Organisation for Economic Co-operation and Development

ENV/CBC/MONO(2021)29

Unclassified English - Or. English

19 October 2021

ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE

Evaluation of Tools and Models for Assessing Occupational and Consumer Exposure to Manufactured Nanomaterials – Part III: Performance testing results of tools/models for consumer exposure

Project: Compilation of Available Tools and Models Used for Assessing Consumer Exposure to Manufactured Nanomaterials and Evaluation of their Applicability in Exposure Assessments

Series on Testing and Assessment, No. 348

JT03483311

SERIES ON TESTING AND ASSESSMENT

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ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT
Paris 2021

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Objective

Inventory of modes/tools

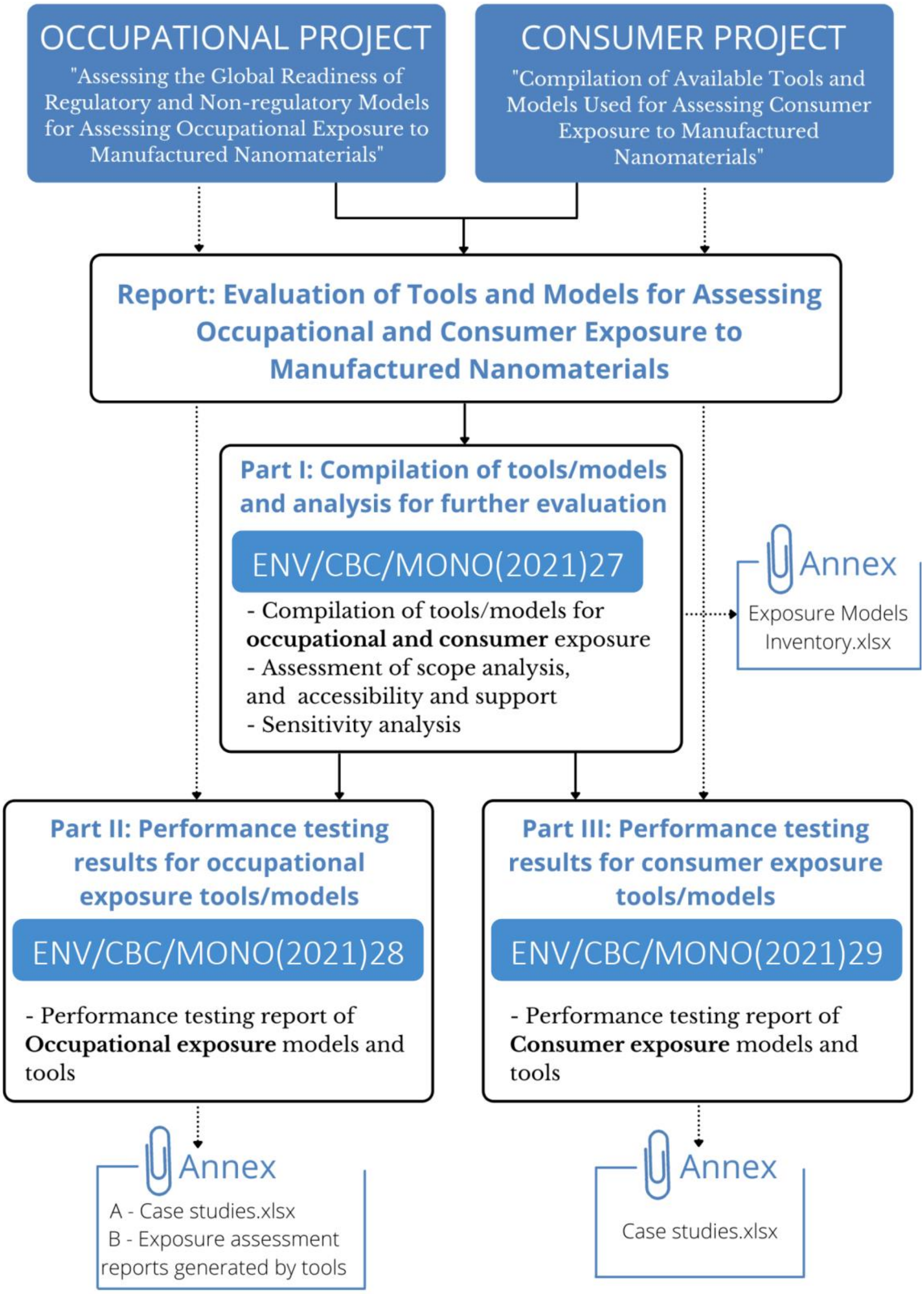
1. Under the first objective of the project, an inventory of available models/tools for assessing consumer exposure to MNM was created through an extensive literature review of peer-reviewed publications, the outcomes from recent international projects and inventories, and consultation with OECD WPMN. The inventory includes 15 nano-specific models/tools relevant to consumer exposure to MNM and 9 chemical exposure tools/ models that in-themselves or adapted could be used in exposure assessments of MNM. The description on how the inventory was constructed is provided in ENV/CBC/MONO(2021)27.

Evaluation of models/tools

2. Under the second objective of the project, an evaluation of the applicability of the 15 nano-specific models/tools was conducted in consultations with OCED WPMN experts and collaborators. The evaluation process was carried out based on scope analysis, accessibility and support examination, sensitivity analysis, and performance testing. The outcomes of scope analysis, accessibility and support examination, sensitivity analysis are provided in ENV/CBC/MONO(2021)27. This document describes the outcomes of the performance testing for seven models/tools for consumer exposure. The tested models/tools were chosen based on the results of the first objective and the outcomes of scope analysis, accessibility and support examination, and sensitivity analysis.

Report description

3. The performance testing assesses the predictive capability of models/tools by comparing the output of models/tools with measurement data. It determines whether the models/tools tend to overestimate or underestimate the exposure (where applicable). It also determines the rank correlation between models/tools estimates and measurement data (where applicable). In addition, the performance testing provides recommendations for consideration where appropriate when conducting studies to collect data relevant to consumer exposure assessment of MNMs.


OCCUPATIONAL PROJECT
"Assessing the Global Readiness of Regulatory and Non-regulatory Models for Assessing Occupational Exposure to Manufactured Nanomaterials"
CONSUMER PROJECT
"Compilation of Available Tools and Models Used for Assessing Consumer Exposure to Manufactured Nanomaterials"
Report: Evaluation of Tools and Models for Assessing Occupational and Consumer Exposure to Manufactured Nanomaterials
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ENV/CBC/MONO(2021)27
- Compilation of tools/models for occupational and consumer exposure
- Assessment of scope analysis, and accessibility and support
- Sensitivity analysis
Annex
Exposure Models Inventory.xlsx
Part II: Performance testing results for occupational exposure tools/models
ENV/CBC/MONO(2021)28
- Performance testing report of Occupational exposure models and tools
Part III: Performance testing results for consumer exposure tools/models
ENV/CBC/MONO(2021)29
- Performance testing report of Consumer exposure models and tools
Annex
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B - Exposure assessment reports generated by tools
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Case studies.xlsx

Executive Summary

4. The project “Compilation of Available Tools and Models Used for Assessing Consumer Exposure to Manufactured Nanomaterials and Evaluation of their Applicability in Exposure Assessments” aimed to (1) compile the available tools and models for assessing consumer exposure to Manufactured Nanomaterials (MNMs), and (2) evaluate their applicability to MNM exposure assessment. This document presents the outcomes of the performance testing for 7 models/tools under the second objective of the project. These models/tools are the Engineered Nanoparticle Airborne Exposure v1.0 tool, Boxall et al. 2007, ConsExpo nano v2.0, the GUIDEnano v3.0 tool, NanoSafer v1.1, The Swiss Precautionary Matrix v3.1, and Stoffenmanager Nano v1.0. The tested models/tools were selected out of 15 nano-specific models/tools compiled through an extensive literature review of peer-reviewed publications, the outcomes from recent international projects and inventories, and consultation with OECD WPMN under the first objective. The performance testing assessed the predictive capability of models/tools by comparing the output of models/tools with measurement data. Due to low availability of measurement data suitable for the performance testing for consumer exposure scenarios, the performance testing was limited to a few case studies in this work. Case studies were selected for the performance testing for each model/tool based on data availability for input and output of model/tool, and scope of model/tool. Since the models/tools have different scopes and algorithms, a unified dataset was not used in the performance testing and the performance testing was conducted for each model/tool individually in the context of their intended use for consumer exposure scenarios.

5. The results of the performance testing showed that the ENAE v1.0 tool, Boxall et al. 2007, GUIDEnano v3.0, and ConsExpo nano v2.0 are suitable for quantitative exposure assessment of MNMs for consumer spray scenarios. Stoffenmanager Nano v1.0 and Swiss Precautionary Matrix v3.1 can be applied in prioritization of MNMs with respect to potential exposure. NanoSafer v1.1 can be used to estimate acute air concentration for consumer spray scenarios. This conclusion is based on a few case studies used in the performance testing and can be influenced by new measurement data when available. Low availability of measurement data on consumer exposure scenarios demonstrates a need to develop measured data for use in developing, evaluating and implementing models/tools to estimate exposure to MNMs for consumer exposure scenarios. This document also contains recommendations for consideration where appropriate when conducting experiment on consumer exposure to MNMs.

