products can be acceptable for professionals in some conditions – but that these conditions/indicators are to be specified.

The iMS noted that:

- the product in question and its dilutions are classified as corrosive (H314), which are high irreversible hazards.
- In accordance with the requirements to have an acceptable risk listed in table 27 of section 4.3.2.5.iv of the Guidance on the BPR: Volume III Human Health, Assessment + Evaluation (Parts B+C), a high level of containment with practically no exposure (i.e., no splashes and no aerosol formation), segregation of the emitting process and minimisation of manual phases is needed to have an acceptable risk for a corrosive product. Such conditions cannot be respected for a spray application.
- As the product is applied by spraying for some uses, and the proposed RMMs and PPEs are not sufficient to achieve a negligible exposure, the local risk is considered unacceptable and these uses should not be authorised.
- Reference was made to the HH WG-II-2022[51] (see also relevant extract in confidential Annex II) where the authorisation of similar uses and claimed PPEs (i.e. full mask with a B-P2 filter as a minimum standard, gloves and chemical resistant shoes for H314 classified dilutions) was discussed and not considered acceptable.
- The effectiveness of PPE cannot be limited to permeation (as it is proposed with breakthrough time) – since it depends on the chemical substance, the formulation, the temperature and the nature of the task. Exposure can also occur through penetration and during the removal of PPEs. This is why it is proposed in biocidal regulation to consider a protection factor of 95% and not 100% for an impermeable coverall (type 4) for the other dossiers.
- The rMS proposed putting tape on the opening between gloves/sleeves and boots/trousers, while the iMS considered that this proposal does not correspond to a PPE (but rather a do-it-yourself technique), thereby raising the concerns on how to ensure that the tape will withstand the damp; how to select the proper tape to be used; and whether the tape has already proved its effectiveness with this type of use and corrosive product. It was noted that this type of RMMs and PPEs has not yet been accepted at European level for a dossier, and that the effectiveness of tape has not been demonstrated with this type of use and with a corrosive product which cause irreversible effects.
- The rMS proposed to limit the use of the BP to a specific category: "trained professionals" - while the "trained professionals" category has been discussed in the past at European meeting, for example CA meeting, and no harmonized definition has been proposed. This raises questions, e.g. in this case, whether a farmer is considered as a "trained professional" and whether a farmer is in capacity to apply these specific RMMs /PPEs.
- Reference to Directive 98/24/CE was made, which establishes the order of preference of different risk mitigation measures for protection of workers, where the application of technical and organisational measures are prioritized over wearing of personal protective equipment.
- The iMS therefore recommended an automatic spray application for this use as it meets the requirements from the table 27 listed in the BPR Guidance in force[41] ; *e.g* high level of containment with practically no exposure, no splashes, no aerosol formation and segregation of the emitting process and minimisation of manual phases. Automatic spray application would permit to keep the use as it was initially intended (*i.e* spraying of walls, floors, surfaces and equipment).

During the discussion, the iMS and SECR noted that the general discussion on coarse spraying of corrosive products at the HH WG-II-2023 was not considered concluded, as it was only an initial discussion to collect the views of the MSs. Reference was also made to this Article 75(1)(g) mandate.

Different views were expressed by the Members States and no agreement was reached on

[51] Final minutes – WGII2022_TOX_7-2 and 7-3 *(restricted access to MSCAs only)*: https://interact-toolbox-docviewer.echa.europa.eu/wopihost-generic-module/OWA?fileID=090236e18807dc16&application=Meetings

whether the local risk is unacceptable with the proposed PPE and RMMs.

2.4.8. "Trained professional" category

From earlier discussions at the CA meeting, it appears that there are no specific definitions under the BPR of the different user categories, including "trained professional".

For example, discussions have taken place at the CA meeting with the aim to achieve a common understanding of the different user categories of anticoagulant rodenticides and to provide guidance on how MSs can adapt the user categories to their national policies in the context of mutual recognition procedures (see *CA-May16-Doc.5.4.a–Final–User categories rodenticides&Art.37.doc*[52]).

More recently, another discussion took place at the CA meeting regarding similar conditions of use for union authorisations (see *CA-Dec23-Doc.4.4-UA_similar conditions of use*[53]).

The following vague definition for "trained professional users" is available in ECHA Guidance Vol III Parts B+C:

> (users who) "*probably have specialised knowledge and skill in handling hazardous chemicals. Protective measures as foreseen in the European Communities regulations on safety and health at work (instruction, training, exposure control, PPE) should be observed. Qualification might be documented by the endorsement of management systems for occupational safety and health, by certification to branch-specific standards or by approval through competent authorities. The term specialised professional user has the same definition as trained professional user.*"

Although the above definition is available for "trained professional users", it is considered too vague for practical implementation of such a user category and is seen more as a description of what may be meant with this term, if used. In conclusion, for practical purposes it is considered in this opinion that there is no agreed definition for "trained professional".

2.4.9. Input from Forum/EU-OSHA and OSH National Focal points consultations

ECHA consulted the Forum, EU-OSHA, OSH national focal points and SLIC-CHEMEX members to collect information on the acceptability of coarse spraying of corrosive products by national authorities, including any guidance, best practices, publications or OELs available in the Member States about the coarse spraying of corrosive products by professionals and the associated exposure controls/personal protection. This input is described in chapters 2.4.9.1 to 2.4.9.3.

2.4.9.1. Guidance for coarse spraying of corrosive products by professionals

None of the respondents were aware of specific guidance regarding coarse spraying of corrosive products.

Portugal (PT)

PT referred to guidance on the application/use of plant protection products.

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[52] CA-May16-Doc.5.4.a: https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/4ed8b6fb-670b-41de-a06c-baaa7c6f12ba/details

[53] CA-Dec23-Doc.4.4: https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/13339b54-ad34-4a6b-84f1-3853e48bfbf7/details

Germany (DE)

DE noted that there are no regulations in Germany that prohibit the spraying of corrosive cleaning agents. DE provided some references, e.g. TRGS 400 "*Risk assessment for activities involving hazardous substances*" which describes general procedures for obtaining information and risk assessment in accordance with the Hazardous Substances Ordinance and TRGS 401 "*Hazards from skin contact: Identification – Assessment – Measures*" which provides general information on information gathering and possible protective measures when exposed to hazardous substances that pose a risk to the skin. DE also provided some references for spray applications (i.e. DGUV information 209-046 and DGUV rule 109-013) which could be useful in particular when it comes to technical protective measures, such as effective suction devices.

2.4.9.2. Coarse spraying of corrosive products and hierarchy of controls

EU-OSHA

EU-OSHA provided detailed input referring to the principles of the hierarchy of controls.

It explained that according to the EU directives for safety and health at work (e.g. the OSH Framework Directive[54], CAD[55] and CMRD[56], employers have to carry out a workplace risk assessment taking into account all hazards and the interaction of those. An isolated assessment of one process/application/substance without considering all circumstances of the workplace is not foreseen.

EU-OSHA further explained that the hierarchy of control measures applies independently of the process and means that employers should set and apply those measures in a certain order of priority, starting with elimination or substitution, then specific technical and organisational measures, with personal protective measures to be applied as a last measure when all the others are not sufficiently protective, prioritising collective over individual protection measures and the elimination at the source. The question whether any preventive measures should be applied in addition to PPE reverses and contradicts this hierarchy of prevention measures. Reference to the dedicated section of the EU-OSHA website[57] was made (subtitle "*Preventive measures and management of dangerous substances*" and some of the info sheets from their recent Health Workplaces campaign 2018-2019 is referenced there. It also refers to reducing the number of workers potentially exposed or the amount used.

The hierarchy of control measures, in particular elimination and substitution, practically also apply to work processes, and EU-OSHA asked whether spraying could be replaced by another process that does not produce aerosols and with less potential for indiscriminate spread, respiratory or skin exposure, or surface contamination in connecting areas.

It should be noted that this input needs to be seen with context: replacing the spraying use by a different use is a consideration for the applicant and at the workplace, while in the authorisation process of a biocidal product (family), the uses must be assessed as proposed in the application.

In addition to the points above, EU-OSHA highlighted the importance of consulting workers in the process described above (workplace risk assessment and setting of preventive measures), to be informed about the hazards they may be exposed to and trained in the application of prevention measures and how to carry out the work in a safe and healthy manner.

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[54] Directive 89/391 - OSH "Framework Directive": https://osha.europa.eu/en/legislation/directives/the-osh-framework-directive/the-osh-framework-directive-introduction
[55] Directive 98/24/EC - risks related to chemical agents at work: https://osha.europa.eu/en/legislation/directives/75
[56] Directive 2004/37/EC - carcinogens, mutagens or reprotoxic substances at work: https://osha.europa.eu/en/legislation/directive/directive-200437ec-carcinogens-or-mutagens-work
[57] Dedicated section of the EU-OSHA website - "Preventive measures and management of dangerous substances": https://osha.europa.eu/en/themes/dangerous-substances

It was noted that the OSH Directives represent minimum regulations and Member states´ legislation can be more protective, strict or detailed.

Finally, EU-OSHA informed that there are more protective measures defined for specifically vulnerable workers, more specifically the so-called "Young workers Directive"[58] (with corrosiveness being one issue mentioned in the annex to the Directive), or the "Pregnant workers Directive"[59], which sets out rules for the protection of pregnant and breastfeeding workers, for instance.

The Netherlands (NL)

Regarding the hierarchy of controls, NL considered that the process of (coarse) spraying of corrosive biocidal products will have to be subject to consideration, in order to determine whether alternative, less dispersive methods of application are possible in a given situation. This refers to the level of "Technical" measures 'at source' (the 'T' in the STOP principle), to limit emission and exposure.

Portugal (PT)

From the point of view of worker exposure, PT considered that since elimination is a practically unfeasible measure, the most desirable measure would be replacement.

Austria (AT)

AT referred to closed systems and noted that spraying corrosive substances outside closed systems is a last resort. AT noted two uses that were not in closed systems, professional spraying of rubbish bins with NaOH solutions and cleaning operating theatres. PPE must be applied. The right choice of PPE would need to be made considering the possible exposure. For example, working above the head will require full protection – wearing gloves, protective suits and RPE.

2.4.9.3. National practices, recommendations and/or acceptability of coarse spraying of corrosive products by professionals

The Netherlands (NL)

NL indicated not having any specific (national) practices or guidelines on coarse spraying of corrosive products. NL does not have the strict opinion that coarse spraying of corrosive products would not be acceptable, if effective control measures are available and applied.

