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Assessing the risk of chemicals to Children's Health: OECD-wide survey 2021 Survey Report

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NO. 376

Assessing the risk of chemicals to Children's Health: OECD-wide survey 2021 Survey Report

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among **FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD**

Environment Directorate

ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT

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or contact:

OECD Environment Directorate,
Environment, Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16
France

E-mail: ehscont@oecd.org

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Foreword

Children can be more vulnerable than adults to environmental hazards, such as those presented by chemicals, due to their physiological differences and unique behaviour. Risk assessment methodologies that specifically consider children are required to ensure that potential risks are addressed. Following an OECD-wide survey of methodologies and tools used to assess the risk of chemicals to children's health in 2011-2012 [ENV/JM/MONO(2013)20] (OECD, 2013[1]) and a workshop held in Utrecht, the Netherlands, on 7-8 October 2013 [ENV/JM/MONO(2014)29] (OECD, 2014[2]), the Children's Health project was launched by the Working Party on Exposure Assessment (WPEA), and a dedicated subgroup was set up.

One of the key programme outputs was a children's exposure decision tree that could be used to identify whether a separate exposure assessment is needed with regard to children or whether the exposure and risk assessment conducted for adults already provides an acceptable level of safety for children [ENV/JM/MONO(2019)29] (OECD, 2019[3]). After the publication of the document, the Working Party discussed potential follow-up activities and in June 2020 the working Party endorsed a new proposal to conduct an OECD-wide survey to update parameters for risk assessment of children. The survey was carried out in the first half of 2021 and the responses were compiled into a report.

The development of the questionnaire, the compilation and analysis of the results and the discussion and drafting in this project, were led by the Netherlands. The subgroup that supported this activity comprised members representing Australia, Canada, Costa Rica, France, Germany, Italy, Japan, Korea, Netherlands, Sweden, the US, the EU, the Business and Industry Advisory Committee to the OECD (BIAC), the World Health Organization (WHO), and the European Environment Bureau. This document was endorsed by the WPEA and is published under the responsibility of the Chemicals and Biotechnology Committee.

Table of contents

Tables

Executive Summary

Children exhibit unique behaviours, such as mouthing and crawling, which may result in exposure scenarios not considered for other population groups, when performing chemical risk assessments. In addition, physiological differences between children and adults may affect the exposure assessment scenarios. In considering global concerns for children's health, OECD member countries have decided to further develop and improve the risk assessment methodologies for children. To facilitate this, a wide survey was conducted, aiming to identify currently available methodologies for assessing the risk of chemicals to children's health and also identify possible needs for additional or missing parameters and for further guidance documents. This document contains the results of the 36 reactions to the survey, which were received from 16 countries. The reactions by the respondents varied greatly with regard to the type of chemical review programmes/legislations, including for chemical substances in consumer products, biocides and industrial substances, plant protection products, and nanomaterials.

The survey first identified the existing methodologies for assessing the risk of chemicals to children's health used by organisations in OECD member countries. There were differences in the definition of children between different programmes/legislations and/or countries. For example, some define children as a group under a specific year of age, e.g., 14 and 18, while others define several age groups, such as infants, toddlers, children, and teens. Several respondents also provided differentiation of physiological characteristics into age groups (such as body weight, breathing rate, and body surface area). With regard to hazard assessment, exposure assessment and risk characterisation, respondents reported various informative guidance, tools and methodologies, including references to documents which are being used to perform children specific hazard assessments, exposure assessments and risk characterisations (twelve references of guidance/tools were provided for hazard assessments, forty for exposure, and fifteen for risk characterisations). Although the overview is not exhaustive, these documents can aid the development of further methodologies and provide a source of information.

The survey also aimed to identify needs for any additional parameters, both with regard to exposure methodology as well as data for these parameters. Of the respondents, 54% indicated the need to include additional exposure parameters in the exposure assessment methodology for children. The most often indicated parameters were "migration from products" for chemical or product specific parameters, "dermal absorption" for physiological parameters, and "mouthing behaviour" and "different use scenarios (e.g. use of higher frequency or amount of cosmetics)" for scenario-related or behavioural parameters. 75% of the respondents indicated the need for better or more data/measurements to be used as input for their methodology for exposure assessment for children to support the parameters. Specifically, "migration from products", "emission from product", "presence/amount of chemicals in specific places/products" for chemical or product specific parameters, and "contact scenarios regarding specific activities (e.g. during playing)", "contact/use scenarios with specific products (e.g. furniture, floor, toys)" for scenario-related or behavioural parameters were indicated most often. Possibly, the overview of existing methodologies might contain some of these parameters, methodologies or data.

Finally, the survey identified the need for developing further guidance documents on specific issues related to the exposure and risk assessment for children. From a list of predefined topics, those addressing

children-specific scenarios or behaviour (e.g. “time spent on specific places”, “use survey for personal care products for children”, “use survey for children and toys”, and “mouthing behaviour”) seemed to receive the most interest. Additional topics were also brought forward by the respondents, which showed several respondents interested in developing guidance on migration from products.

Altogether, the outcome of the survey should further progress and direct the OECD’s work on exposure assessment methodologies for children.

Background and Purpose

The 4th Meeting of the Working Party on Exposure Assessment agreed that a survey should be performed on methodologies used to assess children's exposure to chemicals and to gather information on the needs for any additional parameters. This pertains to parameters in exposure assessment methodology as well as data needed for deriving these parameters. The outcome of the survey should further progress and direct the OECD's work on exposure assessment methodologies for children. The survey can be seen as a follow-up of the OECD-wide survey assessing the risk of chemicals to children's health performed in November 2011 (reported in 2013 in ENV/JM/MONO(2013)20 (OECD, 2013[1])). The specific aims of the current survey were to:

- identify the existing methodologies for assessing the risk of chemicals to children's health used by organisations in OECD member countries;
- identify needs for any additional parameters, both with regard to exposure methodology as well as data for these parameters; and
- identify the needs for further guidance documents on specific issues of importance related to the exposure and risk assessment for children.