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1 Introduction

6. As discussed in ENV/CBC/MONO(2021)27, under the second objective of the project "Compilation of Available Tools and Models Used for Assessing Consumer Exposure to Manufactured Nanomaterials and Evaluation of their Applicability in Exposure Assessments", 15 nano-specific models/tools underwent scope analysis and accessibility and support examination. These models/tools include the ANSES tool, Boxall et al. (2007), the Engineered Nanoparticle Airborne Exposure (ENAE) tool, ConsExpo nano, CB Nanotool, the GUIDEnano tool, I-NANO, LICARA-nanoSCAN, Multiple-Path Particle Dosimetry (MPPD), NonoRiskCat, NanoSafer, Nazarenko et al. (2012[1]; 2014[2]), Swiss Precautionary Matrix, Stoffenmanager Nano, and the SUN Decision Support System (SUNDS) tool. The scope analysis was performed by investigating the algorithms used in each model/tool. It examined input parameters required by the models/tools, their intended domain in terms of scenarios and routes of exposure, outputs of the models/tools, and underlying assumptions for each model/tool. The accessibility and support examination addressed the user interface of the models/tools, and the availability of input parameters in the models/tools. Of these 15 non-specific models/tools, 11 were subjected to sensitivity analysis. These models/tools include Stoffenmanager Nano, the ANSES tool, the Control Banding tool, Boxall et al. (2007[3]), the ENAE tool, ConsExpo nano, SUNDS, the MPPD model, NanoSafer, Nazarenko et al. (2012[1]; 2014[2]), and Swiss Precautionary Matrix. The sensitivity analysis was performed by exploring variations of model/tool outputs with values of input parameters and identifying the least and most sensitive input parameters. The outcomes of the scope analysis, accessibility and support examination, and sensitivity analysis are provided in ENV/CBC/MONO(2021)27.

7. Following the sensitivity analysis, performance testing was conducted on 7 models/tools identified for consumer exposure. The performance testing assessed the predictive capability of the models/tools by comparing the output of models/tools with measurement data. The outcomes of the performance testing are presented in the current document. It should be noted that performance testing of models/tools for occupational exposure is provided in a separate document ENV/CBC/MONO(2021)28].

2 Performance testing

Collection of measurement data

8. Performance testing requires measurement data with sufficient contextual information suitable to cover the parameters requested by models/tools. As such, an exposure release database was constructed by compiling measurement data on consumer exposure to MNM through a data call and literature review of peer-reviewed publications. The data call was performed through the WPMN in April 2019 to collect data from occupational and consumer nanomaterial exposure scenarios considering inhalation, dermal, and oral exposure. A document and an excel spreadsheet with the data requirements (see Table 1) have been circulated to be filled and facilitate the performance testing task.

9. The exposure release database has been shared with WPMN members and provides information on description of processes and activities, material descriptions, and personal and spatial concentration measurements. Case studies were selected for the performance testing for each model/tool based on data availability for input and output of model, and domain applicability of model/tool. The details of the experimental studies and the measured data used in the performance testing are provided in the Appendix and Annex, respectively.

Table 1. Example of common descriptors for inhalation, dermal and oral exposure assessment.

Note: Note that only certain parameters/questions are applicable to consumer exposure scenario.

	Example of data/information needed for performance testing
Demands on study design. We would like to compare the modelling results with the observations (real data) and therefore, we would like to have data on aerosol measurements:	
Pre- and/or post-activity measurements (mass concentrations preferably)	mass concentrations available
Breathing zone measurements (mass concentrations preferably)	mass concentrations available
NF and FF measurements (mass concentrations preferably)	mass concentrations available
Material identifiers	
Material name	CuO nanoparticles
Manufacturer	PlasmaChem GmbH
CAS number	1317-38-0
EINICS number	N/A
Material information	
Is the nanomaterial labeled with a nano-specific word or term? Yes/No	Yes
Is the nanomaterial coated or surface modified (Yes/No)	No
Weight fraction (NM in the product; relevant for NM-enabled products and dispersions)	100%
Physical state (solid or liquid)	Solid
Moisture (for powders; %)	N/A
Morphology (Spherical; granular; flake or clay; rod; fibre etc…)	Spherical

	Example of data/information needed for performance testing
Dimensions of the primary nano-object (a ≤ b ≤ c)	40 nm; Normal distribution has been considered with mean size 40 nm and standard deviation 10 nm (obtained from TEM images)
Relative density (specific gravity) density of the nanomaterial	6.5 g/cm3
Solubility of the material [is the material water soluble?]	Insoluble (< 1 g/L)
The specific surface area of the nanomaterial	15 m2/g
Respirable dustiness of powder (please specify the method)	104 mg/kg (continuous drop method)
Safety data /Hazard	
Is there a nanospecific occupational exposure limit (OEL_{nano}) or target value?	No
Respirable OEL for the nearest analogue material	1 mg/m3
Known hazards of analogue bulk material	No risk sentences or GHS/CLP hazard statements
Contextual information (activity information and occupational exposure situation)	
Description of the work processes and activities	Powder handling; Pouring process under fume hood 700 g CuO/min
Number of workers	1
Activity/Exposure frequency	4 to 5 days a week
Production volume/ use rate	0.7 kg/min
Particle emission rate if constant source emission or leak (mass/time)	In this case, the emission rate calculated by continuous drop dustiness test method (104 mg/kg x0,7 kg/min CuO=72,8 mg/min)
Activity handling energy factor[£]	H2 (0.25)
Total mass of material handled in each work cycle	0.7 kg
Duration of the work cycle	1 min
Pause between work cycles	0 min
Number of work cycles per day	1 time
Amount of material handled in each transfer	0.7 kg
Time required per task in cycle (spoon, bag, big-bag etc.)	1 min
Volume of the work room (width x length x height)	5.24 m x 7.25 m x 3.52 m
General ventilation system (mechanical, natural, etc...)	Mechanical
Air exchange rate	9 times/h
Ventilation rate in the room	139.55 L/s
Type of risk management measures/local controls	Type: Fume hood (standard, 1.35 m height, 1.8 m width and 0.7 m depth); exhaust flow of 300 m3/h)
Personal protective equipment (PPE)	Respirator, lab coat and gloves
Temperature of room	22 ºC
Relative humidity in the room (%)	N/A
Room pressure	1 atm
Description of secondary sources/other indoor activities (diesel engines, cigarette smoke, welding, busy road, etc.)	N/A
Cleaning and maintenance of the room	Yes (daily)
Contextual information (dermal exposure)	
Surface loading (µg/cm^2)	N/A
Dermal contact area (cm^2)	N/A
Number of contacts	N/A
Dermal loading (µg/cm^2)	N/A
Contextual information (oral exposure)	
Transfer efficiency from hand to perioral region	N/A
Hand/finger loading (µg/cm^2)	N/A
Contact area (cm^2)	N/A
Number of contacts	N/A

Criteria to assess the model/tool prediction

10. Models/tools have different application domains and incorporate different algorithms for estimating exposure. As such, a unified dataset and procedure were not used for the performance testing. The performance testing was conducted for consumer exposure scenarios only, based on personal or stationary exposure measurement data and the following criteria agreed in OECD WPMN. These criteria were adapted from the Dutch Social Economic Council. Here, the application domain refers to the intended use and target scenario of exposure of the model/tool.

- The exposure scenarios, for which exposure measurements are conducted, are relevant to consumer exposure that could be assessed by models/tools. Note that due to low availability of measurement data, the performance testing is limited to inhalation exposure to spray and powder products. Thus, caution should be taken when interpreting the results.
- The Spearman correlation coefficient between model/tool estimates and measured exposure values is at least 0.6.
- The model/tool estimates a reasonable worst case, which represents the upper bound of occurring exposure values.
- Real measurements do not exceed the model/tool estimates for more than 50% of the total comparisons
- Evaluation is done separately for solids, liquids and/or gases/fumes whenever possible.

Methods and results of the performance testing on individual models/tools

11. As given in Table 2, the 7 nano-specific models/tools were subjected to performance testing. These models/tools include Stoffenmanager Nano, Boxall et al. (2007[3]), the ENAE tool, ConsExpo nano, the GUIDEnano tool, NanoSafer, and The Swiss Precautionary Matrix. The performance testing on MPPD and Nazarenko et al. (2012[1]; 2014[2]) was not carried out due to the lack of measurement data on internal doses of MNMs. Since SUNDS incorporates ConsExpo-Nano for consumer exposure to MNMs, the performance testing of this tool is based on ConsExpo nano. The performance testing on ANSES tool and CB Nano tool was not performed, as the case studies collected in this project were not suitable for the performance testing of these tools. Mapping data from the case studies to the input values for these two tools resulted in the same value for each input parameter across case studies, which makes comparison across case studies inapplicable.

Table 2. list of models/tools subjected to scope analysis, user friendliness examination, sensitivity analysis, and performance testing

	Scope analysis	Accessibility and Support	Sensitivity analysis	Performance testing
ENAE	x	x	x	x
Boxall et al. 2007	x	x	x	x
ConsExpo nano	x	x	x	x
GUIDEnano	x	x		x
Stoffenmanager Nano	x	x	x	x
Swiss Precautionary Matrix	x	x	x	x
NanoSafer	x	x	x	x
MPPD	x	x	x	
Nazarenko et al. 2014	x	x	x	
ANSES tool	x	x	x	
CB Nano tool	x	x	x	
SUNDS	x	x	x	
I-NANO	x	x		
NanoRiskCat	x	x		
LICARA-nanoScan	x	x		

Engineered Nanoparticle Airborne Exposure v1.0

Introduction

12. The Engineered Nanoparticle Airborne Exposure (ENAE) tool is a web-based tool, intended to estimate air concentrations and surface loading of airborne nanoparticles. The input parameters required by the tool for the estimation are given in Table 3.