Portugal (PT)

PT considered that the coarse spraying of corrosive products by professionals is practicable, noting however that the legal provisions on occupational health and safety must be complied with. Hence, all employers within the scope of obligations relating to the protection of the safety and health of workers, must assess all risks of exposure arising from the activities carried out. The concrete application of specific legislation regarding the exposure of workers to chemical agents therefore requires that before use/application (whatever the process/technique) of any type of biocides, an assessment of the risk of exposure is carried out and the appropriate protection and prevention measures are indicated. In terms of providing information on the prevention of occupational risks, the Working Conditions Authority has a publication[60] on the use of pesticides available on its website, not specifically for coarse spraying of corrosive biocidal products, but for the distribution, sale and application of plant protection products for professional use and plant protection product adjuvants, these activities are regulated, as well as the definition of

[58] Directive 94/33/EC - young workers: https://osha.europa.eu/en/legislation/directives/18
[59] Directive 92/85/EEC - pregnant workers: https://osha.europa.eu/en/legislation/directives/10
[60] https://portal.act.gov.pt/AnexosPDF/Documenta%C3%A7%C3%A3o/Publica%C3%A7%C3%B5es/Agentes%20perigosos/Guia_Pratico_Utilizacao_Pesticidas_Agricolas.pdf

monitoring procedures for the use of those products (transposition of Directive nº. 2009/128/EC, of the European Parliament and of the Council, of October 21, which establishes a framework for action at community level for the sustainable use of pesticides).

Austria (AT)

AT informed that coarse spraying of corrosive products is acceptable in Austria and provided two examples:

- Professional cleaning of rubbish bins with NaOH-solutions;
- Cleaning of operating theatre with sodium hydroxide solutions to remove prions.

A short description of suitable measures is provided on p.24: Umgang mit ätzenden Stoffen M 364 (auva.at)[61] (in German).

Germany

DE informed of the WINGIS system, by which BG BAU[62] provides assistance for risk assessment and the selection of protective measures[63]. In the case of appropriate disinfectants or sanitary cleaners with a corrosive effect, they usually point out additional protective measures when spraying, e.g. sanitary cleaner, corrosive, with volatile acids GISCODE: GS85[64] or disinfectant cleaner, based on phenols GISCODE: GD70[65].

EU-OSHA

EU-OSHA could not elaborate on national practices, recommendations and/or acceptability of coarse spraying of corrosive products by professionals but clarified that the measures at workplaces are to be set following an individual and comprehensive workplace risk assessment by the employer, the result of which depends on the specific conditions of every workplace.

Furthermore, the assessment and setting of measures would have to cover not only the spray applications, but also how the "treated" spaces are cleaned/cleared of the biocide afterwards to avoid exposure to workers once disinfection/biocide application is over.

2.4.10. Response to question 1 of mandate

In light of the information and considerations in sections 2.4.1 to 2.4.9, proposing the use of protective equipment (PPE, RPE) coarse spraying applications of corrosive products can be acceptable and therefore in line with the ECHA BPR guidance. A decision on acceptability will however always be subject to a case-by-case assessment, considering all relevant circumstances and parameters, especially the hierarchy of control discussed in section 2.3.

Some ambiguity has been noted as well in the current BPR guidance as regards the interpretation of the indicators listed in Table 27. These indicators are being revised in the ongoing guidance revision.

As per hierarchy of controls principle, employers have to carry out a workplace risk assessment taking into account all hazards and the interaction of those. While the decision on authorising a biocidal product (family) must be based solely on the use applied for, it must be noted that at workplace, an isolated assessment of one process, application or substance is not foreseen without considering all circumstances. The hierarchy of control

[61] Umgang mit ätzenden Stoffen M 364 (auva.at): https://www.auva.at/cdscontent/load?contentid=10008.544559&version=1547718806
[62] One of the largest professional associations in Germany under the state supervision that promotes occupational safety and health protection in companies and at the workplace, provides statutory accident insurance and enables comprehensive protection of employees and a high level of social security.
[63] https://www.wingisonline.de/
[64] https://www.wingisonline.de/showinfodoc.aspx?gisbaunr=4/00000170020/000000&docid=3745&codeid=4&lang=de (in DE and EN)
[65] https://www.wingisonline.de/showinfodoc.aspx?gisbaunr=4/00000056821/000009&docid=1177&lang=de

measures applies independently of the process and indicates that employers should set and apply those measures in a certain order of priority, starting with elimination or substitution, then specific technical and organisational measures, with personal protective measures to be applied as a last resort when all the other measures are not sufficiently protective, prioritising collective over individual protection measures and the elimination at the source.

2.5. Question 2 of mandate

If this approach is compliant with the ECHA BPR guidance:

> ***a. Clarify for which product classification and working conditions, these conclusions could apply;***
> ***b. Clarify if any additional risk mitigation measures are needed in addition to the use of adequate protective equipment to reduce the exposure of the operators to in practice zero exposure (e.g. directional spraying, recommended pressure spraying, room ventilation, room volume, detection of ambient air chlorine concentration during application, limiting further the time of spraying…).***

The question of the mandate refers to several additional risk mitigation measures (RMMs) that could possibly be considered to reduce the exposure of the operators to in practice zero exposure, in addition to the use of adequate protective equipment.

The principles of the hierarchy of control should be applied as explained in 2.3. Briefly, EU-OSHA noted that the hierarchy of control measures applies independently of the process and means that employers should set and apply those measures in a certain order of priority, starting with elimination or substitution, then specific technical and organisational measures, with personal protective measures to be applied as a last resort when all other measures are not sufficiently protective, prioritising collective over individual protection measures and the elimination at the source. The question regarding whether any preventive measures should be applied in addition to PPE reverses and contradicts this hierarchy of prevention measures.

Similar considerations referring to OSH and hierarchy of control principles were also raised in the context of the CG (see section 2.4.7) and HH WG discussions (see section 2.4.5.2).

Notwithstanding the above, the sections below describe the possible impact that some of these RMMs could have on the exposure levels of the operators and on risk.

It should also be noted that although some exposure models (e.g. ConsExpo) provide possibilities to consider technical (e.g. LEV) and organisational measures (e.g. operational conditions) in the exposure assessment, further adjustment of available exposure models may be needed, where possible, to take into account the claimed product application modes during the exposure modelling.

2.5.1. General input from Forum/EU-OSHA and OSH National Focal points

The questionnaire sent to the Forum/EU-OSHA, National OSH Focal points and CEN asked under which conditions coarse spraying of corrosive products by professionals would be acceptable, if any. A summary of the input received is provided below.

The Netherlands (NL)

NL explained that no specified conditions are in place. The employer should in all cases perform a risk assessment, and on this basis select appropriate control measures.

All options mentioned in the mandate should be considered by the employer (e.g. directional spraying, recommended pressure spraying, room ventilation, room volume, detection of ambient air chlorine concentration during application, limiting further the time of spraying). In these considerations, the employer should stick to the hierarchy of controls.

Portugal (PT)

PT explained that any employer, within the scope of obligations relating to the protection of the safety and health of workers, must assess all risks of exposure arising from the activities carried out. In the context of exposure of workers to chemical agents before the use/application by any process, technique or type of product, an assessment of the risk must be carried out. This implies, in particular, defining protective measures and

appropriate prevention. The activities involving dangerous chemical agents can only be initiated after risk assessment and implementation of appropriate preventive measures.

As part of the risk assessment, it is necessary to consider information relating to safety and health contained in safety data sheets (in accordance with applicable legislation (see Appendix A to Annex I) on classification, packaging and labelling of dangerous substances and mixtures and other additional information necessary for risk assessment provided by the manufacturer, namely the assessment specific risk for users), the nature, degree and duration of exposure, the working conditions that involve the presence of these agents, including their quantity, and the legally established limit values.

Technical and organisational risk mitigation measures are listed in the aforementioned legislation and must be identified and applied to the specific situation based on the correct and adequate risk assessment carried out.

Germany (DE)

DE informed that no statements can be made about effective protective measures or risk reduction measures without concrete knowledge of the operational context in which the spray application is to take place. Technical, organisational and personal protective measures would be determined by the employer as part of the risk assessment in accordance with the Occupational Safety and Health Act in conjunction with the Hazardous Substances Ordinance (GefStoffV). In addition to the less specific requirements of the GefStoffV regarding protective measures, the technical regulations and the information from the safety data sheet of the biocidal product would have to be applied. Any protective measures mentioned in the approval decision would be taken into account.

Austria (AT)

AT informed that employees have a lot of freedom in complying with regulations in the workplace, but risk management measures of the company have to lead to acceptable conditions. The risk mitigation measures, technical measures and/or personal protective equipment have to be specified concerning the possible exposure and properties of the products. In most cases full protection will be needed.

AUVA informed not having special guidance but referred to the guidance SprayExpo of BAuA[66].

EU-OSHA

EU-OSHA explained that it is difficult to assess the questions as the nature of the products considered is not clear. Corrosive substances encompass a wide range of products that may be very different and may have other properties, such as sensitisation or carcinogenicity, that warrant specific attention and can be decisive in any decisions taken by employers on prevention measures. The properties could also lead to fire risks, the extent of which may depend on the machinery or tools used at the respective workplaces or in the near environment, e.g. equipment that may produce sparks or has open flames (from heavy machinery to hand-held tools up to kitchen stoves in the hospitality industry). The products could also interact with other substances or products to produce dangerous effects. Corrosive properties may also be detrimental to equipment and machinery at workplaces, compromising the effectiveness of these devices, for example safety guards or ventilation systems.

Therefore, corrosive properties of single substances and related health effects may not be the only guiding principle in a workplace risk assessment.

[66] BAuA - Biozide - Bewertungsstelle Arbeitsschutz - SprayExpo: Modellierung der Exposition bei Sprühanwendungen - Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
EN: BAuA - Biocides Assessment Unit OSH - SprayExpo: modelling exposure during spray applications - Federal Institute for Occupational Safety and Health

EU-OSHA noted that guidance for fumigation processes may be relevant, depending on the substances that are considered here.

2.5.2. Aspects of spraying affecting exposure pattern

The exposure pattern is affected by numerous parameters, some of which are used directly in quantifying the exposure, such as room size and ventilation rate (see section 2.5.2.1). For other parameters, no quantifiable effect on the exposure level can currently be estimated in the recommended model, and further research or guidance may need to be developed.

In addition to such parameters, other measures affecting the exposure are discussed in section 2.5.3, including training, automation, PPE and EN standards.

2.5.2.1. Quantifiable parameters

For the product families considered under this mandate, quantitative exposure levels to the active substance were estimated using TNsG models, ConsExpo models and/or ART, according to the current guidance.

2.5.2.1.1. Room volume

This is generally a well-defined parameter in the scenario. The default values are available in ConsExpo factsheet, ART models and/or Recommendations of HEAdhoc, based on the type of rooms.

For the product families considered under this mandate, exposure scenarios were sometimes estimated with ART, where the parameter "Any size workroom" in combination with low or no specific room ventilation was considered. Higher exposure levels (worst-case) are expected for small, poorly ventilated rooms, as the dispersion of the contaminant from the emission source is dependent on the size of the workroom and the air changes in this room.

This parameter has a direct impact on the exposure calculations and the resulting quantitative risk assessment. If the other parameters of the scenario (such as room ventilation, amount of product applied) remain identical, a bigger room would generally lead to a lower exposure level. However, this parameter should never be considered alone.

Where the task corresponds to the size of the room, e.g. due to treatment of the entire floor of the room, there is also a direct relationship between the size of the room and the duration of the spraying, and therefore higher exposure is expected when treating a larger room (TNsG on Human exposure[67], p.305).

Room volume can be considered also in a qualitative assessment.