The present document is based on the results of the survey, which was carried out in the first half of 2021, almost 10 years after the earlier survey from 2011. A draft version of the survey was prepared by the Netherlands' National Institute for Public Health and the Environment (RIVM). It was sent to OECD-WPEA members for comments in March 2021. The actual survey was sent in May 2021 to OECD-WPEA members, as well as to other OECD Working Parties, namely on Biocides (WPB), Pesticides (WPP) and Manufactured Nanomaterials (WPMN). The questions of the survey can be found in Annex A. Thirty-six reactions were received from 16 countries, i.e. Australia (AU), Belgium (BE), Canada (CA), Costa Rica (CR), Denmark (DK), Germany (DE), Hungary (HU), Japan (JP), Republic of Korea (KR), the Netherlands (NL), New Zealand (NZ), the Philippines (PH), Sweden (SE), Switzerland (CH), United Kingdom (GB), and the United States (US)[1]. The following organizations took part:

- Australian Industrial Chemicals Introduction Scheme (AICIS), Office of Chemical Safety, Australian Government department of Health, Australia
- Australian Pesticide and Veterinary Medicines Authority (APVMA), Australia
- Therapeutic Goods Administration (TGA), of Health Product Regulation Group (HPRG), Australia
- Therapeutic Goods Administration (TGA), Medicines Regulation Division (MRD) and Medical Devices Surveillance Branch of Medical Devices & Product Quality Division, Health Products Regulation Group (HPRG), Australia
- Federal Public Service (FPS) Public Health, Food Chain Safety and Environment, Belgium
- Scientific Institute of Public Service (ISSeP), Belgium: 1 reaction regarding both contaminated soils health risk assessment and Plant Protection Products.

[1] These abbreviations follow the country ISO codes as described in the ISO 3166 international standard

- Health Canada, Health Products & Food Branch, Food Directorate, Bureau of Chemical Safety, Chemical Health Hazard Assessment Division (CHHAD), Canada
- Health Canada, Existing Substances Risk Assessment Bureau (ESRAB), Canada
- Health Canada, New Substances Assessment and Control Bureau (NSACB), Nanotechnology Section, Canada
- Health Canada, New Substances Assessment and Control Bureau (NSACB), Canada
- Health Canada, Pest Management Regulatory Agency (PMRA), Canada
- Federal Office of Public Health (FOPH), Switzerland: 2 reactions regarding biocides and chemicals
- State Secretariat for Economic Affairs (SECO), Switzerland
- National Poison Center Control (CCSS), Costa Rica
- German Federal Institute for Risk Assessment (BfR), Department of Pesticides Safety, Germany
- German Federal Institute for Risk Assessment (BfR), Germany: 2 reactions regarding REACH and toys
- Danish Environmental Protection Agency (DEPA), Denmark
- National Public Health Center (NNK), Hungary
- Ministry of the Environment, Environmental Health Department, Environmental Risk Assessment Office, Japan
- National Institute of Environmental Research, Republic of Korea
- National Institute for Public Health and the Environment (RIVM), the Netherlands: 2 reactions in collaboration with the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) regarding Plant Protection Products and biocides
- National Institute for Public Health and the Environment (RIVM), the Netherlands: 3 reactions regarding REACH, biocides, consumer exposure, nanomaterials and food
- National Institute for Public Health and the Environment (RIVM), the Netherlands: 1 reaction from the perspective of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) on personal title
- Environmental Protection Authority, New Zealand (EPA NZ): 1 reaction from reassessments programme.
- Industrial Technology Development Institute (ITDI), Department of Science and Technology (DOST), Philippines: 1 reaction regarding environmental and health safety of nanomaterials
- Swedish Chemicals Agency (KEMI), Sweden: 3 reactions regarding Plant Protection Products and Biocides and consumer exposure
- Health and Safety Executive (HSE), Chemicals Regulation Division (CRD), United Kingdom: 1 reaction regarding Plant Protection Products and Biocides
- United States Environmental Protection Agency (US EPA), Office of Pollution Prevention and Toxics (OPPT), United States of America
- United States Environmental Protection Agency (US EPA), Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pesticide Programs, United States of America

The survey (see Annex A for the complete survey questions) was divided into three parts:

- Part I: Currently used methodology to assess children's exposure and risk to chemicals. Respondents were asked to describe their:
  - Type of chemical review programme;
  - Definition of children;
  - Hazard assessment;

  - Exposure assessment; and
  - Risk characterisation.
- Part II: Needs for additional parameters during exposure assessment for children. Respondents were asked for their needs regarding:
  - Parameters in exposure assessment methodology; and
  - Data for parameters in exposure assessment.
- Part III: Needs for further guidance documents on specific issues of importance to the exposure and risk assessment for children.

1 Summary of Survey Responses

The responses received to the questions of the survey are summarised below. A compilation of the complete responses per question can be found in Annex B.

1.1. Currently used methodology to assess children's exposure and risk to chemicals

1.1.1. Type of chemical review programme

Respondents were asked (question 2) to indicate the type of chemicals that are subject to their review programme. Chemical substances in consumer products, biocides, industrial substances and plant protection products were most often indicated (Table 1): by 53%, 47%, 43% and 43% of the respondents, respectively. The category labelled 'Other' (which could be specified) includes: allergens, animate products of biotechnology, biotechnology, endocrine disrupting chemicals, natural health products, non-medicinal ingredients in drugs, polymers, radiation and veterinary medicines/drugs.