Table 3. Input parameters required by ENAE tool for estimating the air concentrations and surface loading

Input Name	
Volume	Ceiling particle deposition velocity
Floor area	Floor resuspension rate
Ceiling area	Wall resuspension rate
Wall area	Ceiling resuspension rate
Envelope penetration factor	Floor resuspension area
Supply airflow rate	Wall resuspension area
Return airflow rate	Ceiling resuspension area
Percent outdoor air	Initial zone concentration
Particle diameter	Initial floor loading
Particle density	Initial wall loading
Release amount (Release rate)	Initial ceiling loading
Operation time	Outdoor Concentration
Floor particle deposition velocity	Exposure time
Wall particle deposition velocity	

Method

13. The performance testing of this tool was conducted by comparing the air concentration of particles predicted by the tool with the measured air concentration of particles determined from case studies. Since the tool provides the conversion between particle mass and particle number, the comparison was performed in both units for cases where measurement data were reported in both units.

14. The case studies were chosen from the peer-reviewed publications listed in Table 4. Based on the case studies, values for the input parameters were determined and they are provided in "ENAE-case studies.xlsx" in the Annex A. It should be noted that a measured background concentration, if reported in the case study, was used to correct a measured concentration.

Table 4. Peer-reviewed publications used for the performance testing of the ENAE tool

Peer-reviewed publications	Number of case studies	Number of comparisons*	Exposure scenario	Product type	Route of Exposure
Park et al. (2018) - Comparison of modeled estimates of inhalation exposure to aerosols during use of consumer spray product	4	10 (A1-A10)	Consumer - Spray	Liquid	Inhalation
Bekker et al. (2014) - Airborne manufactured nano-objects released from commercially available spray product: temporal and spatial influences	2	2 (B1 and B2)	Consumer - Spray	Liquid	Inhalation
Chen et al. (2010) - Nanoparticles-containing spray can aerosol: characterization, exposure assessment, and generator design	1	1 (C1)	Consumer – Spray	Liquid	Inhalation

Note: * Cases A1-A10: nanoparticles released during typical use of a nano-silver contained propellant spray product. Case B1: impregnator spray product containing SIO_2 nanoparticle, B2: antiperspirant spray product containing SIO_2 nanoparticle, and C1: bathroom cleaner spray can product containing nano TiO_2 particles

Results

15. Figure 1 shows the air concentration of particles predicted by the tool and the measured air concentration of particles by mass and by number units across comparison cases. For the particle by mass (Figure 1a), the overall predicted air concentration ranged from ~1660.7 $\mu g/m^3$ to ~53550 $\mu g/m^3$ while the overall measure air concentration ranged from ~424 $\mu g/m^3$ to ~8195 $\mu g/m^3$. The Spearman correlation between predicted data and measured data across cases is 0.75 for the particle by mass. For the particle by number (Figure 1b), the overall predicted air concentration ranged from ~3768 #/cm^3 to ~2720400 #/cm^3 while the overall measure air concentration ranged from ~6200 #/cm^3 to ~160000 #/cm^3. The Spearman correlation between predicted data and measured data across cases is 0.85 for the particle by number.

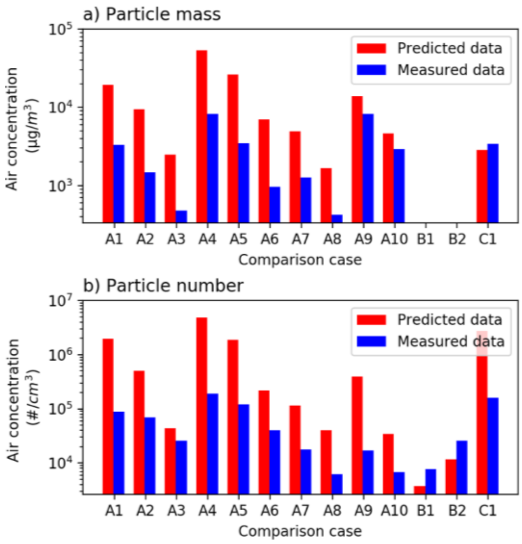

Figure 1. The measured air concentrations and ENAE-predicted air concentrations for 13 comparison cases - a) particle mass unit and b) particle number unit

16. Figure 2 shows the ratio of the predicted air concentrations over the measured air concentrations for particle by mass and by number across comparison cases. The ratios ranged from 1 to 100 for ~90% and ~85% of cases for particle mass and number units respectively, showing that the tool tends to overestimate the exposure. The mean ratios over cases are 4.5 and 10.5 for particle mass and number units respectively.

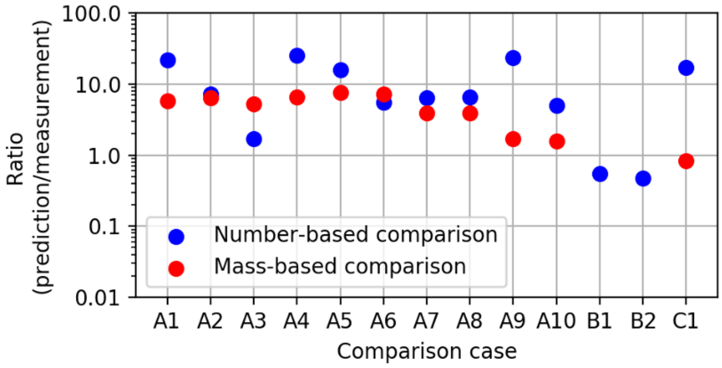

Figure 2. Ratio of ENAE-predicted air concentration of particles over measured air concentration of particles for 13 comparison cases

Conclusion

17. The performance testing of ENAE was carried out using 13 comparisons between the predicted air concentrations and the measured air concentrations for consumer scenarios on nano-containing spray products. The Spearman correlation coefficients are 0.75 and 0.85 for particle mass and particle number units respectively, indicating a good association of rank between the modelled estimates and the measured values. For ~85% of total comparisons, the ratio of the predicted air concentration over the measured air concentration is above 1, which can be interpreted as tending to favor 'worse-case' scenarios. Overall, this performance testing concludes that ENAE v1.0 is suitable for quantitative exposure assessment of nano-containing products for consumer spray scenarios. It should be noted that this conclusion is based on the 13 comparisons on spray products made in the performance testing and can be influenced by new measurement data when they become available.

Boxall et al. 2007

Introduction

18. Boxall et al. (2007[3]) presents a dilution model for estimating cumulative exposure from personal hygiene and skin care products for spraying application. The model is expressed as:

$$E = \int_0^T \frac{f \times Q \times \rho}{V} e^{-kt}\, dt$$

where e^{-kt} accounts for dilution due to the air change rate (k), E is the cumulative exposure, Q is the amount of product used, ρ is the percentage of MNM in product, f is the fraction of product escaping as aerosol, V is the room volume, and t is the time. The integration is from time t=0 (when product is used) to time T when the consumer leaves exospore area. Considering the equation, the model assumes that the air concentration of MNM diminishes exponentially with the time and air change rate. As reported by Boxall et al. (2007[3]), if T is a short time (e.g., 10 minutes), dilution with air change can be ignored and consequently the above equation is reduced to:

$$E = \frac{f \times Q \times \rho}{V} \times T$$

19. The input parameters required by the model for the estimation are given in Table 5.

Table 5. Input parameters required by Boxall et al. 2007 for estimating the cumulative exposure

Input Name	
Amount of product used	Exposure time
Fraction of MNM in product	Air change rate
Room volume	Fraction released to air

Method

20. The performance testing of this model was conducted by comparing the cumulative exposure of particles predicted by the model with the cumulative exposure of particles determined from case studies. Since the model does not provide the conversion between particle mass and particle number, for each case study the comparison was performed based on the reported unit for the amount of product used or released. For the mass-based amount of product used or released, the comparison was made in particle mass, and for the number-based amount of product released, the comparison was made in particle number. For the comparison, the case studies were chosen from the peer-reviewed publications listed in Table 6. Based on the case studies, values for the input parameters were determined and they are provided in “Boxall et al. (2007[3]) - case studies.xlsx” in the Annex A. It should be noted that if a measured background concentration was reported in a case study, the value used in the performance testing was background corrected measurement.

Table 6. Peer-reviewed publications used for the performance testing of Boxall et al. 2007

Peer-reviewed publications	Number of case studies	Number of comparisons*	Exposure scenario	Product type	Route of Exposure
Park et al. (2018[4]) - Comparison of modeled estimates of inhalation exposure to aerosols during use of consumer spray product	4	10 (A1-A10)	Consumer - Spray	Liquid	Inhalation
Bekker et al. (2014[5]) - Airborne manufactured nano-objects released from commercially available spray product: temporal and spatial influences	2	2 (B1 and B2)	Consumer - Spray	Liquid	Inhalation
Chen et al. (2010[6]) - Nanoparticles-containing spray can aerosol: characterization, exposure assessment, and generator design	1	1 (C1)	Consumer – Spray	Liquid	Inhalation

Note: * Cases A1-A10: nanoparticles released during typical use of a nano-silver contained propellant spray product. Case B1: impregnator spray product containing SIO_2 nanoparticle, B2: antiperspirant spray product containing SIO_2 nanoparticle, and C1: bathroom cleaner spray can product containing nano TiO_2 particles

Results

21. Figure 3 shows the cumulative exposure predicted by the model and the measured cumulative exposure for particle mass and number units across comparison cases. For the particle mass unit (Figure 3a), the overall predicted cumulative exposure ranged from ~8160 μg min/m³ to ~8800000 μg min/m³ while the overall measure cumulative exposure ranged from ~8500 μg min/m³ to ~116640 μg min/m³. The Spearman correlation between predicted data and measured data across the cases is 0.72 for the particle mass unit. For the particle number unit (Figure 3b), the predicted cumulative exposure is comparable with the measured cumulative exposure.