Bearing in mind the information above, any deviation from the default values should:

- be considered on a case-by-case basis taking into account the description of the tasks to be performed (specific or niche uses)
- never be considered in isolation, but in conjunction with other relevant parameters, e.g. room ventilation.
- always be substantiated and justified by the applicant (including the measures to ensure that this parameter would be respected by the end-user).

2.5.2.1.2. Room ventilation

This is generally a well-defined parameter, for which default values are available depending on the type of rooms and environment (clean room, house room, food and feed industries).

[67] https://echa.europa.eu/documents/10162/983772/bpd_guid_tnsg+human+exposure+2002_en.pdf/af2020f7-6cd2-471a-8cf2-efd1a0500fa8

This parameter is normally expressed as ACH.

The default values are available in ConsExpo factsheet, ART models and Recommendations of HEAdhoc. This parameter will directly impact the exposure calculations and the resulting quantitative risk assessment.

As mentioned in section 2.5.2.1.1. above, a worst-case scenario will generally assume a relatively small room with no extra ventilation.

While increasing ventilation will normally decrease exposure levels, it may also impact the process. For example, if low pressure spraying is used, turbulence in the air flow can impact the deposition of the substance.

2.5.2.1.3. Duration of spraying

The default duration of spraying is based on HEAdhoc Recommendation No. 6[31] where exposure duration of 120 minutes is given for professional hard surface disinfection by coarse spraying. This default value was used in assessing the coarse spraying uses in scope of this mandate.

Reducing the time of the coarse spraying uses may decrease the potential risk of exposure and adverse effects and may increase the plausibility and acceptability/reliance on using PPEs (see hierarchy of control principles).

As indicated in the BPR Guidance[41] (p. 248) and discussed in the HH WG[15], the likelihood of exposure increases with the frequency and duration of the task/use/process. It was also mentioned in the HH WG that for corrosive products, the highest probability to be exposed is when the PPE is opened, removed and via the openings. This requires special training.

Any deviation from the default values should be therefore considered on a case-by-case basis, as developed in the room volume section 2.5.2.1.1.

2.5.2.1.4. Directional spraying

While ART permits directly considering this parameter, spraying in any direction (including upwards, only horizontal/downward spraying, only downward) in the exposure calculation, this is not the case with other available models. According to the discussion in the working groups, this parameter may not be implemented in all situations. Therefore, as a worst-case and default, spraying in all directions should normally be assumed.

In their study, Berger-Preiss et al., 2005[68], it is noted that the experimental measurements demonstrated dependence of the inhalation exposure on the type of spraying device used, identifying particle diameter of the released spray droplets as the most important parameter. In addition, they noted that inhalation exposure was lowest when the spraying direction was downward. For the potential dermal exposure, the spraying direction was of particular importance: overhead spraying caused the highest contamination of body surfaces.

For the case referred to in sections 2.4.2 and 2.4.3, the BE eCA explicitly noted that the proposed PPEs "*in combination with … the directional spraying*" are "*considered sufficient to mitigate the risks. … there is no cloud formation as the spraying is directional.*" (see Final minutes under point 8.3). However, in the final PAR, it is noted: "*tier 2b* (e.g. calculation taken into account directional spraying) *is for informative purposes only – directional spraying will not be used as RMM*".

[68] Berger-Preiss E, Boehncke A, Könnecker G, Mangelsdorf I, Holthenrich D, Koch W. Inhalational and dermal exposures during spray application of biocides. Int J Hyg Environ Health. 2005;208(5):357-72. doi: 10.1016/j.ijheh.2005.04.006. PMID: 16217920.

Any deviation from the default values should be considered on a case-by-case basis, as further elaborated in the room volume section 2.5.2.1.1.

2.5.2.1.5. Pressure of spray

While ART permits considering spray pressure in the exposure calculation with a high (> 3 L/minute), moderate (0.3 - 3 L/minute), low (0.03 - 0.3 L/minute), or very low application rate (< 0.03 L/minute), this is not the case in other available models. Coarse spraying is expected to provide average droplet sizes above 325 µm, with low pressure spray generally noted as "*Application by spraying with a compression sprayer (1-3 bar)*" and with a moderate application rate of 0.3-3 L/minute), which is a reasonable worst case confirmed by industry data according to RECOM No. 3.

Please note that spraying models from TNsG gives the following inhalation indicative values depending on the spray pressure: Spraying model 1, 1-3 bars: inhalation exposure 104mg/m^3 (50th) and Spraying model 2, 4-7 bars: inhalation exposure 76 mg/m^3 (75th).

In their study, Berger-Preiss et al., 2005[69] note that the experimental measurements demonstrated dependence of the inhalation exposure on the type of spraying device used. "The model experiments indicated that for inhalation exposure the particle diameter of the released spray droplets is the most important parameter. "*In order to reduce inhalation exposure, low-pressure sprayers, which generate aerosol particles with a diameter >100 µm, should be preferred. Using equipment that produced particles with diameters <50 µm (airless sprayer, fogging apparatus) led to increasing inhalation exposure*."

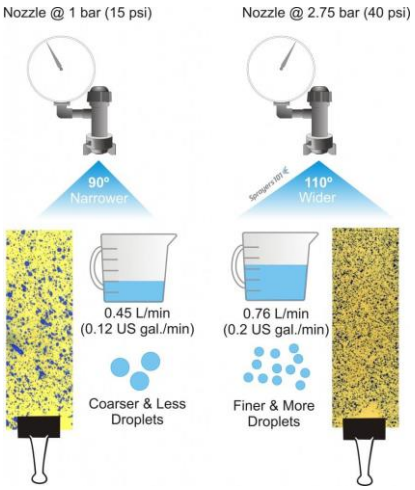
FAO also notes[70] that one of the primary sources of operator hazard from hand-carried portable sprayers relates to high pressure (over 4 bar) with hydraulic nozzles, which can produce fine droplets that are prone to uncontrolled drift and inhalation. High pressures can also increase hazard through failure of sprayer components, resulting in significant leakage of spray liquid. The minimum requirements specify the pressure limits recommended to minimise potential hazard without compromising spraying efficiency.

An increase in the spraying pressure caused the droplets to be smaller regardless of the type of nozzle (Cerutto *et al*., 2021)[71].

Reducing[72] hydraulic pressure reduces nozzle flow rate, increases median droplet size, and typically reduces spray fan angle (see the Figure below). Increasing pressure increases nozzle flow rate, reduces median droplet size and typically increases spray fan angle.

The spray at low pressures is coarser (larger droplets) than at higher pressures, reducing the number of droplets available.

[69] Berger-Preiss E, Boehncke A, Könnecker G, Mangelsdorf I, Holthenrich D, Koch W. Inhalational and dermal exposures during spray application of biocides. Int J Hyg Environ Health. 2005;208(5):357-72. doi: 10.1016/j.ijheh.2005.04.006. PMID: 16217920.
[70] https://www.fao.org/3/y2765e/y2765e.pdf
[71] Cerruto, E.; Manetto, G.; Papa, R.; Longo, D. Modelling Spray Pressure Effects on Droplet Size Distribution from Agricultural Nozzles. Appl. Sci. 2021, 11, 9283.
[72] https://sprayers101.com/relationship/



©Sprayers101

Using a flat fan nozzle as an example, **a lower pressure increases the median droplet diameter**, reduces the droplet count, reduces the nozzle flow rate and typically reduces the spray angle. Alternately, a higher pressure decreases the median droplet diameter, increases the droplet count, increases the nozzle flow rate and typically increases the spray angle.

Taking all these information into consideration, higher spray pressure is expected to increase the inhalation exposure. It has to be noted that these considerations do not include inhalation exposure linked to the evaporation of the substance. The default parameter considered for the assessment of the products under this mandate were "*Application by spraying with a compression sprayer (1-3 bar)*" and with a moderate application rate of 0.3-3 L/minute and could be seen as worst-case default parameters.

Any deviation from the default values should be considered on a case-by-case basis, as discussed in the room volume section 2.5.2.1.1.

2.5.2.1.6. Increasing the distance from the worker

In the consultation input from Forum/EU-OSHA and OSH National Focal points, the Netherlands authority mentioned the option of increasing the distance from the worker, e.g. by using long-stemmed spraying devices. Increasing the distance from the worker by using a spraying lance would be expected to reduce the exposure level.

ART and ConsExpo permit directly including this parameter in the exposure calculation, by considering that the source of emission is located inside or outside the breathing zone of the user. As a default, the emission source should be considered as located in the breathing zone of the worker, i.e. the volume of air within 1 metre in any direction of the worker's head.

Any deviation from the default values should be considered on a case-by-case basis, as discussed in the room volume section 2.5.2.1.1.

2.5.2.2. Non-quantifiable parameters

2.5.2.2.1. Nozzles

In the Plant Protection Product area, the type of spray nozzle has been extensively studied and developed in order to avoid spray drift (numerous literature data are available). According to EFSA guidance[21], "*drift-reducing nozzles of 50% can be considered as a risk mitigation measure in this guidance*". For biocides, this kind of measure has not been applied. In a recent study[73] on airborne particles from different cleaning sprays, it was concluded that further developments and modification of the nozzles might minimise the exposure to aerosols from cleaning products.

[73] Loven et al., 2019 Characterization of airborne particles from cleaning sprays and their corresponding respiratory deposition fractions J. Occup. Environ. Hyg., 16 (9) (2019), pp. 656-667. https://www.tandfonline.com/doi/full/10.1080/15459624.2019.1643466

2.5.2.2.2. Spraying vs. foaming

In the consultation of the EU-OSHA, OSH and SLIC-CHEMEX, DE (ChemG) provided a reference to a publication[74] from Hazardous Substances, Clean Air 2022 (see section 1.6.2.6 in Annex I). The publication relates to the aerosol exposures during spraying and foaming of cleaning agents under standardized conditions.

Abstract:

> *"In order to obtain orienting findings on the level of inhalation exposure during the application of cleaning agents in the spray process and in the foaming process, standardized test series were carried out in various pilot plant rooms. From the measurement results for the inhalable and alveolar fraction it can be deduced that a maximum of about 2 mg/m³ is reached for non-volatile components. For sodium hydroxide, the maximum activity-related exposure is about 1 mg/m³. An expected several times increased exposure during spraying compared to foaming could not be proven – eventually a factor of 2 was derived here. The type and settings of the spraying or foaming equipment have a major influence on the exposure level, so that no generally valid approach to a ratio of spraying to foaming is possible."*

From the abstract, it is understood that the type and settings of the spraying or foaming equipment have a major influence on the exposure level – and that it cannot be generalized that foaming would lead to a lower exposure than spraying.

The German authority (ChemG) further informed that they are currently investigating aerosol exposures during spraying and foaming of cleaning agents.

During the discussion on the case referred to in 2.4.2 and 2.4.3 (see confidential Annex II), the HH WG members noted the *difference between spraying and foaming applications, where foaming may lead to lower risk",* while no such distinction was made by the applicant in that UA case. In this regard, the eCA and the applicant agreed that "*foaming may include less risk than spraying",* but also noted that the current BPR guidance "*does not specify how to differentiate and quantify them".*

At HH WG-II-2023[17], it was suggested that foaming could reduce the exposure when compared to spraying. The applicant suggested a distinction to be made between spraying and foaming since foaming triggers are designed to reduce exposure (negligible formation of particles < 10 µm). The eCA clarified that the guidance does not currently differentiate spraying from foaming, therefore the same PPE/RPEs should apply.