Table 1. Type of chemicals reviewed. For details, see the answers to question 2 in Annex B.

Type of Chemical	Times indicated	
	(n)	*(%)*
Chemical substances in consumer products	19	53
Biocides, including household pesticides	17	47
Industrial substances	15	42
Plant Protection Products, including pesticides for agricultural use	15	42
Nanomaterials	14	39
Cosmetics	9	25
Environmental contaminants	9	25
Food Contact Materials	6	17
Food additives	5	14
Food contaminants	5	14
Drugs, medicinal products	4	11
Medical devices	4	11
Other	8	22

The respondents were asked (question 3) how the risks for children were assessed. Twenty-two of the respondents (61%) indicated risks were assessed in a generic way as part of the assessment of consumers and the general public. Twenty-five (69%) of the respondents indicated that they had performed specific risk assessments dedicated to the risks to children (For details, see the answers to question 3 in Annex B).

1.1.2. Definition of children

Respondents were asked (question 4) whether they have a definition of "children" and, if so, whether a differentiation between different age groups is made. Sixty-nine per cent of respondents did have a definition, while 31% indicated that they did not. Ninety-six per cent of the respondents that indicated to have a definition, indicated a differentiation between different age groups. In addition, 3 respondents that indicated not to have a definition of "children" did indicate a differentiation between different age groups is made. A summary of definitions of "children" and age groups in different programmes/legislations which were provided by the OECD member countries can be seen in Table 2 (the complete answers to question 4 can be found in Annex B). The overview on definitions of "children" shows that these are very much dependent on the legal framework, programme or type of risk at hand. Therefore, it is important to state and explain what kind of child an exposure or risk assessment is looking at.

Table 2. Summarised definitions of "Children" by the respondents of the survey.

Definition	Programme/Legislation	Country
Children 1-2 years: 11 kg Children 2-3 years: 15 kg Children up to 12 years are considered in certain risk activities	Australian Pesticides and Veterinary Medicines Authority (APVMA)	AU
Under 18 years: "Children" Depending on medicine/clinical trial, differentiation made between <2, 2-6, 6-12, and 12-18 years old children	Therapeutic Goods Administration (TGA), Medicines Regulation Division (MRD) of Health Products Regulation Group (HPRG)	
Age as discriminant with specific default values (weight, inhalation rate, body part surface area) based on age. Adolescents (= 11 years) generally grouped with adults	EFSA Plant Protection Product (PPP) active substance assessment	BE
Age groups of 1-<6 years and 6-<15 years for risk assessment, and age groups of 6-<10, 3-<6, 6-<10, and 10-<15 for exposure assessment (with different exposure parameters for weight, breathing rate, exposure duration, etc.)	Contaminated soils health risk assessment program (S-Risk)	
Children: 1-3 years	Pesticides exposure: Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products (PPP)	
No formal definition of children, however, an infant is defined in the Food and Drug Regulations as "a person who is under the age of one year". In risk assessments, typical age groups from the Canadian Community Health Survey are considered: 0-5 months: "infants" (exclusively breast-fed or formula-fed) 6-11 months: "infants" (consume foods in addition to breastmilk or formula) 1-3 years: "toddlers" or "young children" 4-8 years: "young children" or "children"(<9 years of age typically have both sexes together) 9-13 years: "children" (M/F) 14-18 years: "teenagers" (M/F)	Chemical Health Hazard Assessment Division (CHHAD), Bureau of Chemical Safety, Food Directorate, Health Canada	CA
Children are considered to be under 18 years of age. Body weight differentiation: 0-5 months: 6.3 kg 6-11 months: 9.1 kg 1 year: 11 kg 2-3 years: 15 kg 4-8 years: 23 kg 9-13 years: 42 kg 14-18 years: 62 kg 19+ years: 74 kg	New and Existing Substances Risk Assessment Bureau Reference for body weights: (Health Canada, 2022[4]).	
No legal definition per se in narrative form, however, age groups with specific exposure default values are defined in line with existing	Nanotechnology Section, New Substances Assessment and Control Bureau (NSACB), Health Canada	