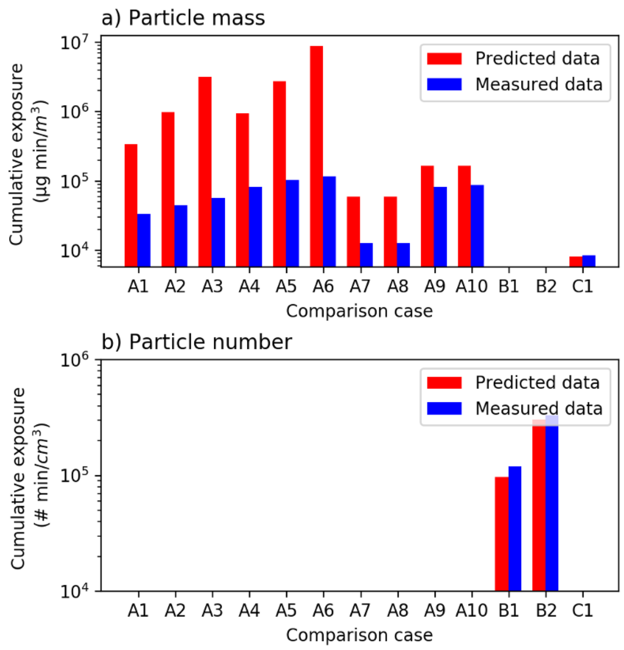

Figure 3. The measured cumulative exposure and Boxall et al.-predicted cumulative exposure for 13 comparison cases

Note: a) particle mass unit and b) particle number unit

22. Figure 4 shows the ratio of the predicted cumulative exposure over the measured cumulative exposure for particle mass and number units across comparison cases. For the particle mass unit, the ratios ranged from ~1 to ~100, showing that the tool tends to overestimate the exposure. For the particle number unit, the ratio is ~ 1. The mean ratios over case studies is 23.8 and 0.85 for particle mass and number units respectively.

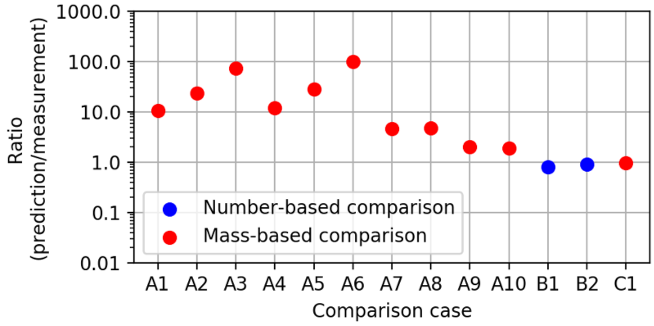

Figure 4. Ratio of the predicted cumulative exposure over the measured cumulative exposure for 13 comparison cases

Conclusion

23. The performance testing of Boxall et al. (2007[3]) was carried out using 13 comparisons between the predicted cumulative exposure and the experimentally determined cumulative exposure for scenarios including nano consumer spray products. The Spearman correlation coefficients is 0.72 for particle mass unit, indicating a good association of rank between the predicted cumulative exposure and the experimentally determined cumulative exposure. For the comparisons made in particle mass units, the ratio of predicted cumulative exposure over the experimentally determined cumulative exposure is above 1, showing that the model tends to overestimate the exposure. For particle number units, the performance testing is limited to two comparisons, and it shows that the predicted cumulative exposure is close to the measured cumulative exposure. Overall, this performance testing concludes that this model is suitable for quantitative exposure assessment of nano-contained products for consumer spray scenarios. It should be noted that this conclusion is based on the 13 comparisons made in the performance testing and can be influenced by new measurement data when they become available.

Swiss Precautionary Matrix v3.1

Introduction

24. The Swiss Precautionary Matrix (SPM) v3.1 tool is a web-based or standalone tool, intended to assess the need for nanospecific measures (precautionary need) for synthetic MNMs and their applications for professional end-users, consumers and the environment. It enables a preliminary risk assessment based on the current state of knowledge and indicates when further clarification is needed to help ensure safety in connection with the development of new products. The tool includes a short questionnaire with several single and multiple-choice answers. Depending on the answers to each question, the tool calculates a score as output, which indicates the need for further clarification if it exceeds 20. The calculation uses the following equation:

$$\text{Precautionary need} = N \times (W \times E + I),$$

25. where N represents nano definition according to the precautionary matrix defined within the tool, W represents the potential effect accounting for hazard score, I represents the available information on life cycle, and E accounts for the potential exposure of consumer, occupational or environmental. For the

consumer exposure, it is assumed that the potential exposure depends on three factors and is estimated using the following equation

$$E = E_{A,V} \times E_{2.4} \times E_{2.5}$$

where $E_{A,V}$ represents the carrier material of the MNM (air, liquid, solid), $E_{2.4}$ accounts for the amount of MNMs which a consumer handles daily through the product, and $E_{2.5}$ accounts for frequency which a consumer uses the product. Based on these factors, the input parameters required by the tool for estimating the potential exposure of consumer are given in Table 7.

Table 7. Input parameters required by the SPM tool for estimating the potential exposure of consumer

Input Name
Amount of product used
Type of carrier material
Frequency of task

Method

26. The performance testing on this tool was performed using 9 case studies on consumer spray products. The case studies were chosen from the peer-reviewed publications listed in Table 8. Values for input parameters were determined based on the case studies and they are given in "SPM-case studies.xlsx" in the Annex A. It should be noted that the direct comparison between the tool estimate and measured exposure was not made, as the tool estimates a qualitative score considering both potential effect and potential exposure.

Table 8. Peer-reviewed publications used for the performance testing of the SPM tool

Peer-reviewed publications	Number of case studies
Park et al. (2018) - Comparison of modeled estimates of inhalation exposure to aerosols during use of consumer spray product	4 (A1-A4)
Bekker et al. (2014) - Airborne manufactured nano-objects released from commercially available spray product: temporal and spatial influences	2 (B1-B2)
Lorenz et al. (2011[7]) - Nanosized aerosols from consumer sprays: experimental analysis and exposure modeling for four commercial products	2 (C1-C2)
Chen et al. (2010) - Nanoparticles-containing spray can aerosol: characterization, exposure assessment, and generator design	1 (D1)

Results

27. Table 9 shows the overview of the SPM score for each of the scenarios assessed. The selected scenarios are related to exposure to nanoparticle-contained consumer spray products. The SPM score ranged from 735 to 3651, which is above the critical threshold of twenty points. While the scenarios A1-A4, B2, and C1 had different exposure conditions, the resulting SPM scores were at the same level. This is attributed to the fact that for these scenarios SPM v3.1 was not able to differentiate spray amount of 7 g, 14 g and 40 g or spray duration of 5 seconds, 9 seconds, and 14 seconds. The lower score for the scenario B1 was caused by shorter exposure duration, which was only once a week instead of a daily basis. This reduction of exposure duration dropped the SPM score by ~ 45% compared to the higher score scenarios. The lowest score was attributed to the C2 scenario with exposure duration of once a month.

Table 9. SPM results of the performance testing

Case study	Reference	Short description of scenario	SPM score	W score	E score	I score
A1	Park et al (2018)	Spraying of 14 g of AgNP contained deodorant spray for 5 seconds	3651	45	81	6
A2	Park et al. (2018)	Spraying of 40 g of AgNP contained deodorant spray for 15 seconds	3651	45	81	6
A3	Park et al. (2018)	Spraying of 40 g of AgNP contained deodorant spray for 15 seconds with air exchange of 35 /h	3651	45	81	6
A4	Park et al. (2018)	Spraying of 14 g of AgNP contained deodorant spray for 5 seconds with air exchange of 35 /h	3651	45	81	6
B1	Bekker et al. (2014)	Spraying of ~ 8 g SiO_2 contained leather impregnator spray for 9 seconds	2031	45	45	6
B2	Bekker et al. (2014)	Spraying of ~7 g SiO_2 contained antiperspirant spray for 9 seconds	3651	45	81	6
C1	Lorenz et al. (2011)	Spraying of 4 g Ag contained antiperspirant spray for 5 seconds	3651	45	81	6
C2	Lorenz et al. (2011)	Spraying of ~13 g ZnO contained shoe impregnator spray for 5 seconds	735	81	9	3
D1	Chen et al. (2010)	Spraying of ~ 2.5 g TiO_2 contained bathroom cleaner spray for 125 seconds	3651	45	81	6

Conclusion

28. The performance testing of SPM was carried out using 9 scenarios relevant to nano consumer spray products. The results have shown that detailed information on exposure conditions may not influence outcomes when comparing small differences of input for parameters intended to cover a broader range of differences in exposure conditions with a low tier screening tool. Since SPM is intended for risk screening, it gives guidance to prioritize nano-enabled products and activity related to MNMs for further actions, according to their potentials to result in exposure to consumers.