In a recent published study[75], it was suggested that switching to foaming nozzle may decrease considerably the exposure to airborne particles and VOCs. The authors proposed that, in case of use of cleaning products, foam application should be preferred to spray application.

In conclusion, foaming application seems to reduce the airborne particles compared to spraying application and therefore may reduce the inhalation exposure of users, however not considering the possible exposure to vapours. It is however currently not possible to distinguish the exposure between the two types of application and the guidance does not provide means for this. The impact on dermal exposure is unclear.

[74] Aerosol exposures during spraying and foaming of cleaning agents under standardized conditions; U. Musanke, S. Dietel, N. Neubauer, T. Reinecke; GEFAHRSTOFFE 82 (2022) NR. 09-10 261 (in German)

[75] Lovén K, Gudmundsson A, Assarsson E, Kåredal M, Wierzbicka A, Dahlqvist C, Nordander C, Xu Y, Isaxon C. Effects of cleaning spray use on eyes, airways, and ergonomic load. BMC Public Health. 2023 Jan 13;23(1):99. doi: 10.1186/s12889-022-14954-4. PMID: 36639638; PMCID: PMC9840290.

2.5.2.2.3. Decreasing the distance between the spraying device and the object

In the input from Forum/EU-OSHA and OSH National Focal points consultations, the Netherlands authority mentioned the option of decreasing the distance between the spraying device and the object in order to reduce overspray, i.e. to maximise the amount of substance that is sprayed onto the area for which it is intended.

It should be noted that when reducing the spraying distance, the bounce needs to be considered, including the effect of the spraying pressure and the possibility of exposure modelling or measured data, in assessing the efficiency of this mitigation measure.

2.5.3. Other measures affecting exposure

2.5.3.1. Automation

The option of automation was raised in several fora.

In the Input from Forum/EU-OSHA and OSH National Focal points consultations, the Netherlands authority mentioned a few additional options, including automation/ robotisation.

The option of automation was also discussed at the HH WG. See section 2.4.5.2 for details. It was noted that the use of an automatic spray equipment allowing the operator to leave the room during the treatment could lead to an acceptable coarse spraying use.

Similarly, the option of automation was also discussed at the CG. See section 2.4.7 for details. The iMS recommended an automatic spray application for the coarse spraying use as it would meet the requirements from the table 27 listed in the BPR Guidance[41] ; *e.g.* high level of containment with practically no exposure, no splashes, no aerosol formation and segregation of the emitting process and minimisation of manual phases. Automatic spray application would permit keeping the use as it was initially intended (*i.e.* spraying of walls, floors, surfaces and equipment).

Only on a general basis it is possible for applicants and eCA to propose automation of uses and substitution with less hazardous substances since this is strongly dependent on the individual workplace situation and is in the remit of the employer.

2.5.3.2. Detection of ambient air chlorine concentration

After treatment, ambient air chlorine concentration is measured. Measurements below 0.5mg/m^3 would indicate the possibility for professionals tore-enter safely.

For the case referred to in sections 2.4.2 and 2.4.3, this is explicitly mentioned in the SPC:

> ***"After disinfection by coarse spraying or foaming**, the treated area can be re-entered only when an ambient air concentration of chlorine is ensured to be below 0,5 mg/m^3. If no appropriate method to determine the chlorine air concentration after use is available, contact the supplier."*

2.5.3.3. PPE/RPEs and EN standards

2.5.3.3.1. Specific input from Forum/EU-OSHA and OSH National Focal points consultations

EU-OSHA

EU-OSHA noted that at workplaces several products, substances and mixtures are usually applied/used or generated by work processes. PPE that can be appropriate for one substance or under certain conditions may be compromised by the use of other substances or other circumstances at workplaces, which could seriously affect their effectiveness.

Humidity, corrosiveness or resistance to solvents could play an important role in deciding on the use of gloves, respiratory protection or protective clothing. If PPE is to be used at a workplace, EU-OSHA did not consider it relevant to define PPE for one aspect only, since all need to be considered, for instance also temperature or the amount used, which may be decisive for the protectiveness of filter cartridges for respiratory protection.

Germany

The following personal protective measures were mentioned by the German authority:

- Eye protection: Frame goggles. In case of splash hazard: Basket goggles.
- Hand protection: Gloves made of butyl rubber.
- Body protection: Wear closed, long-sleeved work clothes. Wear closed shoes (no sandals).
- In case of spraying: Full protective suit and plastic boots.

Germany noted that the necessary respiratory protection will depend on the respective ingredients. Particle filter or full-face mask with gas filters.

The Netherlands

The Netherlands authority informed that no specific EN standards could be recommended since it will depend on the actual substances being used.

It was further explained that the employer should follow instructions and advice provided by 1) the supplier of the biocidal product (in the MSDS) and 2) the supplier of the PPE/RPE.

Portugal

Whenever PPE are recommended, the Portuguese authority explained that there is a duty on the employer to supervise their supply, validity and conservation, with their use implying that they are in accordance with standards (European or international) and approved technical specifications. This provision is also provided for in the RJPSST[76].

The guarantee that the use of PPE for the application/handling of corrosive products is safe for workers is supported by the employer's obligation to supervise the supply, validity and conservation of personal protective equipment.

PT also informed of available support guides (see them in the Appendix A to Annex I), namely:

- **General guide for the selection of Personal Protective Equipment**, which addresses general and transversal issues for all types of PPE, from the selection phase, through distribution, and use to the maintenance phase.

- **General guide for the Control of Exposure to Chemical Agents**, which helps in the implementation of risk assessment methods associated with chemical agents, in order to consolidate the minimum requirements in terms of worker protection, in accordance with the REACH and CLP Regulations.

- **Selection guide for filtering respiratory protection devices**, which helps in choosing the appropriate respiratory protection device, based on the identification of hazards and the assessment of risks present in workplaces.

- **Guide to selecting protective gloves (Chemical Risks)**, which assists in the selection of equipment to protect your hands.

Austria

[76] https://diariodarepublica.pt/dr/legislacao-consolidada/lei/2009-56365341-56371389

The Austria authority informs that for RPE, they use the cited guidance of HSE[10] and for gloves EN 374.

2.5.3.3.2. Specific input from CEN TC 162 WG 3 consultations

The input provided by CEN TC 162 WG 3 "Protective clothing against chemicals, infective agents and radioactive contamination" is summarised below.

Specific standards and/or guidance for the coarse spraying of corrosive products by professionals

There would be a specific standard of relevance for the skin protection from coarse spraying of corrosive products:

> EN 14605:2005+A1:2009 *"Protective clothing against liquid chemicals – Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4]"* standard.

The minimum protection for skin from corrosive liquids would be using the Type 4 products, the next level of protection would be a Type 3 liquid jet spray protection with higher pressure garment test.

To meet the requirements of the Type 4 products, they must undergo both permeation testing of chemicals and a garment test ISO 17491-4:

- The permeation will need to cover the needs from the biocidal product or a surrogate corrosive material permeation testing. This would need to be defined if the standard chemicals in ISO 6529 (permeation testing standard) don't provide an appropriate chemical in the list of standard chemicals (see below). Also the breakthrough time (Normalized breakthrough time at 1.0 µg/cm²/min) or cumulative permeation time will need to be determined to provide the right protection.
- The garment test ISO 17491-4 which uses a low surface tension liquid of $30x10^{-3}$ N/m and a spray at 300 kPa of 1.14 l/min using a specific hollow cone spray nozzles (e.g. disk DC-04 and core CR-25) which provides medium spray (236-340 µm). The round robin report of the interlaboratory testing did a specific review of the nozzle to understand which ones were appropriate. The ISO 17491-4 is getting ready for FDIS balloting in the coming month taking into account the latest state of the art.

It was noted that EN 14605 is currently being revised in an EN ISO 16602 series of standards but will provide similar protection. ISO 6529 is under revision.

Specific PPEs, EN standards for the PPE and assessment of the PPEs

Considering the specific use of coarse spraying of corrosive products by professionals:

For skin protection, as a minimum a Type 4 chemical protective garments with the appropriate permeation protection level was recommended.

EN 14605 standard for the requirements of Type 4 PPE was recommended. The Type 4 garment provide more comfort that a Type 3 garment depending on the length of exposure and the chemical protection required.

The assessment of the PPE's efficiency/resistance to ensure that the wearing of protective equipment (PPE, RPE) for the use of the corrosive products is safe for the workers would be done by the Type testing whether it is for Type 4 (or if higher protection is deemed necessary Type 3).

The issue noted however is that "corrosive" covers a large list of chemicals, therefore providing guidance is difficult, without referring to a specific chemical or class of chemicals:

- **strong acids** - Examples include nitric acid, sulfuric acid, and hydrochloric acid
- **concentrated weak acids** - Examples include concentrated acetic acid and formic acid.
- **strong Lewis acids** - These include boron trifluoride and aluminium chloride
- **strong bases** - These are also known as alkalis. Examples include potassium hydroxide, sodium hydroxide, and calcium hydroxide.
- **alkali metals** - These metals and the hydrides of the alkali and alkaline earth metals act as strong bases. Examples include sodium and potassium metal.
- **dehydrating agents** - Examples include calcium oxide and phosphorus pentoxide.
- **strong oxidizers** - A good example is hydrogen peroxide.
- **halogens** - Examples include elemental fluorine and chlorine. The halide ions are not corrosive, except for fluoride.
- **acid anhydrides**
- **organic halides** - An example is acetyl chloride.
- **alkylating agents** - An example is dimethyl sulfate.
- **certain organics** - An example is phenol or carbolic acid.

The main question is linked to the length of permeation protection that is required - this will be specific for each material. The ISO 6529:2013 in its Annex A.2 provides a standardised list of chemicals (corrosive chemicals highlighted in *italic*):

- acetone (2-propanone) [67-64-1],
- acetonitrile (cyanomethane, methyl cyanide) [75-05-8],
- carbon disulphide [75-15-0]
- dichloromethane (methylene chloride) [75-09-2],
- diethylamine [109-89-7],
- ethyl acetate [141-78-6],
- n-hexane [110-54-3], or n-heptane,
- methanol (methyl alcohol, carbinol) [67-56-1],
- *sodium hydroxide (40 % by mass), r = 1,33 kg/l [1310-73-2],*
- *sulphuric acid (96 % by mass), r = 1,83 kg/l to 1,84 kg/l [7664-93-9],*
- *sulphuric acid (18 % by mass),*
- tetrahydrofuran (THF, 1,4-epoxybutane) [109-99-9], and
- toluene (toluol) [108-88-3].