Definition	Programme/Legislation	Country
substance assessments conducted under the Canadian Chemicals Management Plan (CMP). See row above		
Children are one of the vulnerable populations included by Health Canada's PMRA in risk assessments. NB Fetuses and nursing infants are also vulnerable populations. Infants (<1 year), children (1<2, 3<6, 6<11 years) and youth (11-<16 years) are considered in exposure and risk assessments of pesticides depending on the scenario, as well as sex and gender. For dietary exposure scenarios, all age groups are included in the assessment (infants (<1 year), children (1-6 and 7-12 years), females and males aged 13-19 and 20+ years, and seniors (55+ years), as indicated in the references). For non-dietary and aggregate exposure scenarios (dermal, inhalation, incidental oral), index life stages are used to represent exposure for children of all ages. PMRA follows the US EPA approach (US EPA, 2012[5]).	Pest Management Regulatory Agency (PMRA), Health Canada Reference for vulnerable populations: (Health Canada, 2019[6]; Health Canada, 2019[7]) Reference on sex- and gender-based considerations: (Health Canada, 2020[8]). Reference on age-specific groupings for dietary exposure: (Health Canada, 2002[9]). Reference on groupings for non-dietary exposure: (US EPA, 2012[5]). Reference on summary of these groupings: (Health Canada, 2014[10]) (appendix I).	
<0 days: "preterm newborn infants" 0-27 days: "term newborn infants" 28 days-23 months: "infants and toddlers" 2-11 years: "children" 12-16/18 years (dependent on region): " adolescents"	National Poison Center Control (CCSS) Reference: (EMEA, 2001[11]).	CR
Children under 14 years (definition from Toy Safety Directive). Exposure values from mainly used from Norden. Different age groups used: newborn babies, 1-3 years old children, children >3 years, teenagers (when relevant)	The national chemical action plan 2018-21. Reference Toy safety Directive: (EC, 2009[12]). Reference: Norden	DK
Dietary exposure assessment of PPPs: German exposure models for pesticide residues differentiate between the general population (14-80 years) and young children (2-4 years).Further consumption data are available for infants/toddlers (0.5-<2 years) and adolescents (8-12 years). EFSA's EU PRIMO model includes multiple children subpopulations from various countries. Dietary exposure to biocides: for non-professional uses of biocides, typically, a 10 kg toddler is considered. Non-dietary exposure assessment of PPPs: worst case scenario for children up to 11 years: <3 years child of 10 kg with typical exposure values (breathing rate). Non-dietary exposure to biocides: age groups with typical default values (body weight, body part surface areas, inhalation rate, etc.): <1 year (infants):8 kg 1-<2 years (toddlers): 10 kg 2-<6 years (children): 15.6 kg 6-<12 years (children): 23.9 kg	Assessment of pesticides (biocides and plant protection products) within the legal framework Reference for Dietary exposure assessment of PPPs: (BfR, 2011[13]; EFSA, 2018[14]). Reference for dietary exposure to biocides: (ECHA, 2017[15]; ECHA, 2017[16]) Reference for non-dietary exposure assessment of PPPs: (EFSA, 2014[17]). Reference for non-dietary exposure of biocides: (ECHA, 2017[16]).	DE
Children under 14 years (definition from Toy Safety Directive).	Reference Toy safety Directive: EC, 2009.	
Children aged between 6-11 years	SPECIMEn study carried out in the framework of the HBM4EU project	HU
For biocidal uses: 2-3 years (toddler): 9 kg 3-4 years (older child): 14 kg	Reassessments programme	NZ
In Korea's Environmental Health Act, children are defined as below 13 years old. However, generally, children are defined differently according to relative law in Korea.	Comprehensive measures for the protection of children's health (by Environmental Health Act). Soil Environment Conservation Countermeasures (by Soil Environment Conservation Act)	KR
Biocides human health exposure methodology guidance document contains definitions of different age groups: 6-<12 months: infants 1-<2 years: toddlers 6-<11 years: children	(ECHA, 2015[18])	SE
In biocides HEADhoc recommendation no 14	Product authorization of biocides and plant protection products	

Definition	Programme/Legislation	Country
	Biocides/PPP: HEAdhoc recommendation 14 (ECHA, 2017[16])	
We have no specific definition of children. However, we choose age categories most appropriate for the product category we assess. On a case by case basis, we differentiate between age groups.	The Swedish Chemicals Agency is conducting risk assessments specific for children as part of government assignments and within various enforcement projects targeting consumer products.	
In biocides HEADhoc recommendation no 14	Biocidal Product Regulation (BPR) Reference: HEAdhoc recommendation 14 (ECHA, 2017[16])	CH
Adolescent trainees normally aged 16 years, with the exception of 15 years.	Assessment of occupational exposure.	
Non-dietary exposure: age groups with typical default values (body weight, body part surface areas, inhalation rate, etc.): <1 year (infants):8 kg 1-<2 years (toddlers): 10 kg 2-<6 years (children): 15.6 kg 6-<12 years (children): 23.9 kg Dietary exposure: Where relevant, dietary exposure of children is only estimated for toddlers (10 kg) as they represent the worst case age group and are considered to cover all other age groups. Infants have the highest food intake on a body weight basis, but as they consume mainly breast milk and formula milk, most dietary exposure scenarios do not apply to them. For drinking water, there is not yet harmonized approach for biocides with regard to intake volumes for specific age groups. In a recent evaluation, the WHO values were used.	Evaluation of biocidal active substances and products under the BPR (Regulation (EU) No. 528/2012).	NL
Residential exposure: a child with a body weight of 10 kg, which is representative of children around 1 year old. Drinking water exposure: A 10 kg toddler drinking 1 L of water a day and a 5 kg bottle-fed infant drinking 0.75 L of water a day. These age groups are considered to represent a worst-case scenario for all children. Dietary exposure: For the dietary exposure, it depends on the country if the consumption data differentiates between different age groups. For the Netherlands, the diets used in the consumer exposure assessment are divided into the general population (age 1-97, weight 65.8 kg), children (age 2-6 years, weight 18.4 kg) and toddlers (age 8-20 months, weight 10.2 kg).	Evaluation of plant protection products and active substances under Regulation (EC) No. 1107/2009 Reference for residential exposure assessment of PPPs: (EFSA, 2014[17]). Reference on dietary exposure: (EFSA et al., 2018[19]).	
<12 months: infants 12-<36 months: toddlers 36 months -<10 years: children 10-<18 years: adolescents	MCRA 9.1. MCRA uses food surveys which provide age and BW per respondent.	
depends on the question and the type of product (e.g. age groups for squishy toys can be quite different from age groups for clays)	SCHEER	
In biocides HEADhoc recommendation no 14	REACH and Biocides Reference biocides: HEAdhoc recommendation 14 (ECHA, 2017[16]) Reference: The ConsExpo Fact Sheet: General Fact Sheet contains anthropometric data on several age groups, including the range of children age groups.	
Non-dietary exposure to biocides: age groups with typical default values (body weight, body part surface areas, inhalation rate, etc.): <1 year (infants):8 kg 1-<2 years (toddlers): 10 kg 2-<6 years (children): 15.6 kg 6-<12 years (children): 23.9 kg Non-dietary exposure assessment of PPPs: worst case scenario for children up to 11 years: <3 years child of 10 kg with typical exposure values (breathing rate).	Plant protection products and their active substances Biocidal products and their active substances Reference for non-dietary exposure assessment of PPPs: (EFSA, 2014[17]). Reference for non-dietary exposure of biocides (ECHA, 2017[16])	GB
As appropriate, the risk assessments differentiate between age groups and other factors, as defined in the U.S. EPA's Child-Specific Exposure Factors Handbook	New Chemicals Program, Existing Chemicals Program Reference: child specific exposure handbook, US EPA 2009.	US
Residential exposure assessment:	Office of Pesticide Program, Health Effects Division	