Stoffenmanager Nano v1.0

Introduction

29. Stoffenmanager Nano v1.0 is a web-based control banding tool, developed to manage the potential risk from occupational exposure to MNM. The output of Stoffenmanager Nano is risk bands derived from a combination of hazard and exposure bands. The exposure band is obtained by estimating a relative exposure score using the following equation:

$$B = \left[(C_{nf}) + (C_{ff}) + (C_{ds})\right] \times \mu_{imm} \times \mu_{ppe} \times t_h \times t_f$$

$$C_{nf} = E \times H \times \mu_{lc\_nf} \times \mu_{gv\_nf},$$

$$C_{ff} = E \times H \times \mu_{lc\_ff} \times \mu_{gv\_ff},$$

$$C_{ds} = E \times a,$$

$$E = weight\ fraction \times dustiness \times moisture\ content$$

30. where B is exposure score, t_h is duration of task, t_f is frequency of task, C_{ds} is background concentration (score), C_{ff} is concentration (score) due to far-field sources, C_{nf} is concentration (score) due to near-field sources, $\mu_{imm}$is reduction exposure factor due to separation, μ_{ppe} is reduction exposure factor due to use of personal protective equipment, E is intrinsic emission factor, a is factor for the relative

influence of background sources, H is activity exposure factor, μ_{lc} is ventilation factor, and μ_{gv} is dilution factor in relation to the room size. The score estimated by the equation is converted to the exposure bands based on Stoffenmanager Nano categorization matrix. The input parameters used by the tool for the estimation are given in Table 10. To apply the equation to consumer exposure scenarios, the parameters μ_{ppe} and μ_{imm} need to be set to one, as personal protective equipment is not commonly used in consumer exposure scenarios and there is no separation between receptor and source.

Table 10. Input parameters used by Stoffenmanager Nano v1.0 for exposure assessment

Input Name	
Activity description	Personal protective equipment
Duration of task	Personal enclosure
Frequency of task	Surface contamination
Air exchange rate	Local control measure
Dustiness	Room volume
Viscosity of the liquid product	Weight fraction of the MNM in product
Dilution of MNM in water	Moisture content

Method

31. The performance testing of this tool was conducted by comparing the exposure score predicted by the tool with the measured exposure levels in particle number concentration determined from case studies. The case studies were chosen from the peer-reviewed publications listed in Table 11. Based on the case studies, values for the input parameters were determined and they are provided in “Stoffenmanager Nano-case studies.xlsx” in the Annex A.

Table 11. peer-reviewed publications used for the performance testing of Stoffenmanager Nano

Peer-reviewed publications	Number of case studies	Number of comparisons	Exposure scenario	Product type	Route of Exposure
Park et al. (2018) - Comparison of modeled estimates of inhalation exposure to aerosols during use of consumer spray product	4	10 (A1-A10)	Consumer - Spray	Liquid	Inhalation
Bekker et al. (2014) - Airborne manufactured nano-objects released from commercially available spray product: temporal and spatial influences	2	2 (B1-B2)	Consumer - Spray	Liquid	Inhalation
Nazarenko et al. (2012[8]) - Potential for inhalation to engineered nanoparticles from nanotechnology-based cosmetic powders	3	3 (C1-C3)	Consumer - Powder	Solid	Inhalation
Chen et al. (2010) - Nanoparticles-containing spray can aerosol: characterization, exposure assessment, and generator design	1	1 (D1)	Consumer - Spray	Liquid	Inhalation

Results

32. Figure 5 shows the measured particle concentrations across the exposure bands determined by the tool. For the average exposure band, the respective median and geometric mean of particle concentrations are equal to 6200 #/cm3 and 4385 #/cm3 respectively. For the high exposure band, the respective median and geometric mean of particle concentrations are equal to 26000 #/cm^3 and 32848 #/cm^3 respectively, both being greater than those of the average exposure band. There is no overlapping between respective interquartile ranges of measured particle concentrations lying in average and high exposure bands. Figure 5 also shows that there is a positive correlation between the measured particle concentrations and the predicted scores. Scenarios with particle concentrations above 25000 #/cm^3 (blue

points) scored 15 while scenarios with particle concentrations below 15000 #/cm^3 scored 0.15. The Spearman correlation between the measured particle concentrations and the predicted score is 0.79. It should be noted that scores are calculated based on the values of the input parameters, and not based on measured particle concentrations.

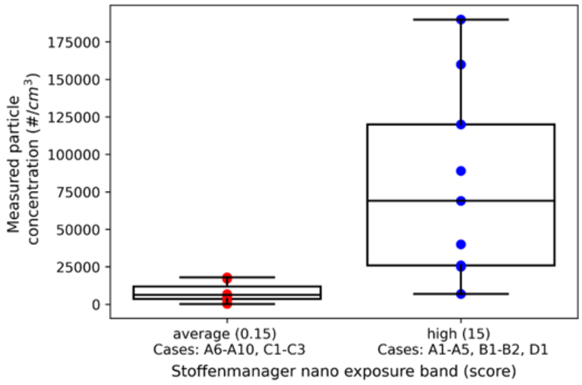

Figure 5. Classification of measured exposure in the model estimated exposure bands.

Note: The lower and upper limits of the box plots represent the 25th and 75th percentiles and the line within the box marks the median. Whiskers above and below the box indicate the maximum and minimum concentration

Conclusion

33. The performance testing of Stoffenmanager Nano was carried out using 16 scenarios including nano consumer powder and spray products. The measured particle concentrations were classified in two estimated exposure bands of the tool without overlapping between respective interquartile ranges of measured particle concentrations. The Spearman correlation coefficient between the measured particle concentrations and the predicted score is 0.79, indicating that there is a positive correlation between them. Overall, this performance testing suggests that Stoffenmanager Nano v1.0 could be used in prioritization of MNMs in the spray or powder products examined in this work.

GUIDEnano v3.0

Introduction

34. GUIDEnano v3.0 is a web-based tool, intended to assess human and environmental health risks of nano-enabled products along their life cycle. The tool provides different outputs depending on the assessment that the user would like to perform. For exposure assessment, the tool estimates air concentration of MNMs in environmental compartments. The required input parameters for estimating air concentration of particles are given in Table 12. For the case studies used in this performance testing, the local control measure and personal protection parameters are not taken into account in exposure estimation, as personal protective equipment and localized control were not used in the case studies.

Table 12. Input parameters used by GUIDEnano v3.0 for estimating air concentration of particles

Input Name
Amount of product used
Particle size distribution
Density of MNM
Specific surface area of MNMs
Emission rate
Frequency of activity
Time required per task in cycle
Room volume
Air exchange rate
Activity input
Activity release
Time span
Personal protection
Local control measure

Method

35. The performance testing of this tool was conducted by comparing the air concentration of particles predicted by the tool with the measured air concentration of particles determined from case studies. Since the tool provides the conversion between particle mass and particle number, the comparison was performed in both units for cases where measurement data were reported in both units.

36. The case studies were chosen from the peer-reviewed publications listed in Table 13. Based on the case studies, values for the input parameters were determined and they are provided in “GUIDEnano-case studies.xlsx” in the Annex A. It should be noted that if a measured background concentration was reported in a case study, the value used in the performance testing was a background corrected measurement.

Table 13. Peer-reviewed publications used for the performance testing of the GUIDEnano tool

Peer-reviewed publications	Number of case studies	Number of comparisons* (label)	Exposure scenario	Product type	Route of Exposure
Park et al. (2018) - Comparison of modeled estimates of inhalation exposure to aerosols during use of consumer spray product	2	4 (A1-A4)	Consumer - Spray	Liquid	Inhalation
Bekker et al. (2014) - Airborne manufactured nano-objects released from commercially available spray product: temporal and spatial influences	2	2 (B1 and B2)	Consumer - Spray	Liquid	Inhalation
Chen et al. (2010) - Nanoparticles-containing spray can aerosol: characterization, exposure assessment, and generator design	1	1 (C1)	Consumer – Spray	Liquid	Inhalation

Note: * Cases A1-A4: nanoparticles released during typical use of a nano-silver contained propellant spray product. Case B1: impregnator spray product containing SIO_2 nanoparticle, B2: antiperspirant spray product containing SIO_2 nanoparticle, and C1: bathroom cleaner spray can product containing nano TiO_2 particles

Results

37. Figure 6 shows the air concentration of particles predicted by the tool and the measured air concentration of particles for particle mass and number units across comparison cases. For the particle

mass unit (Figure 6a), the overall predicted air concentration ranged from ~3436 μg/m^3 to ~99900 μg/m^3 while the overall measure air concentration ranged from ~1482 μg/m^3 to ~8195 μg/m^3. The Spearman correlation between predicted data and measured data across the cases is 0.70 for the particle mass unit. For the particle number unit (Figure 6b), the overall predicted air concentration ranged from ~8800 #/cm^3 to ~11000000 #/cm^3 while the overall measure air concentration ranged from ~7700 #/cm^3 to ~190000 #/cm^3. The Spearman correlation between predicted data and measured data across the cases is 0.78 for the particle number unit.