ISO 6529 is under revision. EN 14605 is being revised in an EN ISO 16602 series of standards, which will provide similar protection. ISO 16602-3 covers more chemicals and provides more details from a chemicals perspective as well as which chemicals are represented in that class of chemicals:

Table B.2 – Chemicals and groups of chemicals for permeation testing

Chemical	**Concentration****	**Phase**	**CAS number**	**Dermal Toxicity**	**Class / compound**	**Use / representative class**
Acids and Bases						
Sodium Hydroxide*	40-50%	liquid	1310-73-2	Other	inorganic base	strong alkali
Sodium Hydroxide	10%	liquid	1310-73-2	Other	inorganic base	alkali
Sulfuric Acid, concentrated* (>93%)	96%	liquid, fuming	7664-93-9	Other	inorganic mineral acid, oxidising	acid
Sulfuric Acid	30%	liquid	7664-93-9	Other	inorganic mineral acid	acid
Sulfuric Acid*	18%	liquid	7664-93-9	Other	inorganic mineral acid, non oxidising	acid

Hydrofluoric Acid	40-50%	liquid	7664-39-3	Very Toxic	inorganic mineral acid	acid
Nitric Acid	65-70%	liquid	7697-37-2	Other	inorganic mineral acid, oxidising	acid
Acetic Acid, glacial	99%	liquid	64-19-7	Other	organic acid	acid
Ammonium Hydroxide solution	25-32%	liquid	1336-21-6	Other	organic base	alkali solution
Organics						
Methanol*	analytical	liquid	67-56-1	Toxic	primary alcohol (smallest)	alcohol
Butan-1-ol	analytical	liquid	71-36-3	Other	primary alcohol	alcohol
Isopropanol	analytical	liquid	67-63-0	Other	aliphatic alcohol	
Acetone*	analytical	liquid	67-64-1	Other	ketone (smallest)	industrial solvent
Ethyl Acetate*	analytical	liquid	141-78-6	Other	ester	industrial solvent
n-Hexane*	analytical	liquid	110-54-3	Other	alkane, saturated hydrocarbon	petroleum fuels
Formaldehyde (dimer with methanol)	37%	liquid	50-00-0	Toxic	aldehyde	
Tetrahydrofuran* (THF – 1,4 epoxybutane)	analytical	liquid	109-99-9	Other	heterocyclic and ester (smallest)	readily permeates chemical barriers
Toluene*	analytical	liquid	108-88-3	Other	aromatic hydrocarbon (one of smallest)	aromatic solvent
o-Xylene	analytical	liquid	95-47-6	Other	aromatic hydrocarbon	aromatic solvent
Carbon Disulfide*	Analytical	liquid	75-15-0	Other	sulfur containing organic compound (smallest)	
Acetonitrile*	Analytical	liquid	75-05-8	Other	nitrile (smallest)	nitrile monomers
Diethylamine*	Analytical	liquid	109-89-7	Other	organic amine (smallest most agressive)	alkaline
Nitrobenzene	analytical	liquid	98-95-3	Toxic	aromatic nitro compound (one of smallest)	industrial chemical, aniline
Dimethyl Formamide DMF	analytical	liquid	68-12-2	Other	amine, Aprotic solvent	industrial chemical
Dimethyl Sulfate	analytical	liquid	77-78-1	Toxic	methylating agent	industrial chemical

Halo-alkanes						
Dichloromethane * (Methylene Chloride)	analytical	liquid	75-09-2	Very toxic	chlorinated hydrocarbon (smallest chloroalkane)	halogenated solvent
Tetrachloroethylene*	analytical	liquid	127-18-4	Very toxic	chlorinated hydrocarbon	
Oxidizing agents						
Hydrogen Peroxide	30%	liquid	7722-84-1	Other	peroxide	
Sodium Hypochlorite	13%	liquid	7681-52-9	Other	hypochlorite	
GASES						
Chlorine*	>99 %	gas	7782-50-5	Other	halogens	extensively used as disinfectant
Ammonia (anhydrous)*	>99 %	gas	7664-41-7	Other	base	refrigerant gas
Hydrogen Chloride*	>99 %	gas	7647-01-1	Other	polar inorganic gas	given of by concentrated hydrochloric acid
1,3-Butadiene	99%	gas	106-99-00	Very Toxic	monomer	monomer to produce rubber
Ethylene Oxide	>99 %	gas	75-21-8	Very Toxic	cyclic ether (simplest epoxide)	industrial chemical
Methyl Chloride	>99 %	gas	74-87-3	Very Toxic	haloalkane	refrigerant, chemical intermediate
Hydrogen Fluoride	>99 %	gas	7664-39-3	Very Toxic		
Phosgene	>99 %	gas	75-44-5	Toxic		
Methylbromide	>99 %	gas	74-83-9	Very Toxic		
Nitrogen Dioxide	>99 %	gas	10102-44-0	Very Toxic		
Sulfur Dioxide	>99 %	gas	7446-09-5	Toxic		
Cyanogen Chloride	>99 %	gas	506-77-4	Very Toxic		
* Chemicals found in the ET list of chemicals. ** Some of the concentrations are ranges as either because globally slightly different concentrations are used or for different PPE (e.g. gloves) different concentration are used.						

A reference to the Safe Spec UK[77] was shared, which provides information for Type 4 or Type 3 products. For purely corrosive materials a Tyvek® 600 Plus (Type 4) would be the lower end protection, while Tyvek® 800J (Type 3) would provide a slightly better protection, and Tychem® 2000C would provide a broader permeation protection against corrosive materials and some solvents (attached the technical guides to these products including permeation data). See section 2.1.1 in the confidential Annex I.

A number of standards are under revision to provide better information to the end-users on

[77] Safe Spec UK: https://www.safespec.dupont.co.uk/tyvek/featured-products.html

the protection provided by chemical protective clothing.

CEN TR 15419 provides a Selection, Use, Care and Maintenance (SUCAM) guidance[78] on the selection of protective clothing. This document is largely updated in the ISO 16602-6 SUCAM guidance document.

2.5.3.3.3. HH WG & BPC discussions

Case-specific

For the coarse spraying operations with corrosive products in the case referred to in sections 2.4.2 and 2.4.3, PPEs were defined.

More details on the PPEs proposed in this case can be found in Annex II of SCBP78-Doc.B.05[23] (see also section 2.2 in Annex II) – see the *highlighted* text below for coarse spraying:

GLOVES			
norm	**Test acc to (norm)**	**subject**	**challenge**
EN 374-1	EN16523-1 clause 7	permeation	Chemical wetting of sample & determining breakthrough time
	EN 374-2 clause 5	Penetration	Air or water leaks
	EN 374-4 clause 5.1	Degradation	Puncture resistance after continuous contact with chemical
type of application	**Specifications**	**details**	**remarks**
M&L, maintenance & repair (concentrated product)	Performance level 2 Code K Type B	-Permeation performance minimal level 2 Breakthrough time >30 min Resistant against 40% NaOH Resistant against minimal 3 chemicals	Clarification of specifications: -*Performance level* indicates breakthrough time 1: >10 min 2: >30 min 4:>120 min 5:>240 min -*Code* + *letter* = tested against substance x at y%; code K tested against 40% NaOH -*Type* + *letter* indicate minimal permeation performance level & resistance against min. number of chemicals; e.g. type B: permeation performance of minimal level 2 and resistant against minimal 3 chemicals User should ascertain whether the specifications on the technical data sheets of the PPE are in agreement with PPE requirements
brushing, pouring + wiping (working solution)	Performance level 5 Code K Type B	-Permeation performance minimal level 5 Breakthrough time >240 min -Resistant against 40% NaOH -Resistant against minimal 3 chemicals	
Dipping (working solution)	Performance level 2 Code K Type B	-Permeation performance minimal level 2 Breakthrough time >30 min -Resistant against 40% NaOH -Resistant against minimal 3 chemicals	
Trigger spray (working solution)	Performance level 2* Code K	-Permeation performance minimal level 2*	

[78] https://standards.iteh.ai/catalog/standards/cen/8c5cd88f-9000-4c29-9b9c-a684ac236f13/cen-tr-17620-2021

	Type B	-Breakthrough time >30 min -Resistant against 40% NaOH -Resistant against minimal 3 chemicals * same gloves can be worn for multiple applications	
Coarse spraying/foaming (working solution)	*Performance level 4* *Code K* *Type B*	*-Permeation performance minimal level 4 -* *Breakthrough time >120 min* *-Resistant against 40% NaOH* *-Resistant against minimal 3 chemicals*	
post-appl: cleaning + disposal (concentrated product/working solution)	Performance level 2 Code K Type B	-Permeation performance minimal level 2 Breakthrough time >30 min -Resistant against 40% NaOH -Resistant against minimal 3 chemicals	
COVERALLS			
norm	**Test acc to (norm)**	**subject**	**challenge**
EN 14605	EN 17491-4 type 4	Spray-tight clothing	Exposure to sprayed particles of liquid (water with dye tracer) & detection of coloration on absorbent overall under test item
	EN 17491-3 type 3	Liquid-tight clothing	Exposure to water jet with dye tracer) & detection of coloration on absorbent overall under test item
	EN16523-1	permeation	Chemical wetting of sample & determining breakthrough time
type of application	**Specifications**	**details**	**remarks**
M&L, maintenance & repair (concentrated product)	Type 3 Breakthrough time >10 min	Liquid-tight	<u>Clarification of specifications:</u> Specifications on the technical data sheets of the PPE indicate *breakthrough time together with tested chemical*. User should ascertain whether the specifications on the technical data sheets of the PPE are in agreement with PPE requirements. Ascertain that breakthrough time is assessed with appropriate corrosive chemical.
brushing, pouring + wiping (working solution)	Type 3 Breakthrough time >240 min	Liquid-tight	
Dipping (working solution)	Type 3 Breakthrough time >30 min	Liquid-tight	
Trigger spray (working solution)	Type 4 Breakthrough time >30 min	Spray-tight same coverall can be worn for multiple applications	
Coarse spraying/foaming (working solution)	*type 4 breakthrough time >120 min*	*Spray-tight*	

post-appl: cleaning + disposal (concentrated product/working solution)	Type 3 Breakthrough time >30 min	Liquid-tight	
EYE PROTECTION			
norm	**Test acc to (norm)**	**subject**	**challenge**
EN166 clause 7.2.4	EN168 clause 12.1	Liquid droplets	Spraying solution from 600 mm distance in all directions towards PPE which is fixed on a head form, & detecting coloration in ocular regions
EN166 clause 7.2.4	EN168 clause 12.2	Liquid splashes	Pointing a laser beam in all directions to PPE which is fixed on a head form & detecting interception of face shield
EN166		Corrosion of the eye protection	corrosion test: immersing the PPE in several solutions + physical inspection
type of application	**Specifications**	**details**	**remarks**
M&L, maintenance & repair, brushing, pouring + wiping, Dipping, post-appl: cleaning + disposal	face shield	protection from liquid splashes	
Trigger spray	Goggles + face shield	protection from liquid droplets +protection from liquid splashes	
Coarse spraying/foaming	*Eye protection is covered by RPE, full face mask*		
RESPIRATORY PROTECTION			
norm	**Test acc to (norm)**	**subject**	**challenge**
MASK EN136		Inward leakage	Exposure of subjects to test atmosphere of 1 of 2 standard substances in the form of aerosol during exercise/talking & measuring inward leakage
FILTER EN143	EN 13274-7	Filter penetration	Exposure of filter to test atmosphere of 1 of 2 standard substances in the form of aerosol & measuring filter penetration
type of application	**Specifications**	**details**	**remarks**
Trigger spray metaSPC1	disposable half mask FFP2	Protection factor 10	P2: Max filter penetration of test aerosols: 6%
Coarse spraying/foaming	*Full face mask Particle filter P3*	*Protection factor 40*	*P3: Max filter penetration of test aerosols: 0.05%*
Maintenance and repair of pressurized systems	disposable half mask FFP2	Protection factor 10	P2: Max filter penetration of test aerosols: 6%
RTU Trigger spray	No RPE	exposure is short	Guidance on BPR VolIII HH

metaSPC2		and MMAD > 100µm (inhalable fraction is limited)	Parts B+C : "In humans, particles with aerodynamic diameters below 100 µm have the potential to be inhaled."
Other applications	Not required, no aerosol formation expected		

Case-specific

A discussion on the acceptability of the compression spraying of corrosive products by professionals and associated PPEs took place in the context of two cases referred to in section 2.4.4.1. The eCA provided detailed information on PPEs (see also presentation[47] in confidential Annex II).