Definition	Programme/Legislation	Country
different life stages for children with different behavioural characteristics and body weights. Dietary exposure assessment: infants (<1 year old) children 1-2 years children 3-5 years children 6-12 years	Reference residential exposure assessment: Standard Operating Procedures for Residential Pesticide Exposure Assessment, (US EPA, 2012[5]).	

1.1.3. Hazard assessment

Respondents were asked (question 5) if they perform specific hazard assessments for children, and, if so, whether these include additional, children-specific endpoints (i.e. particularly sensitive for children) and to specify these. Eighteen of the respondents indicated they perform specific hazard assessments for children, with seventeen of them indicating additional children-specific endpoints (see the answers to question 5 in Annex B for details). The endpoints reported include specific repeated dose toxicity, developmental toxicity, developmental neurotoxicity, toxicities to respiratory system and skin sensory organ system, and allergies. It was noted that toxic effects and relevance for children is assessed case-by-case. Further, it was mentioned that in some cases an additional safety factor is included.

In addition, they were asked if their children-specific hazard assessment for regular endpoints includes children specific-dose levels (i.e. from toxicological studies). Eight respondents indicated this was the case (if available). To the question of whether the results from epidemiological studies are taken into account in children specific hazard assessments, thirteen respondents answered positively.

Respondents were also asked (question 6) if they had any guidance or tools on methodology for hazard assessment for children that could be shared. Six respondents indicated they did and provided the titles of existing guidance or methodologies (see Table 3). The complete answers to question 6 can be found in Annex B. Note that some of the guidance is not specific to children.

Table 3. Existing guidance/tools for hazard assessments for children reported by the respondents of the survey.

Title of guidance/tools	Produced by / Reference	Other information
Button/coin battery safety - a guide for business on the application of mandatory standards	(ACCC, 2021[20])	For button and coin batteries
Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products	(EFSA, 2014[17])	
Science Policy Note: The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides	(Health Canada, 2008[21])	
Science Policy Note: Children's Health Priorities within the Pest Management Regulatory Agency.	(Health Canada, 2002[9])	
Framework for Human Health Risk Assessment to Inform Decision Making	(US EPA, 2014[22])	
Exposure Factors Handbook	(US EPA, 2011[23])	
A Framework for Assessing Health Risk of Environmental Exposures to Children	(US EPA, 2006[24])	
Guide to Considering Children's Health When Developing EPA Actions: Implementing Executive Order 13045 and EPA's Policy on Evaluating Health Risks to Children	(US EPA, 2006[25])	
Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants	(US EPA, 2005[26])	
Guidelines for Reproductive Toxicity Risk Assessment	(US EPA, 1996[27])	
Policy on Evaluating Health Risks to Children	(US EPA, 2013[28]; US EPA, 1995[29])	
Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens	(US EPA, 2005[30])	

1.1.4. Exposure assessment

Respondents were asked (question 7) if they perform specific exposure assessments for children and, if so, whether they use specific physiological characteristics of children and/or specific scenarios or behavioural characteristics as parameters in the exposure assessment. Respondents were also asked to provide further details on these specific scenarios or behavioural characteristics.

Thirty-one respondents reported that they perform specific exposure assessments for children, and, of these, thirty reported that they use specific physiological characteristics for children and twenty-eight reported that they use specific scenarios or behavioral characteristics for children. Specified physiological characteristics which were mentioned frequently included body weight, body part surface area and inhalation rate, but also the use of specific values for height and dermal absorption were indicated. Specific scenarios or behavioural characteristics for children which were mentioned frequently included mouthing behaviour, object-to-mouth behaviour, hand-to-mouth behaviour, crawling, ingestion of soil, playing on relevant surfaces, ingestion of dust, and inhalation of volatilized substances. In addition, also laying on the lawn, food consumption, ingestion of craft materials, contact with soil, groundwater and plants, increased oral intake, and altered frequency or duration of contact with certain substances or products were mentioned.

In addition, respondents were asked (question 8) whether they use specific guidance, tools or default values to perform exposure assessments and, if so, to specify these. Twenty-eight respondents reported using specific guidance, tools or default values to perform exposure assessments. Thirty respondents listed guidance documents or methodologies for assessing exposure to children (Table 4). See the references in Table 4 and the answers to questions 7 and 8 in Annex B for details. Note that Table 4 is an overview of the information on guidance and tools provided by the respondents; it might not be a complete overview. Note that some of the guidance is not specific to children.

Table 4. Existing guidance/tools for exposure assessments specified by the respondents of the survey.