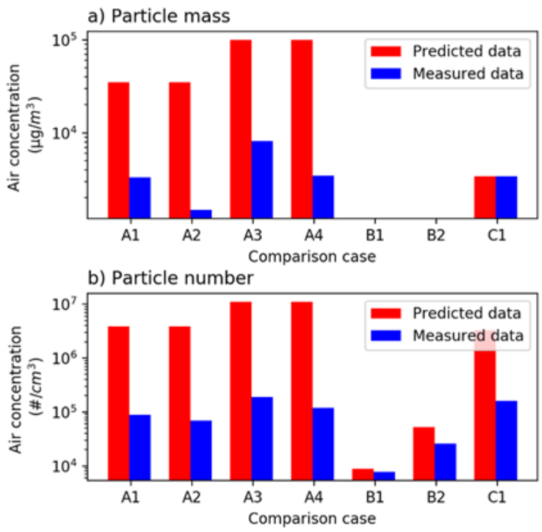

Figure 6. The measured air concentrations and GUIDEnano-predicted air concentrations for 7 comparison cases

Note: a) particle mass unit and b) particle number unit

38. Figure 7 shows the ratio of the predicted air concentration over the measured air concentration for particle mass and number units across the cases. For the particle mass unit, for case studies A1-A4, the ratio ranges from 10 to 100. Similarly, for the particle number unit, the ratios ranged from 1 to 100 for the cases A1-A4, and C1. Such a range shows that the tool tends to overestimate the exposure. The mean ratios over the cases are ~15 and ~39 for particle mass and number units respectively.

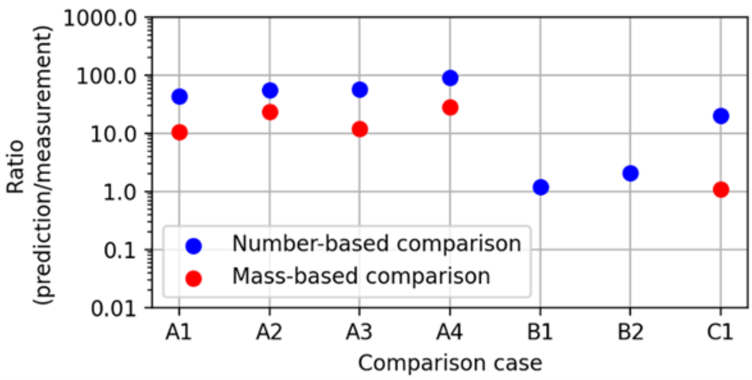

Figure 7. Ratio of GUIDEnano-predicted air concentration of particles over measured air concentration of particles for 7 comparison cases

Conclusion

39. The performance testing of GUIDEnano v3.0 was carried out using 7 comparisons between the predicted air concentrations and the measured air concentrations for exposure to spray products containing nanomaterials. The Spearman correlation coefficients between the predicted and measured values are 0.7 and 0.78 for particle mass and particle number units respectively, indicating a good association of rank between the modelled estimates and the measured values. For all the total comparisons made, the ratio of the predicted air concentration over the measured air concentration is above 1, which can be interpreted as tending to favour 'worse-case' scenarios. Overall, this performance testing concludes that GUIDEnano v3.0 is suitable for exposure assessment of consumer nano-contained spray products. However, this conclusion is based on the 7 comparisons made in the performance testing and can be influenced by new measurement data when they become available. It should be noted that since GUIDEnano is based on the mass balance, making assumptions on the amount of product used and release rate can strongly influence the output of GUIDEnano v3.0. Thus, caution should be taken by the user when dealing with these parameters.

ConsExpo nano v2.0

Introduction

40. ConsExpo nano v2.0 is a web-based tool, used to estimate inhalation exposure to nanomaterials in consumer spray products. The tool combines predictions of aerosol concentration in indoor air with the predictions of alveolar load in the lungs. Input parameters required by the tool are given in Table 14.

Table 14. Input parameters required by ConsExpo nano v2.0 for estimating the air concentrations of particles and alveolar load in the lungs

Input Name	
Exposure duration	Deposition model
Spray duration	Inhalation rate
Aerosol particle diameter distribution	Ventilation rate
Mass generation rate	Airborne fraction
Weight fraction of MNM is product	Nanomaterial density
Aerosol density	Nanomaterial particle diameter distribution
Room volume	Exposure
Room height	Simulation duration

Method

41. The performance testing of this tool was conducted by RIVM (the model developer) as part of the caLIBRAte project. In the performance testing, the human exposure module of the tool was evaluated by comparing the air concentration of particles predicted by the tool with the measured air concentration of particles determined from case studies. The case studies described release of non-volatile substances, whether they are nanomaterials or not, from spray products. The reason to consider non-volatile substances in the performance testing is that the tool algorithms to simulate the inhaled dose are applicable to non-volatile substances in general. However, owing to the scope of this project, this report focused on the results obtained based on nano-specific case studies (i.e., case studies with nano-contained spray

products). The selected nano-specific cases studies were chosen from the peer-reviewed publications listed in Table 15. Based on the case studies, values for input parameters were determined and they are provided in “ConsExpo nano-case studies.xlsx” in the Annex A. In cases where tool parameters could not be determined unambiguously, ranges of parameter values were estimated based on other sources. For the case study taken from the work of Chen et al. (2010[6]), ranges of values were defined for the mass generation rate and room volume parameters, and for the case studies taken from the work of Park et al (2018[4]), ranges of values were defined for substance weight fraction and particle density parameters. The upper and lower bounds of the ranges were used for the performance testing, resulting in a range of the tool outputs. A measured value within the outputs range was interpreted as an agreement between measurement and model, and a measured value outside the range was interpreted as a deviation.

42. It should be noted that since ConsExpo nano does not provide air concentrations as an output, and only calculates these as an intermediate (internally used) values, the tool runs were performed in ConsExpo Web tool. ConsExpo Nano and ConsExpo Web use the same algorithms for estimating air concentrations.

Table 15. Peer-reviewed publications used for the performance testing of ConsExpo nano v2.0

Peer-reviewed publications	Number of case studies	Number of comparisons	Exposure scenario	Product type	Route of Exposure
Park et al. (2018) - Comparison of modeled estimates of inhalation exposure to aerosols during use of consumer spray product	4	6	Consumer - Spray	Liquid	Inhalation
Chen et al. (2010) - Nanoparticles-containing spray can aerosol: characterization, exposure assessment, and generator design	1	1	Consumer – Spray	Liquid	Inhalation

Results

43. Figure 8 compares the predicted air concentrations with the measured air concentration from Chen et al. (2010[6]) who studied nanoparticles released during typical use of a consumer spray (a bathroom cleaner) containing (nano-)TiO_2. The range of air concentrations predicted by the tool spans almost two order of magnitude. The upper bound of the peak concentrations was estimated to be around 3.1 mg/m^3, which is comparable with the reported measured value of 3.4 mg/m^3. Note that the study only reports a peak air concentration in the breathing zone of the user. Figure 9 compares the predicted air concentrations with the measured air concentration from Park et al. (2018[4]) who studied nanoparticles released during typical use of a nano-silver contained propellant spray product (an indoor air freshener). The measured air concentrations are within the range of air concentrations predicted by tool based on the upper and lower bounds of the input ranges. This may be interpreted as that the model is not in contradiction with the data given the uncertainty in the experimental setup parametrisation.

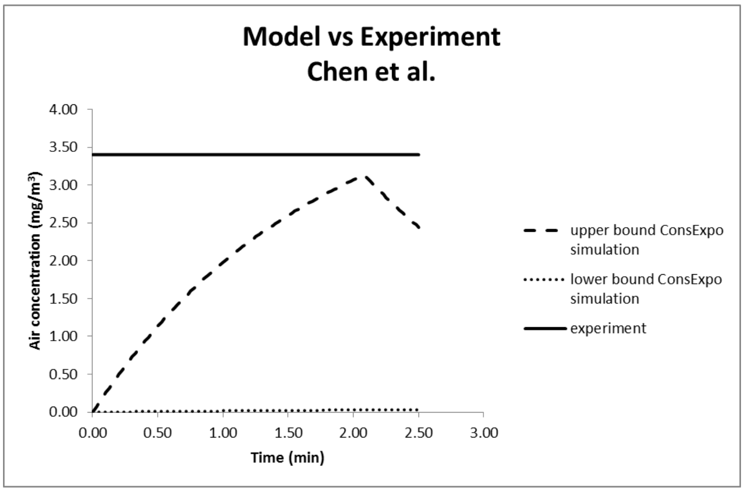

Figure 8. Comparison of ConsExpo nano simulations with data from Chen et al. (2010[6])

Note: The measured air concentration was the average nano TIO2 air concentration during spraying. For the ConsExpo model simulations, upper and lower bounds represent uncertainty in the model parametrisation.
Source: The figure is taken from the caLIBRAte documents.