Briefly, the following was explained by the eCA.

PPE / RPE efficiency

- PPE does not provide 100% protection
- For systemic effects, unacceptable risk is possible even with PPE/RPE (coverall, gloves, RPE)
    - Professionals can be exposed to the product even with PPE/RPE
- Spraying application: mode of application leading to the highest exposure levels (spraying in all directions (ART terminology "Spraying in any direction (including upwards))
    - For systemic effects the exposure assessment needs to be refined by selecting the "downward only" option in ART

Protective clothing conforming to Standard EN 14605

Protective clothing is required to protect against liquid chemicals – Performance requirements for clothing whose connecting elements are liquid-tight (type 3) or spray-tight (type 4), including articles of clothing protecting only certain parts of the body (type PB [3] and PB [4])

The performance requirements are:

- Materials: norm EN 14325
    - Resistance to abrasion, cracking, tearing, traction, puncture and permeation
- Seams, junctions and assemblies: norms EN 14325; EN 17491-3 and EN 17491-4
    - Resistance to permeation, to penetration and of seams
- Whole protective clothing: norms EN 17491-3 and EN 17491-4
    - Penetration resistance

Difference between permeation & penetration

Permeation is the process by which a solid, liquid or gaseous chemical passes through protective clothing material on a molecular level. The permeation test measures the amount of chemical absorbed or diffused through the coverall material.

Permeation is:

- Tested on the material and on seams, junctions and assemblies
- Specific to a chemical substance

Penetration is the process by which a chemical passes through the material of protective clothing through its pores and imperfections.

Permeation is:

- Tested on the whole coverall
- Not specific to the chemical substance

The eCA also elaborated on technical aspects of permeation resistance and breakthrough times which are covered in more detail in their presentation (see it[47] in confidential Annex II).

The eCA concluded that PPE is not sufficient to ensure no exposure of the professional (not 100% protection). It was noted that PPE efficiency depends on different criteria (e.g. chemical substance, formulation, concentration, temperature, humidity) and that PPEs are not tested in real conditions of exposure (e.g. duration of exposure, nature of the task, quantity of product used, workplace area).

EN standards

Discussions took place at the HH WG-II-2023[17] and HH WG-IV-2023[20] (see Annex II for relevant extracts) regarding the requirement to assign an EN standard (or equivalent) when prescribing personal protective equipment.

It was noted that the assignment of a protection factor is important, while the EN standard was seen as less relevant for safe use, also noting that an EN standard would not define e.g. the protection factor or material of the PPE/filter, and it is not straightforward to translate the necessary protection to an EN standard.

The following are some of the specific aspects that were commented on by MSs in the context of the second HH WG discussion:

- The MSCAs would not be able to verify that the material, thickness of material, breakthrough times, filters etc. are adequate but this is generally the responsibility of the applicant. Selecting appropriate materials for a product composition can be challenging or impossible for MSCAs.
- There are only few standards for gloves and coveralls and the MSCAs will be able to check these, while there are much more standards for RPE.
- The EN standards and protection factors are not linked and there is no direct correlation between these. For example, only EN374 may be relevant for gloves but there are other parameters that are not defined by the standard – material, thickness, breakthrough time etc. Furthermore, the protection factor is not linked to the PPE/RPE only, but also to the way these are used.
- Specifying the EN standard does not guarantee that the PPE/RPE are appropriate, and it will not be possible for the MSCAs to specify the exact PPE/RPE with all details.
- To assign the details of the appropriate PPE/RPE, it will be necessary to know how the materials were tested and with which chemical mixtures, and the physical stress applied in testing and needed in use.

It was noted that the applicants can provide the information that the means of protection are adequate to reduce the risk to an acceptable level and the MSCAs would be asked to look into this and assess whether the applicant's proposal can be supported. The parameters that are important for ensuring the safe use of biocidal products should be verified.

2.5.3.3.4. CG discussion

In the CG discussion[79] on the coarse spraying of corrosive products, the following PPEs were proposed by the rMS/eCA:

- "*Wear protective chemical resistant gloves, coverall and boots (at least type X, EN XXXXX) which is impermeable for the biocidal product when handling the pure product, during application and post-application rinsing (glove and coverall material to be specified by the authorisation holder within the product information)*".
- The gaps between sleeves/gloves and boots/trousers must be sealed with tape to prevent any dermal exposure.
- Face shield (covered by RPE): in combination with the respiratory protection a full-face mask with appropriate RPE would be necessary.
- For this specific BP, an impermeable coverall – EN 14605 type 4, is proposed which has a breakthrough time of >120 min (i.e. the application duration). An additional requirement of the coverall is to meet the EN 468 norm, which guarantees resistance to penetration by sprays.

2.5.3.3.5. Other MSs input

Following the discussion and request for information at the BPC in June 2023, Germany (BAuA) provided the following input to SECR regarding question 2 of the mandate:

a. PPE is in their view generally applicable for all spray applications (trigger spray, but also coarse spraying, knapsack spraying, pressure sprayers, etc.).

b. they consider that adequate training of the workers, especially including sealing/taping of the connections (gloves/boots/face mask to the coverall) and correct undoing of the PPE necessary, as an additional measure.

See also section 2.1.42.4.6. for the German input on question 1 of the mandate, i.e. PPE (coveralls, RPE, gloves, boots) can adequately protect against coarse spraying of corrosive products. Impermeable coveralls specially designed for spray applications (Types 3 or 4) shall be used and workers shall be trained in the use of this PPE, especially for taping of the connections between gloves/boots and the coverall and undoing the coveralls after use. If exposure of the head region cannot be excluded, adequate protection of the face must be provided, e.g., by a full-face mask).

2.5.3.4. Training

2.5.3.4.1.1. Input from Forum/EU-OSHA and OSH National Focal points consultations

The Netherlands (NL)

NL informed that the set administrative measures do not deviate from training and supervision that is obligatory in all cases in which workers can be exposed to hazardous substances. The actual content of the training should be tailored to the substances and the processes in question. In the specific case of certain plant protection products, the spraying worker should possess a 'spraying certificate'.

[79] Referral: https://interact-toolbox-collaboration.echa.europa.eu/collaboration-frontend/collaborations/754707

Portugal (PT)

PT explained that the duty to inform and train workers are also obligations set out in legislation, and they must have up-to-date information on risks to safety and health, as well as protection and prevention measures, and receive appropriate training in the field of safety and health at work, taking into account the workplace and the performance of high-risk activities. Furthermore, the employer must ensure that workers' health is monitored depending on the risks they are potentially exposed to in the workplace.

Austria (AT)

AT informed that the administrative measures, training and supervision are highly dependent on the use and the product, and e.g. toxic acids (HF, HCl) will need different measures than just corrosive products (NaOH, KOH).

Professional use of toxic chemicals (acute tox 1, 2, 3 and STOT SE 1) have to comply with Chemikaliengesetz (RIS - Chemikaliengesetz 1996 - Bundesrecht konsolidiert, Fassung vom 20.09.2023 (bka.gv.at)[80]), and Giftverordnung (RIS - Giftverordnung 2000 - Bundesrecht konsolidiert, Fassung vom 20.09.2023 (bka.gv.at)[81]).

2.5.3.4.1.2. HH WG discussions

As discussed in the HH WG-II-2023[15] (see section 2.4.5.2 for details), it should be ensured that no corrosive products come through at the connection points between gloves, sleeves, hood, head - the highest probability to be exposed being when the PPE is opened, removed and via the openings. This requires special training. Only "trained professionals" can perform coarse spraying of corrosive products.

The question on how it could be ensured that this training takes place was raised, as it would be a prerequisite for having no risk. Another issue is the lack of agreed and harmonised definition for a "trained professional".

2.5.3.4.1.3. CG discussion

Similar issues were raised in the context of the CG discussion. Noting that there is no agreed "trained professional" category, the question was raised whether a farmer would be a "trained professional" and would be in capacity to apply these specific RMMs/PPEs.

In addition, concerns were raised regarding the proposal of the reference MS to put tape on the opening between gloves/sleeves and boots/trousers, noting that this proposal does not correspond to a PPE and raises concerns on how to ensure that the tape will withstand the damp; how to select the proper tape to be used; and whether the tape has already proved its effectiveness with this type of use and corrosive product. HEEG opinion no. 9[82] also states that: *the degree of protection afforded by protective clothing and gloves will be dependent on the behaviour of the operator in correctly fitting, removing and maintaining the protective clothing/gloves.* The rMS noted that this will be overcome by the RMM that the professional user should be trained prior to using the product.

2.5.3.4.1.4. Other MS input

See section 2.4.6 for details on question 1 of the mandate.

For question 2 of the mandate, Germany informed SECR that according to them, PPE (coveralls, RPE, gloves, boots) can adequately protect against coarse spraying of corrosive

[80] RIS - Chemikaliengesetz 1996 - Bundesrecht konsolidiert, Fassung vom 20.09.2023 (bka.gv.at) : https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011071
[81] RIS - Giftverordnung 2000 - Bundesrecht konsolidiert, Fassung vom 20.09.2023 (bka.gv.at): https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20001104
[82] HEEG opinion 9: https://echa.europa.eu/documents/10162/1060554/heeg_opinion_9_default_protection_factors_for_clothing_and_gloves_en.pdf/07fd65d3-8ec8-4f7c-9247-4159841ca9fd?t=1388670045811

products. However, workers shall be trained in the use of this PPE, especially for taping of the connections between gloves/boots and the coverall and undoing the coveralls after use.

2.5.3.4.2. Any relevant activities on occupational exposure limits (OELs)

OELs were mentioned as part of the mandate and therefore covered in the questionnaire sent to the Forum/EU-OSA and OSH National Focal Points. The input is briefly summarized below.