Title of guidance/tools	Produced by / Reference	Other information
Assessment of the European Committee for Standardisation (CEN) report on methods development	(CSTEE, 2004[31])	Toys
Assessment of the European Committee for Standardisation (CEN) report on the risk assessment of organic chemicals in toys	(CSTEE, 2003[32])	Toys
ECETOC's Targeted Risk Assessment Tool	(ECETOC, n.d.[33])	
Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017). (See also other HEadhoc recommendations[2])	(ECHA, 2017[16])	
Guidance on the Biocidal Products Regulation. Volume III Human Health - Assessment & Evaluation (Parts B+C)	(ECHA, 2017[15])	
Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.15: Consumer exposure assessment	(ECHA, 2016[34])	
Biocides Human Health Exposure Methodology	(ECHA, 2015[18])	
HEEG opinions	(ECHA, n.d.[35])	
Use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3)	(EFSA et al., 2018[19])	
Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products	(EFSA, 2014[17])	
Canadian Exposure Factors Used in Human Health Risk Assessments	(Health Canada, 2022[4])	

2 https://echa.europa.eu/nl/view-article/-/journal_content/title/recommendations-of-the-ad-hoc-working-group-on-human-exposure

Title of guidance/tools	Produced by / Reference	Other information
Science Policy Note (SPN2014-01): General Exposure Factor Inputs for Dietary, Occupational, and Residential Exposure Assessments	(Health Canada, 2014[10])	
Validation of methodologies for the release of di-isononylphthalate (DINP) in saliva simulant from toys	JRC (Simoneau et al., 2001[36])	
Korean Exposure Factors Handbook for Children	(NIER, 2019[37])	
Estimating mouthing exposure in children – compilation of case studies	(OECD, 2019[38])	
Considerations when assessing children's exposure to chemicals from products	(OECD, 2019[3])	
ConsExpo General Fact Sheet	RIVM (Te Biesebeek et al., 2014[39])	
Exposure to chemicals via house dust	RIVM (Oomen et al., 2008[40])	Dust/soil ingestion defaults
Guidance for assessment of chemical risks for Children	RIVM (Wolterink, van Engelen and van Raaij, 2007[41])	
Children's Toys Fact Sheet (See also other ConsExpo Facstheets[3])	RIVM (Bremmer and van Veen, 2002[42])	
Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements	RIVM (van Engelen et al., 2008[43])	toy materials ingestion
ConsExpo Web	(RIVM, 2011[44])	
SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 10th revision, 24-25 October 2018, SCCS/1602/18	SCCS, 2018[4]	
Toxicological reference values for certain organic chemicals emitted from squishy toys with regard to adopting limit values under the Toy Safety Directive 2009/48/EC 'Chemicals in squishy toys'.	(SCHEER, 2021[45])	
Final Opinion on Estimates of the amount of toy materials ingested by children	(SCHER, 2016[46])	Ingestion of toys/craft materials
Risk from organic CMR substances in toys.	(SCHER, 2010[47])	
CEN's response to the opinion of the CSTEE on the assessment of CEN report on the risk assessment of organic chemicals in toys	(SCHER, 2007[48])	
Exposure Assessment Tools by Media - Soil and Dust	(US EPA, 2021[49])	
Guidelines for Human Exposure Assessment	(US EPA, 2019[50])	
Indoor Exposure Product Testing Protocols. Version 2.0.	(ECHA, 2017[15])	
Update for Chapter 5 of the Exposure Factors Handbook. Soil and Dust Ingestion.	(US EPA, 2017[51])	
Child-Specific Exposure Scenarios Examples (Final Report)	(US EPA, 2014[52])	
Standard Operating Procedures for Residential Pesticide Exposure Assessment	(US EPA, 2012[5])	
Child-Specific Exposure Factors Handbook (2008, Final Report)	(US EPA, 2008[53])	
A Framework for Assessing Health Risks of Environmental Exposures to Children	(US EPA, 2006[24])	
Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants	(US EPA, 2005[26])	
EPA ExpoBox (A Toolbox for Exposure Assessors)	(US EPA, 2021[54])	
E-FAST-Exposure and Fate Assessment Screening Tool Version 2014	(US EPA, 2014[55])	
DEEM-FCID/Calendex Software Installer	(US EPA, 2012[56])	
What We Eat in America - Food Commodity Intake Database, 2005-2010 (WWEIA-FCID 2005-10)	(US EPA, n.d.[57])	
Principles for evaluating health risks in children associated with exposure to chemicals	(WHO, 2006[58])	
Principles and methods for the risk assessment of chemicals in food	(WHO, 2008[59])[5]	

Note: The Australian Therapeutic Goods Administration suggested a governmental website with links to international scientific guidance documents (https://www.tga.gov.au/ws-sg-index).

3 https://www.rivm.nl/en/consexpo/fact-sheets

4 11th revision is now available (SCCS, 2021[70])

5 Chapter 6 "Dietary Exposure Assessment of Chemicals in Food" is presently undergoing revisions to which our group has provided input (https://www.who.int/docs/default-source/food-safety/publications/chapter6-dietary-exposure.pdf?sfvrsn=26d37b15_6)

Note: BfR mentioned that for Mouthing of toys and ingestion of toy material additional information is given in our questionnaire sheet filled in for "Toys in the scope of the European Toy Safety Directive 2009/48/EG"

1.1.5. Risk characterisation

Respondents were asked (question 9) if they perform specific risk characterisation for children and, if so, if they had guidance or tools on methodology for risk characterisation for children. Twenty-three respondents reported that they perform specific risk characterisations for children, and twelve indicated that they have guidance documents or tools on methodology for risk characterisation for children. Seventeen respondents listed guidance documents or methodologies for assessing exposure to children. For details, see the references in Table 5 and the answers to question 9 in Annex B. Note that Table 5 does not provide an exhaustive overview of all such guidance and tools available. Note that some of the guidance is not specific to children.