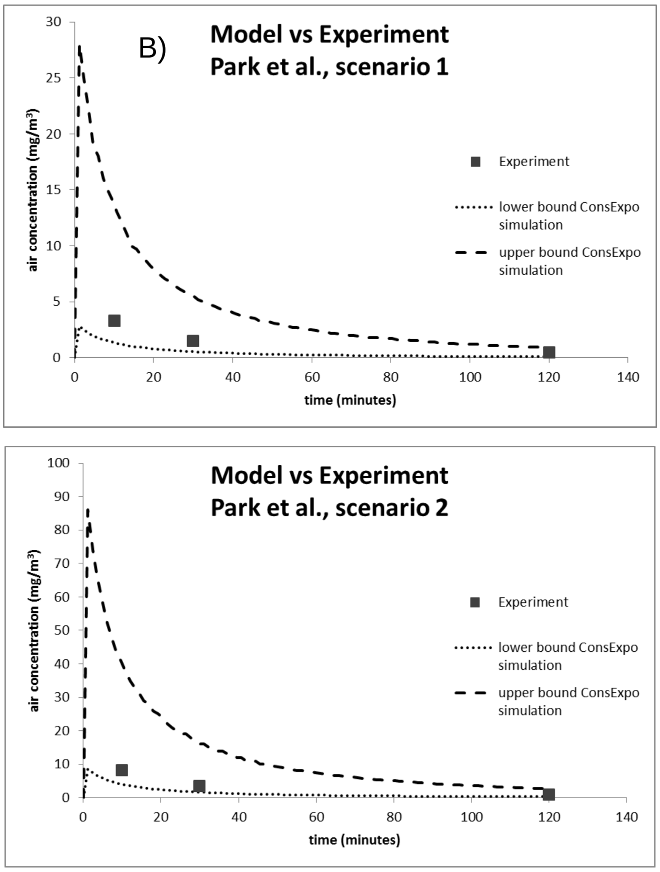

Figure 9. Comparison of ConsExpo nano simulations with data from Park et al. (2018)

Note: For the ConsExpo model simulations, upper and lower bounds represent uncertainty in the model parametrisation. A) scenario 1, with a spray duration of 5 seconds and B) scenario 2 with a spray duration of 15 seconds

Conclusion

44. The performance testing of ConsExpo nano v2.0 was carried out using case studies describing release of non-volatile substances, whether they are nanomaterials or not, from spray products. The results obtained based on nano-specific case studies (i.e. case studies with nano-contained spray products) show that there is good agreement between tool estimates and measurement data while there is uncertainty in model estimates. This uncertainty stems from simplifications in the model formulation, such as assumed complete mixing of indoor air and complete non-volatility of the substance monitored. Overall, this performance testing concludes that ConsExpo nano v2.0 is suitable for exposure assessment of nano-contained products for spray scenarios.

NanoSafer v1.1

Introduction

45. NanoSafer v1.1 is a web-based control banding tool, developed to address risks associated with occupational inhalation exposure during production and use of MNMs. The output of NanoSafer are risk levels expressed in control bands by combining hazard and exposure bands. The exposure band is allocated using air concentration of MNMs and the volume-specific surface area of the nearest analogue bulk. The underlying algorithm of NanoSafer for allocating the exposure band can be expressed as:

$$C_{NF} = \frac{(E_i + NF_{FF\to NF} - NF_{NF\to FF} + NF_{residual})}{V_{NF}}$$

$$C_{FF} = \frac{(NF_{NF\to NF} - NF_{FF\to NF} + FF_{residual})}{V_{FF}}$$

$$NF_{FF\to NF} = \left[\frac{Q_{NF}.C_{FF}}{\Delta t.(Q_{NF})^2}\right].\left[Q_{NF}.\Delta t + e^{(-Q_{NF}.\Delta t)} - 1\right]$$

$$NF_{NF\to FF} = \left[\frac{Q_{NF}.C_{NF}.(E_i.\Delta t)}{\Delta t.(Q_{NF})^2}\right].\left[Q_{NF}.\Delta t + e^{(-Q_{NF}.\Delta t)} - 1\right]$$

$$EXP_{Acute} = \frac{C_{Acute}}{2.OEL.\frac{30.\frac{1}{\delta}}{SSA}}$$

$$EXP_{8-hour} = \frac{C_{8-hour}}{OEL.\frac{30.\frac{1}{\delta}}{SSA}}$$

where E_i represents emission rate, Q_{NF} is ventilation rate between the near and far fields, C_{NF} is air concentration of particles in the near field, C_{FF} is air concentration of particles in the far field, Δt is time interval, $NF_{NF\to FF}$ is mass transfer from the near field to the far field, $NF_{FF\to NF}$ is mass transfer from the far field to the near field, V_{NF} is volume of the near field, V_{FF} is volume of the far field, $NF_{residual}$ is background concentration in the near field, and $FF_{residual}$ is background concentration in the far field, EXP is exposure band, δ is specific density of MNM, SSA is specific surface area of MNM, and OEL is occupational exposure limit for analogue bulk material. Input parameters used by the tool for allocating the exposure band is given in Table 16. To apply the tool to consumer exposure scenarios, the values of the parameters pause between work cycle and number of work cycles per day need to be set 0 min and 1 respectively.

Table 16. Input parameters used by NanoSafer for determining exposure band

Input Name
Specific surface area of the MNM
Respirable OEL for the nearest analogue material
Total mass of material handled in each work cycle
Emission rate
Duration of work cycle
Time required per task in cycle
Amount of material handled in each transfer
Volume of work room
Air exchange rate
Pause between work cycles
Number of work cycles
Activity level in the room

Method

46. The performance testing of this tool was conducted by comparing the air concentration of particles predicted by the tool at near field with the measured air concentration of particles determined from case studies. The tool runs were performed by. The near field was chosen because of experimental setups in case studies, where measurement instruments were located within 1 m distance from exposure sources.

47. The case studies (A1-A4) were chosen from the work of Park et al. (2018) who studied nanoparticles released during typical use of a nano-silver contained propellant spray product (an indoor air freshener). Values for input parameters were determined based on the case studies, and they are provided in "NanoSafer-case studies.xlsx" in the Annex A. It should be noted that if a measurement of background concentration were reported in a case study, the value used in the performance testing was a background corrected measurement.

Table 17. Peer-reviewed publications used for the performance testing of NanoSafer v1.1

Peer-reviewed publications	Number of case studies	Number of comparisons	Exposure scenario	Product type	Route of Exposure
Park et al. (2018) - Comparison of modeled estimates of inhalation exposure to aerosols during use of consumer spray product	4	4 (A1-A4)	Consumer - Spray	Liquid	Inhalation

Results

48. The tool provides 15-min (acute) and 8-hour (daily) average air concentration as outputs and the case studies reported 10-min, 30-min, and 2-hour average air concentrations. As such, the 15-min average predicted air concentration and 10-min average measured air concentration were chosen for comparison. Figure 10 shows the 15-min predicted average air concentration of particles and the 10-min average measured air concentration of particles across comparison cases. The predicted air concentration ranged from ~3177.5 μg/m^3 to ~67328.0 μg/m^3 while the measure air concentration ranged from ~1273 μg/m^3 to ~8195 μg/m^3. Considering the ranges, it can be concluded that the 10-min average predicted air concentration is also greater than the 10-min average measured air concentration, as air concentration decreases over time during exposure (i.e., 10-min average air concentration > 15-min average air concentration). The Spearman correlation coefficient between predicted data and measured data across the cases is 0.63.

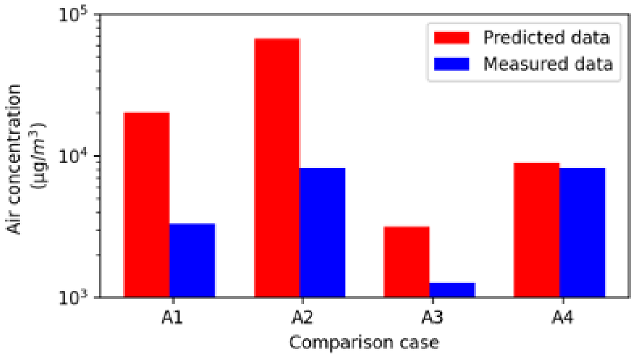

Figure 10. The measured air concentrations and NanoSafer-predicted air concentrations for 4 comparison cases

Figure 11 shows the ratio of the predicted air concentration over the measured air concentration across the cases. The ratios ranged from 1 to 10, indicating that the tool tends to overestimate the exposure across comparison cases. The mean ratio over the cases is 5.24.

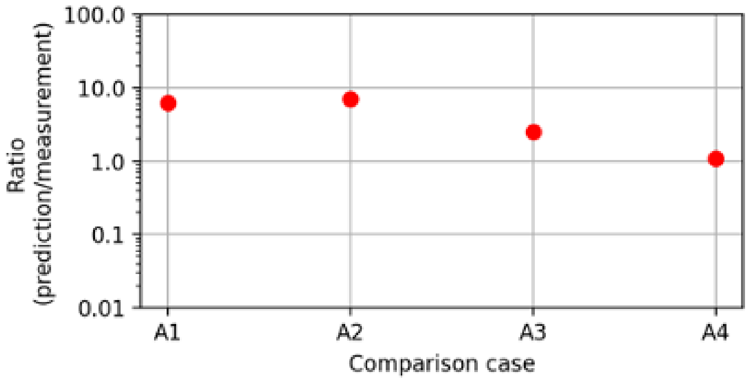

Figure 11. Ratio of NanoSafer-predicted air concentration of particles over measured air concentration of particles for 4 comparison cases

Conclusion

49. The performance testing of NanoSafer was carried out using 4 case studies on spray products containing nanomaterials. The Spearman correlation coefficient between the predicted and measured values is above 0.6 and the predicted values fall within one order magnitude of the measured values. Considering this, the NanoSafer v1.1 can be applied to estimate acute air concentrations for consumer spray scenarios. It should be noted that this conclusion is based on the 4 comparisons made in this performance testing and can be influenced by new measurement data when they become available.