Input from Forum/EU-OSHA and OSH National Focal points consultations

EU-OSHA

EU-OSHA informed that corrosiveness alone is not a criterion for the setting of OELs, but in addition the most sensitive and decisive endpoint as regards health effects. OELs are set in a complex process that considers all relevant properties of a specific substance or substance group. EU-OSHA recommended consultation of the GESTIS database[83] or the relevant Directives[84] on specific OELs for substances of interest.

It was remarked that the OELs are to be seen in the specific legal context of the country, which defines the frame in which they should be applied.

In addition, OELs should not be seen as a "permissible" exposure, as there is a principle of minimisation of exposure. Furthermore, they do not usually encompass fire or explosion risks, which need to be assessed too.

The Netherlands

The Netherlands authority informed not having relevant activities in OEL specific to corrosive biocidal products. The development of OELs is taken up by the Dutch government in case of carcinogenic substances, mutagenic substances or inhalation sensitisers, and in case of process generated substances. Substances to be taken up by the Dutch Health Council, are annually prioritised in an annual work plan ('public' OELs). In case of other substances, the Dutch system has placed the responsibility of developing OELs on the employers or manufacturers (so-called 'private OELs').

Germany

The German authority informed that they do not have any specific information on the spray application of such products. In Germany there are no "non-specific" or "summary" occupational exposure limits (AGW) for such products, but there are "corrosive" biocidal active substances for which an occupational exposure limit has been set in Germany (see confidential Annex I). If substance specific AGWs are specified for the active ingredients, these must also be used when spraying to assess the effectiveness of the protective measures. In German occupational safety law, the workplace limit values of TRGS 900 are generally used as a basis. However, these largely only refer to inhalation hazards, but not to the skin-corrosive properties. TRGS 900 Section 2.10 stipulates that the presence of aerosols during activities with hazardous substances must be taken into account when determining exposure and that both exposure to aerosols (as an inhalable fraction) and to vapours must be determined (whereby the measurement methods for the corresponding active ingredients are generally designed for determining the concentration in the vapor phase).

[83] GESTIS - International limit values for chemical agents (Occupational exposure limits, OELs): https://www.dguv.de/ifa/gestis/gestis-internationale-grenzwerte-fuer-chemische-substanzen-limit-values-for-chemical-agents/index-2.jsp

[84] Exposure to chemical agents and chemical safety – OSH Directives: https://osha.europa.eu/en/legislation/directives/exposure-to-chemical-agents-and-chemical-safety

ECHA

The OEL work at ECHA has been focused so far on CMRs and respiratory sensitizers.

2.5.3.4.3. Substitution of the hazard/corrosive product

Although out of scope of the specific questions of this mandate, as per hierarchy of control principles, it should also be questioned whether the surface disinfection by coarse spraying could be performed with an efficacious non-corrosive biocidal product/solution.

The ECHA Guidance[85] on analysis of alternatives to biocidal active substances for applicants and authorities (January 2024) may be a useful recommendation in this regard, as it refers to different chemical and non-chemical substitution options.

This was for example raised in the context of the discussion at HH WG-II-2023[15].

2.5.4. Response to question 2 of mandate

The mandate refers to the coarse spraying of corrosive products. Question 2a requests clarifying also for which product classification the conclusion would apply: this response concerns biocidal products and/or dilutions classified as "*H314 – Causes severe skin burns and eye damage*".

It must be highlighted that most of the products or dilutions classified as "*H314 – Causes severe skin burns and eye damage*" are generally classified based on their extreme pH or by calculations according to CLP classification rules. Considering the significant RMM and PPE proposed/needed for this type of products classified as corrosive, one of the first steps to consider in order to eliminate the hazard, should be the consideration of actual studies (according to the tiered approach in CLP and BPR guidance on information requirements) on these products or dilutions as this might avoid a worst-case classification by default.

Several RMMs are possible for reducing the exposure and the risk when applying corrosive products by coarse spraying. These need to be considered together in a holistic manner and a risk assessment performed on-site as required by OSH regulation. The hierarchy of control and STOP principles should be followed and PPEs should be applied only as last resort.

A combination of appropriate PPEs/RPEs applicable for the specific biocidal product and use, RMMs (e.g. ventilation) and proper training (e.g. on using the PPEs, sealing opening points with tape) may also lead to a safe use. This requires expert judgment noting the irreversible damage that corrosive products may cause.

It should also be ensured that the prescribed PPEs/RPEs are protective for the product/use, including the tape material used to seal the opening points of these PPEs. Noting that the exact type of PPE will depend on the actual substances being used, the following PPEs for the coarse spraying with corrosive products were referred to as an indicative starting point, noting that safe use would need to be demonstrated by the applicant:

- Impermeable coveralls specially designed for spray applications (e.g. EN 14605 Type 3 or Type 4), tested according to test method EN 468 (The impermeable coverall must incorporate a hood if exposure to the head is possible);
- Respiratory protective equipment (RPE) such as full-face mask/particle filter P3 (protection factor 40), reference to HSE[10];
- Gloves such as EN 374 (performance level 4); gloves made of Butyl rubber;
- Chemical-resistant boots;
- Eye protection: full-face mask, chemical goggles.

It was noted that the employer and employee should follow instructions and advice provided by the suppliers of 1) the biocidal product (in the SDS) and 2) the PPE/RPE.

[85] https://echa.europa.eu/documents/10162/1276600/guidance_analysis_alternatives_biocides_en.pdf

The applicant for a biocidal product should provide the information on the appropriate PPEs, including the resistance of the tape material, if used for sealing the opening points of PPEs for the duration of the application.

The importance of proper training was emphasized, noting however that 'trained professional' lacks a harmonised definition in EU and that practices may vary between Member States. This may lead to difficulties in ensuring that the proper training of the professionals has taken place, ensuring safe use. Nevertheless, employers must ensure that their employees are properly trained on PPE wearing and maintenance, in particular when RPE and protective coveralls (including taping) are recommended to mitigate the workplace risks from any biocidal product uses.

The applicants may consider a combination of the RMM options discussed in section 2.5.2, as well as any additional RMMs, to reduce exposure and ensure a safe use. Any of the RMMs should not be considered in isolation but they also affect each other. For example, shorter application time for coarse spraying would be expected to decrease exposure and it could increase the acceptability of PPEs/RPEs, including the tape, if used.

Overall, the acceptability of a use is affected by the combination of the pattern and situation of use, all risk management measures taken and any possible PPE. Since all of these need to be considered in conjunction, it is not possible to establish definite rules or values for a certain parameter. As an example, the same acceptability criteria should not be valid for exposure time in situations that may be the same with regard to containment RMMs and appropriate PPE, but when in one case automation is also included: this additional RMM should enable longer theoretical exposure time if this leads to significantly reduced extent of exposure.

In light of the above, it becomes clear that it is not possible to set a definite list of (working) conditions and risk management measures that would render the coarse spraying use acceptable, but instead, all parameters, conditions and specificities of the use have to be considered together in assessing whether the risk is acceptable or not. The acceptability of the use is a case-by-case decision that is based on all the information on the application and the product.

The following two options are possible in considering the acceptability of coarse spraying of corrosive products:

1) **Not acceptable use – if exposure cannot be in practice excluded.**

    - Due to the severe irreversible damage that exposure could cause, any use where exposure is expected would not be acceptable.

2) **Acceptable use – if exposure can be in practice excluded.**

    - The arguments for excluding exposure in practice may include for example automation and training.

    - Full automation of the application process could in principle lead to a safe use. Automation of application would avoid exposure to the operators to corrosive products and safe re-entry could be ensured by e.g. the use of sensors. This would be in line with the hierarchy of control principles where exposure to hazardous chemicals is avoided by eliminating the source. However, such automation process may not always be implementable in all settings/areas to be disinfected.

    - Trained professionals should have adequate instruction on the use of PPEs to ensure that they will not be exposed to corrosive substances. Additionally, the PPEs (and sealing tapes if necessary) should be selected to ensure no exposure.

- Other measures/RMMs could be put in place that can ensure that there is no exposure.

The burden of proof stays with the applicant.

Establishing definite rules on acceptable use patterns or obligatory RMMs could be established at the regulatory level if seen necessary. However, scientifically it is not possible to establish clear rules because of the number of variables that need to be considered in conjunction.

2.6. Question 3 of mandate

Taking into account the answers that will be provided by ECHA to questions 1 and 2, consider whether a review/clarification of the existing ECHA BPR guidance is necessary.

The ECHA Guidance Vol III Parts B+C is currently under revision. In addition to the work performed internally within ECHA, the Human Health Working Group has been involved in discussions (see 2.1.1.3.42.4.5.2), and the Forum/EU-OSHA and OSH National Focal points have been consulted (see 2.1.1.1).

2.6.1. Human Health Working Group

For the discussion at WG-II-2023 (Annex II for relevant extract), please refer to the specific topics on local risk assessment described in chapter 2.4.5.2.

In preparation for WG-I-2024, an e-consultation was launched on 12 January 2024 on SECR proposals to revise some specific aspects of the guidance.

In addition, clarifications are needed on several aspects regarding situations where both quantitative and qualitative assessment seem valid, but the conclusions could be different. ECHA is working to provide clarity in the guidance, considering the minutes of this discussion:

> *"The members reflected on possible situations as follows:*
>
> - *For a locally acting active substances (AS) in water solution, a quantitative assessment for inhalation (AEC) could replace a qualitative assessment.*
> - *It is important to consider whether the effect leading to classification is the same as the one for which a reference value is available. An AEC value might not be necessary for an effect that is appropriately covered by robust classification. On the other hand, the RMMs following from classification would not be needed if quantitative assessment shows they are not necessary. Furthermore, even if the effect is the same, the study used in deriving the AEC could be different from the one used for classification.*
> - *It would be possible to decide not deriving AEC values when classification covers the effect in question. This would mean qualitative assessment only, which could greatly facilitate the assessments. The question remained whether there would be the need to consider an AEC derived for AS when product is not classified.*
> - *For secondary exposure, PPE would not be relevant and an AEC could be used.*
> - *Simple examples might not be helpful because the assessment for biocides should concern products that most often are not simple dilutions in water.*
> - *It may not be possible to conclude on a general level that classification would override quantitative assessment or could be considered sufficiently protective without a quantitative assessment.*
> - *A decision tree could help in deciding the appropriate way forward in different cases, but the principles discussed were not generalisable but require expert judgment case-by-case. This might suggest that the approach in current Tables 26 and 27 may be used, providing arguments for and against acceptability. The members were requested to suggest a decision tree and send to SECR if possible. If necessary, such a decision tree could be endpoint specific, e.g. dermal effects only.*
>
> *It was not possible to reach conclusions on the main questions and there was no agreement on any clear principles to be included in the guidance. SECR will consider the need to launch another e-consultation on specific topics including this one.*

The most relevant SECR proposal for the mandate is that it is unrealistic to assume that PPE and RMMs ensure in all situations no direct contact with corrosive substances as the substance may penetrate, permeate or by-pass the PPE. This assumption is currently made in the guidance (TAB entry TOX-19) but it could lead to underestimating serious health risks and is also not in line with REACH *Guidance on Information Requirements and Chemical Safety Assessment, Part E: Risk Characterisation*.