Table 5. Existing guidance/tools for risk characterisation specified by the respondents of the survey.

Title of guidance/tools	Produced by / Reference	Other information
Chemical safety assessment of toys. Guidance and inspiration for manufacturers, importers and distributors	(Danish EPA, 2019[60])	Toys
Guidance on the Biocidal Products Regulation. Volume III Human Health - Assessment & Evaluation (Parts B+C)	(ECHA, 2017[15])	
Guidance on Information Requirements and Chemical Safety Assessment. Part E: Risk Characterisation	(ECHA, 2016[61])	
Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products	(EFSA, 2014[17])	
PMRA Guidance Document, A Framework for Risk Assessment and Risk Management of Pest Control Products	(Health Canada, 2021[62])	
Science Policy Note: The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides	(Health Canada, 2008[21])	
Assessing exposure of Canadians and the environment to substances in products	(Health Canada, 2022[63])	
Chemicals and Children's Health	(Health Canada, n.d.[64])	
Consideration of endocrine-related effects in risk assessment	(Health Canada, 2022[65])	
Uses of human biomonitoring data in risk assessment	(Health Canada, 2022[66])	
Button/coin battery safety - a guide for business on the application of mandatory standards	(ACCC, 2021[20])	For button and coin batteries
Opinion on Chromium VI in toys	(SCHER, 2015[67])	
Standard Operating Procedures for Residential Pesticide Exposure Assessment	(US EPA, 2012[5])	
Risk Characterization Handbook	(US EPA, 2001[68])	
General Principles for Performing Aggregate Exposure and Risk Assessments for Pesticides	(US EPA, 2001[69])	

1.2. Needs for additional parameters during exposure assessment for children

1.2.1. Parameters in exposure assessment methodology

Respondents were asked whether there were exposure parameters which should be included in the methodology for exposure assessment for children that are not currently used (question 10). Nineteen (54%) of the 35 responses to this question indicated that this was the case. These responses could be differentiated in needs for chemical or product specific parameters, physiological parameters, and/or scenario-related or behavioural parameters in exposure assessment methodology. These different areas were mentioned, 13 (68%), 10 (53%) and 12 (63%) times, respectively, indicating the highest need for

chemical or product specific parameters. The circumstance that a majority of the 35 respondents did not indicate a need for specific parameters might indicate that these are already used in present exposure assessment methodologies.

The need for specific parameters in exposure assessment methodology could be stated by pre-defined options and/or by other options which the respondents themselves could specify. The results by number can be seen in Table 6.

Table 6. Indicated need for specific parameters in exposure assessment methodology.

Chemical or product specific parameters			Physiological parameters			Scenario-related or behavioural parameters		
Parameter in methodology	Times indicated		Parameter in methodology	Times indicated		Parameter in methodology	Times indicated	
	(n)	(%)		(n)	(%)		(n)	(%)
Migration from products	5	38	Dermal absorption	6	60	Mouthing behaviour	5	42
Presence/amount of chemicals in specific places/products	4	31	Skin/body surface area(s)	4	40	Different use scenarios (e.g. use of higher frequency or amount of cosmetics)	5	42
Vapour pressure of chemicals	2	15	Body weight	4	40	Time spent in specific places (e.g. indoors/outside, or on the grass/floor)	4	33
Particle characteristics (e.g. of nanomaterials)	2	15	Higher need/dietary intake of water/calories	3	30	Contact scenarios regarding specific activities (e.g. during playing)	4	33
Emission from products	2	15	Breathing rate	1	10	Crawling behaviour	4	33
						Contact/use scenarios with specific products (e.g. furniture, floor, toys)	2	17
						Time spent as bystander during or after use of specific products (e.g. use of DIY products)	2	17
Other	7	54	Other	5	50	Other	4	33

Of the 13 responses indicating a need for chemical or product specific parameters in exposure assessment methodology, migration from products and presence/amount of chemicals in specific places/products were indicated most often (Table 6). However, 7 of these 13 responses indicated also a need for other chemical or product specific parameters. Among the other specifications for this option, the following parameters were given: half-life in water/air/soil, differentiation between dispersed and embedded, product matrix composition, and relative weight compared to air (mentioned twice).

Of the 10 responses indicating a need for physiological parameters in exposure assessment methodology, dermal absorption, skin/body surface area(s) and body weight were indicated most often from the predefined options (Table 6). Five of these 10 respondents also indicated a need for other physiological parameters. Among the other specifications by the respondents, the toxicokinetic differences between adults and children were three times indicated (more than the predefined option 'breathing rate'). Also, specialized dietary restrictions or food allergies and intolerances were mentioned.

Of the 12 responses indicating a need for scenario-related or behavioural parameters in exposure assessment methodology, mouthing behaviour and different use scenarios, but also time spent in specific places, contact scenarios regarding specific activities, and crawling behaviour were indicated most often (Table 6). Four respondents also indicated a need for other scenario-related or behavioural parameters. Among the other specifications, both cleaning behaviour and avoidance were mentioned twice. This included the limited information about whether children will clean themselves or actively avoid bad smells or tastes were mentioned. Also, the limited information on the use pattern for certain products used by children (e.g. hand sanitiser, hair products, make-up, glues, toys), such as product amount used, frequency and duration, was specifically mentioned, as was incidental ingestion of, for instance, swimming water (higher on a relative basis for children than adults). In addition, house dust was mentioned.