3 Conclusion and Recommendation

50. Performance testing was conducted on 7 nano-specific models/tools for consumer exposure scenarios using case studies summarized in Table 18. These models/tools include Stoffenmanager Nano v1.0, Boxall et al. (2007[3]), the ENAE tool v1.0, ConsExpo nano v2.0, the GUIDEnano v3.0 tool, NanoSafer v1.1, and The Swiss Precautionary Matrix v3.0. The case studies were taken from the exposure release database created by compiling measurement data on consumer exposure to MNM through the WPMN data call and literature review of peer-reviewed publications.

Table 18. Summary of case studies used in the performance testing

Peer-reviewed publications	Number of case studies	Exposure scenario	Product type	Route of Exposure	Applied to testing of which models/tools
Park et al. (2018) - Comparison of modeled estimates of inhalation exposure to aerosols during use of consumer spray product	4	Consumer - Spray	Liquid	Inhalation	ENAE, GUIDEnano, Boxall et al. 2007, Stoffenmanager - Nano, ConsExpo nano, SPM, NanoSafer
Bekker et al. (2014) - Airborne manufactured nano-objects released from commercially available spray product: temporal and spatial influences	2	Consumer - Spray	Liquid	Inhalation	ENAE, GUIDEnano, Boxall et al. 2007, Stoffenmanager - Nano, SPM
Nazarenko et al. (2012[8]) - Potential for inhalation to engineered nanoparticles from nanotechnology-based cosmetic powders	3	Consumer - Powder	Solid	Inhalation	Stoffenmanager –Nano
Chen et al. (2010) - Nanoparticles-containing spray can aerosol: characterization, exposure assessment, and generator design	1	Consumer - Spray	Liquid	Inhalation	ENAE, GUIDEnano, Boxall et al. 2007, Stoffenmanager - Nano, ConsExpo nano, SPM
Lorenz et al. (2011[) - Nanosized aerosols from consumer sprays: experimental analysis and exposure modeling for four commercial products	2	Consumer - Spray	Liquid	Inhalation	SPM

51. The results of performance testing have shown that Boxall et al. (2007[3]), the ENAE v1.0 tool, the GUIDEnano v3.0 tool, and ConsExpo nano v3.0 tend to overestimate exposure. For each of these models/tools, the ratios of predicted values over measured values ranged from 1 to 100 for more than 80% of comparison cases. Such a comparison was not made for Swiss Precautionary Matrix v3.1 and Stoffenmanager Nano v1.0, as their outputs are not relevant to measurable quantities. The results have also shown that the computed Spearman correlation coefficients were above 0.6 for Boxall et al. (2007[3]), the ENAE v1.0 tool, Stoffenmanager Nano v1.0, the GUIDEnano v3.0 tool, indicating a good association rank between predicted values and measured values across products tested in the studies. The performance testing of Swiss Precautionary Matrix v3.1 has shown that detailed information on exposure conditions may not influence outcomes when comparing small differences of input for parameters intended to cover a broader range of differences in exposure conditions with a low tier screening tool. A summary of the results of the performance testing is given in Table 19.

52. Based on the results obtained in this work, the performance testing concludes Boxall et al. (2007[3]), the ENAE v1.0 tool, GUIDEnano v3.0, and ConsExpo nano v2.0 are suitable for quantitative

exposure assessment of MNMs for consumer spray scenarios. Stoffenmanager Nano v1.0 and Swiss Precautionary Matrix v3.1 can be applied in prioritization of MNMs with respect to potential consumer exposure. NanoSafer v1.1 can be used to estimate acute air concentration for consumer spray scenarios. However, these conclusions are based on a limited number of case studies on spray and powder products. As shown in the summary table (Table 19), the number of comparisons ranged from 4 (NanoSafer v1.1) to 16 (Stoffenmanager Nano v1.0) across the models/tools. Such a low number of comparisons are due to low availability of measurement data suitable for the performance testing for consumer exposure scenarios, which makes the performance testing limited to a few case studies. From the exposure release database, a considerable portion of measurement data were rejected as unsuitable for the performance testing mostly because of missing information on emission rates, amount of product used, particle size distribution, and time evolution of air concentration. To fill out these data gaps, the following information is recommended to be considered where appropriate when conducting experiment on consumer exposure to MNMs.

- Amount of product used for the experiment
- Fraction of MNMs in product
- Emission rate
- Characterization of particle size distribution characterization during the exposure
- Time evolution of air concentration during the exposure

Table 19. Summary of results of performance testing on Stoffenmanager Nano v1.0, Boxall et al. 2007, the ENAE v1.0 tool, ConsExpo-Nano v3.0, the GuideNano v3.0tool, NanoSafer v1.1, and The Swiss Precautionary Matrix v3.1

Model/Tool	Tester	Number of comparisons	Spearman correlation	Trend over total comparison (overestimation/underestimation)
ENAE v1.0	HC	13	0.75	overestimation
GUIDEnano v.30	HC	7	0.70	overestimation
Boxall et al. 2007	HC	13	0.72	overestimation
Stoffenmanager Nano v1.0	HC	16	0.79	N/A*
ConsExpo nano^ v3.0	RIVM	7	N/A	overestimation
Swiss Precautionary Matrix v3.1	HC	9	N/A	N/A
NanoSafer v1.1	NRCWE and HC	4	0.63	overestimation

Note: * Not applicable, ^ Performed in EU H2020 caLIBRAte project

References

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Boxall, A. et al. (2007), *Current and future predicted environmental exposure to engineered nanoparticles*, Central Science Laboratory, http://randd.defra.gov.uk/Document.aspx?Document=CB01098_6270_FRP.pdf. [3]

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Nazarenko, Y., P. Lioy and G. Mainelis (2014), “Quantitative assessment of inhalation exposure and deposited dose of aerosol from nanotechnology-based consumer sprays”, *Environmental Science: Nano*, Vol. 1/2, pp. 161-171, http://dx.doi.org/10.1039/c3en00053b. [2]

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Nazarenko, Y. et al. (2012), “Potential for Inhalation Exposure to Engineered Nanoparticles from Nanotechnology-Based Cosmetic Powders”, *Environmental Health Perspectives*, Vol. 120/6, pp. 885-892, http://dx.doi.org/10.1289/ehp.1104350. [8]

Park, M. et al. (2018), “Development of a systematic method to assess similarity between nanomaterials for human hazard evaluation purposes – lessons learnt”, *Nanotoxicology*, Vol. 12/7, pp. 652-676, http://dx.doi.org/10.1080/17435390.2018.1465142. [4]

Annex A. Data Sheets for Different Models and Tools

Values of Input parameters and measurement data used in the performance testing of models/tools can be found in the attached files as Excel tables. All files are packed to a single Annex_case_studies_consumer_models.zip file. The filenames of the files are:

- ENAE-case studies.xlsx
- Boxall et al-case studies.xlsx
- SPM-case studies.xlsx
- Stoffenmanager Nano-case studies.xlsx
- GUIDEnano-case studies.xlsx
- ConsExpo nano-case studies.xlsx
- NanoSafer-case studies.xlsx

Appendix. Summary of Experimental Studies

Table 20. Summary of experimental studies used in the performance testing.

Publications	Brief description of study	Product type	NM name	Stationary measurement data	Personal measurement data	Application duration(s)	Room/Chamber volume (m^3)	Ventilation conditions (ACH)
Park et al. (2018) - Comparison of modeled estimates of inhalation exposure to aerosols during use of consumer spray product	The study describes nanoparticles released from a propellant spray product (an indoor air freshener containing nano-silver) in a cleanroom under different ventilation conditions. Particle size distribution and concentrations from 10 to 10000 nm were measured using SMPS and OPS located within 1 m distance from the sprayer. Exposure measurements were carried out for 120 minutes.	Spray	Ag	X		5 and 15	40	0 and 35
Bekker et al. (2014) - Airborne manufactured nano-objects released from commercially available spray product: temporal and spatial influences	This work describes nanoparticles released from commercially available nano-spray products in a chamber with well-controlled ventilation conditions. Particle concentration, particle size distribution, and surface area concentration were measured using SPMS, APS, and ELPI at ~ 30 and 290 cm from the source. Exposure measurements were carried out for 12 minutes.	Spray	SIO_2	X		9	19.5	0
Nazarenko et al. (2012[8]) - Potential for inhalation to engineered nanoparticles from nanotechnology-based cosmetic powders	This study describes nanoparticles released from three nanotechnology-based cosmetic powders. The powders include moisturizer, blusher, and sunscreen powders. Particle size distribution and number concentration from 10 to 10000 nm were measured using SMPS and APS. Exposure measurements were carried out for 3 minutes.	Powder	Mix		X	< 180	0.072	0
Chen et al. (2010) - Nanoparticles-containing spray can aerosol: characterization, exposure assessment, and generator design	This work describes nanoparticles released from a bathroom cleaner/sanitizer spray can product containing nano TIO_2. The particle size distribution and concentration were measured using SPMS and APS in the breathing zone of the operator. Exposure measurements were carried out for 2.5 minutes.	Spray	TIO_2		X	125	-	0.34
Lorenz et al. (2011) - Nanosized aerosols from consumer sprays: experimental analysis and exposure modeling for four commercial products	This study describes nanosized aerosols released from consumer spray products including antiperspirant and shoe impregnation sprays. Particle size distribution and number concentration from 10 to 500 nm in the breathing zone of the operator were measured using SMPS. Exposure measurements were carried out for 3 minutes.	Spray	Ag	X		5	0.1	0

Abbreviation: SPM, Scanning Mobility Particle Sizer; OPS, Optical Particle Spectrometer; APS, Aerosol Particle Sizer; ELPI, Electrical Low Pressure Impactor