SECR proposes including in the guidance that, as the starting point, systemic risk characterisation is needed also when corrosive concentrations of the active substances are used. It would however be possible to justify that exposure is negligible due to a thorough description of technical RMMs, but this should not be the starting point of the assessment.

This section will be updated once the conclusions reached at WG-I-2024 are available.

2.6.2. Input from Forum/EU-OSHA and OSH National Focal points consultations

The questionnaire (see section 2.1.1.1) asked for input on which aspects in chapter 4.3.2 of the current ECHA guidance would require a revision. The input received is summarized below.

Tables 26 and 27

NL considered the strict limit of exposure duration to "few minutes per day or less" too absolute and unnecessary, as long as proper control measures are applied. Furthermore, additional control measures could be included, such as:

- automation/robotisation
- increasing the distance from the worker for example by using long-stemmed spraying devices
- decreasing the distance between the spraying device and the object to reduce overspray.

➔ A clarification regarding the timing and the additional measures proposed above will be included in the draft revision of ECHA Guidance Vol III Parts B+C.

In Table 27, DE suggested referring to approval decisions for the biocidal products used and their safety data sheets. These documents should list very specifically the requirements for personal protective equipment, among other things, and it should be clear which technical protective measures the manufacturer considers necessary. DE suggested to name these documents as sources of information in the table.

➔ A similar proposal was discussed at WG-II-2023, where it was suggested to include examples of cases discussed and agreed, which would enable an assessor to search for earlier cases that are similar to the one being assessed. To conclude, the WG "supported examples to be provided as (a) living document(s) and not to be included in the guidance revision."

➔ While the proposal discussed at the WG was not identical to the current proposal, it is proposed to keep the guidance document stable, without including lists that would need to be updated, but instead it would be possible to have living documents, however noting that such information should be maintained only if the MSCAs are active in keeping such lists up to date.

In addition, DE considered that "regular cleaning of equipment and work area" currently listed under technical measures is, in their opinion, an organisational measure. This can also be clarified in the guidance.

AT proposed to revise the table with the following suggestions:

- Restructure the table to follow the suggested format of exposure scenarios,
- Especially working with strong bases, tightly fitting goggles are normally obligatory if splashes are possible, for which shields could be added as an alternative (in the table, only safety goggles are identified),
- EN 13962 should be checked in the table,
- The table could be complemented by including that when handling corrosive liquids, also acid/base resistant shoes are needed.

EU-OSHA

EU-OSHA recommended including a reference to the OSH legislation and to the obligation of employers to assess all risks at the specific workplace in question and their interaction, including those from the wearing of PPE. The hierarchy of prevention should be respected throughout the guidance, for example not presenting technical measures and PPE as equal alternatives.

EU-OSHA noted that in their guidance, employers are recommended to check national legislation on OSH and more specific national guidance. It would also be appropriate to consider all risks, including safety risks, such as fire risks.

Appendix B to Annex I provide some useful links to OSH legislation and OSH authorities.

2.6.3. Response to question 3 of mandate

The ECHA Guidance Vol III Parts B+C is currently under revision and expected to be published in 2025, where several changes are envisaged. At this stage, final revisions cannot be provided as these will be pending the full guidance review that involves MSCAs, associated stakeholder organisations and the Commission.

In addition, some of the clarifications needed concern details relevant for the assessment of human exposure. Such details are envisaged to be developed in the context of the HEAdhoc for inclusion in *Biocides Human Health Exposure Methodology*[86] (BHHEM).

The following aspects are being considered and/or drafted in the Vol III Parts B+C guidance or as revisions in the BHHEM.

- Terminology will be clarified related to droplet sizes applicable to spraying and other application types where droplets are formed. Such terms include droplet sizes that are described for example as "inhalable", "fine" or "coarse". Clarification is also needed regarding any differences there may be in assessing exposure from spraying vs. foaming applications.

- It will be clarified what should be considered as inhalable. The following information needs to be considered in this context:

    - BPR Annex II, information requirements: the data requirement for acute inhalation toxicity requires considering whether *"the active substance is included in products that are powders or are applied in a manner that generates exposure to aerosols, particles or droplets of an inhalable size (MMAD < 50 micrometers)"* (information requirement 8.7.2). There is a similar wording for repeated dose toxicity via inhalation (information requirement 8.9),

    - BPR Guidance Vol III Parts B+C, p. 44: *"Particles with aerodynamic diameters below 100 µm have the potential to be inhaled, particles below 50 µm may reach the thoracic region and those below 15 µm the alveolar region of the respiratory tract."* This text only refers to particles, while elsewhere these diameters are referred to in the context of droplets,

    - BPR Guidance Vol III Parts B+C, p. 68: *"inhalable particles are capable of entering the respiratory tract via nose and/or mouth, and are generally smaller than 50 µm in diameter. Particles larger than 50 µm are less likely to be inhalable."*

    - In some BPC Opinions, the droplet size is included as an element to be taken into account when authorising products: *"An assessment of the risk during spraying may be required at product authorisation where use of the product may lead to inhalable aerosol formation (droplets < 40 µm)."* This is the case for at least DDAC[87] and ADBAC-BKC[88] in PT 2, where this value differing from the BPR and the relevant guidance is justified by TGD, EN 481 and WHO classification for droplet sizes.

[86] https://echa.europa.eu/documents/10162/992289/bpr_exposuremethodbiochh_en.rtf
[87] https://echa.europa.eu/documents/10162/0bff908b-a41b-950f-7f59-59dd0a4cd287
[88] https://echa.europa.eu/documents/10162/766dc7f3-68a6-97dc-e08c-d7714e8720eb

These substances are classified as H314 (*Causes severe skin burns and eye damage*).

- Terminology needs to be clarified related to equipment (e.g. nozzles) and type of spraying, including terms such as low-pressure spraying, pressure spraying, mist/aerosol/foam spraying.
- Hierarchy of control needs to be better incorporated in the whole approach of the guidance.
- Tables 26 and 27 will be revised, complementing the information with additions proposed and intending to clarify the conditions for acceptability. In this context it must however be stressed that acceptability of one indicator is affected by the combination of the conditions, and it will not be possible to establish strict rules. For example, the same acceptability criteria should not be valid for exposure time in situations that may be the same with regard to containment RMMs and appropriate PPE, but when in one case automation is also included (automation should enable longer theoretical exposure time if this leads to significantly reduced extent of exposure).
- Table 25 will be complemented with further arguments to support acceptable or unacceptable risk. These changes include the input received at WG-II-2023 and the corresponding response to comments table[89].
- Information on application methods and best practices are available in various guidance documents; merging some of the principles into Vol III Parts B+C and/or BHHEM will be considered[90].
- Clarification of situations where both quantitative and qualitative assessment may be used: it should be made clearer when either type of assessment is required and whether one of these should be decisive where the resulting conclusions are not the same. As a subtype of qualitative assessment, conclusions can in some situations be based on classification only.

Apart from the above, the guidance will be revised in accordance with the response to comments table[91] provided for WG-II-2023, where MSCAs commented on the needs to revise the guidance with regard to local risk assessment.

3. Case-specific questions (questions 4 to 6)

3.1. Question 4 of mandate

Taking into account the information provided on 3 February 2023 by the applicant for authorisation of the product family 'active chlorine-based products BPF - CID Lines', and the answers that will be provided by ECHA to questions 1 and 2 of this mandate:

a. clarify whether the diluted products applied by coarse spraying still needs to be classified as skin corrosive 'H314 – Causes severe skin burns and eye damage';

b. clarify which personal protective equipment is necessary for the use by coarse spraying of this product, for which meta-SPCs and justify;

[89] WGII2023_TOX_8-1a, available to members of the Human Health Working Group and Associated Stakeholder Observers.
[90] For example, the following sources will be considered: *Controlling exposure to disinfectants used in the food and drink industries* (https://www.hse.gov.uk/food/disinfectants.htm); *Principles of good control practice* (https://www.hse.gov.uk/coshh/detail/goodpractice.htm)
[91] WGII2023_TOX_8-1a, available to members of the Human Health Working Group and Associated Stakeholder Observers.

c. provide an updated versions of the SPC, as necessary, in particular as regards to any additional risk mitigation measure to reduce the exposure of the operators to in practice zero exposure.

3.1.1. General considerations and methodology applied

3.1.1.1. Question 4a

An e-consultation was launched in July-August 2023, based on an eCA BE proposal to address question 4a of the mandate.

The feedback received have been considered by the eCA in an updated proposal and further discussed at the HH WG-III-2023 meeting.

3.1.1.2. Question 4b-c

NOTE: as indicated above this section will be inserted later following an agreement on the general questions 1 to 3.

3.1.2. Response to question 4 of mandate

3.1.2.1. Question 4a

A discussion took place at the HH WG-III-2023 (see the case minutes[92]). It was concluded that:

- the OECD TG 431 and 439 studies submitted by the applicant are not acceptable;
- the buffering capacity of the dilutions of Meta-SPCs 7 and 8 is low;
- the classification of the Meta-SPC 7 and 8 dilutions applied for coarse spraying should remain as in the PAR (i.e. H314 and EUH071 labelling);
- the classification of the dilutions of Meta-SPC 1, 9, 10 and 12 applied for coarse spraying should remain as in the PAR (H314 and EUH071 labelling).

In light of the above, it can be concluded that the diluted products applied by coarse spraying still needs to be classified as skin corrosive '*H314 – Causes severe skin burns and eye damage*'.

[92]HH WGIII2023_TOX_8-1_Art75_C&L_activechlorine_Minutes *(access restricted to MSCAs only)*: https://interact-toolbox-docviewer.echa.europa.eu/wopihost-generic-module/OWA?fileID=090236e189b7eb38&application=Meetings

3.1.2.2. Question 4b-c

NOTE: as indicated above this section will be inserted later following an agreement on the general questions 1 to 3.

3.2. Question 5 of mandate

Taking into account the answers that will be provided by ECHA to questions 1, 2 and 3 of this mandate, review its previous opinions on those two families, as necessary (i.e. if the wearing of PPE and RPE can or cannot be recommended for the application of products classified as corrosive by coarse spraying with appropriate risk mitigation measures).

NOTE: as indicated above this section will be inserted later following an agreement on the general questions 1 to 3.

3.3. Question 6 of mandate

If different recommendations in risk mitigation measures of the product family 'active chlorine-based products BPF - CID Lines' on one side, and on the product families 'Sodium hypochlorite – general and water disinfection' and 'Sodium hypochlorite – general disinfection' on the other side, are eventually proposed, explain the differences between the three families and the intended methods of use that justify different measures.

NOTE: as indicated above this section will be inserted later following an agreement on the general questions 1 to 3.

4. Overall conclusions

NOTE: as indicated above this section will be inserted later following an agreement on the general questions 1 to 3.

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5. Annexes

Annex I (*CONFIDENTIAL*) - ECHA consultations - Questions and answers received.

Appendix A to Annex I – Relevant National Laws and Guidance documents from Portugal.

Appendix B to Annex I – Other relevant information (e.g. useful links to PPE guidance documents, EN standards, OSH authorities).

Annex II (*CONFIDENTIAL*) - Relevant WG minutes extracts and other confidential CG/SCBP documentation