1.2.2. Data for parameters in exposure assessment

Respondents were asked whether regarding the data/measurements used as input for their methodology for exposure assessment for children, needed better or more data to support the parameters (question 11). Twenty-seven (75%) of the 36 responses indicated that this was the case. The positive responses could differentiate whether there is a need for chemical or product specific data, physiological data, and/or scenario-related or behavioural data. These different areas were stated, respectively, 24 (89%), 17 (63%) and 20 (74%) times, indicating the highest need for data for chemical or product specific parameters.

Of the 24 responses indicating a need for chemical or product specific parameters in exposure assessment methodology, migration from products, emission from products and presence/amount of chemicals in specific places/products were indicated most often (Table 7). Seven of these 24 responses also indicated a need for other data for chemical or product specific parameters. Among the other specifications, the following parameters were mentioned, and are related or even similar to the predefined options: chemical specific data including levels in products, nanospecific data, leaching, product design (spray, powder, fluid), and also product use data including amounts and frequency of use (which can also be considered scenario-related or behavioural parameters). It was indicated that the predefined parameters were identified primarily for consumer products related exposure assessments, whereas data for the exposure assessment of pesticides are usually well characterized.

Of the 17 responses indicating a need for data for physiological parameters in exposure assessment methodology, dermal absorption, skin/body surface area(s) and body weight were indicated most often from the predefined options (Table 7). Four of these respondents also indicated a need for data for other physiological parameters. These included the volume of urine and/or grams of creatinine excreted in urine per day, bronchoalveolar lavage (BAL) test data, and with regard to food consumption: distribution, food frequency information, including brand loyalty.

Of the 20 responses indicating a need for data for scenario-related or behavioural parameters in exposure assessment methodology, contact scenarios regarding specific activities and contact/use scenarios with specific products were indicated most often (Table 7). Six of the respondents also indicated a need for other scenario-related or behavioural parameters. The other specifications by the respondents included time spent outdoors, exposure to dermal and inhalation antigens (for allergies) and/or exposure to solar UV radiation, time spent conducting specific activities, the duration of these activities, and the frequency of contact with areas treated with pesticide products. Also, bystanders and dust and drift scenarios were mentioned.

Table 7. Indicated need for specific data for parameters in exposure assessment.

Chemical or product specific parameters			Physiological parameters			Scenario-related or behavioural parameters		
Data for parameter	Times indicated		Data for parameter	Times indicated		Data for parameter	Times indicated	
	(n)	(%)		(n)	(%)		(n)	(%)
Migration from products	20	83	Dermal absorption	13	76	Contact scenarios regarding specific activities (e.g. during playing)	18	90
Emission from products	18	75	Skin surface area(s)	7	41	Contact/use scenarios with specific products (e.g. furniture, floor, toys)	17	85
Presence/amount of chemicals in specific places/products	16	67	Body weight	7	41	Different use scenarios (e.g. higher use of cosmetics)	13	65
Identity of chemicals	13	54	Breathing rate	5	29	Time spent in specific places (e.g. indoors/outside)	12	60
Particle characteristics (e.g. of nanomaterials)	12	50				Time spent as bystander during or after use of specific products (e.g. use of DIY products)	11	55
Product size	8	33				Mouthing behaviour	8	40
Vapor pressure of chemicals	6	25				Crawling behaviour	5	25

log Kow values of chemicals	5	21						
Molecular weight of chemicals	4	17						
Other	7	29	Other	4	24	Other	6	30

1.3. Needs for further guidance documents on specific issues of importance to the exposure and risk assessment for children

The last part of the survey was aimed to identify needs for further guidance documents on specific issues of importance related to the exposure and risk assessment for children. Seven pre-defined topics could be ranked by the respondents (question 12). The topics were based on earlier recommendations and member interests discussed at the Children's Health subgroup webinar in February 2020 and on input on the draft version of the current survey. The ranking was used to give the topics a score (see Table 8). The ranking of the pre-defined topics indicates that guidance with regard to time spent on specific places is ranked highest followed by performing a use survey for children and personal care products. The lowest score was given to guidance with regard to house dust and the review of children specific elements in existing Emission Scenario Documents (ESDs).

Table 8. Ranked list with scores of specific issues of importance to the exposure and risk assessment for children, based on a ranking of importance by the respondents (highest score means most important).

	Topic/issue	Score
1	*Time spent on specific places (e.g. indoors/outside)*	96
2	*Use survey for children and personal care products (amount, frequency; to be used for setting defaults)*	85
3	*Use survey for children and toys (type, frequency; to be used for setting defaults)*	83
4	*Mouthing behaviour (defaults with regard to amounts of hand-to-mouth contact and mouthing times)*	82
5	*Bystander or post-application exposure from use of DIY products*	71
6	*House dust (definitions; defaults with regard to ingestion)*	64
7	*Review of children specific elements in existing Emission Scenario Documents (ESDs)*	58

In addition, respondents could provide additional topics. An overview of the additional topics brought forward by the respondents is given in Table 9. For example, several respondents showed interest in developing guidance on migration from products.

Table 9. Additional topics of importance to the exposure and risk assessment for children provided by the responding countries.

Topic	
Survey on the feeding of adult foods to infants and young children. Many regulations and maximum levels have specific provisions for "foods for infants and young children" but this would presumably exclude foods that are not distinctly marketed as such. For instance, feeding of regular adult breakfast cereals (e.g. cheerios, corn flakes) to young children, parents making their own baby foods from raw ingredients.	CA
Survey on the impact of dietary choices and food fads of parents/families on the diets of their children. Increasing popularity of seaweed snacks, probiotic foods, water drops, alternative milks, vegan and low carb diets, intermittent fasting, etc., suggesting emerging issues for contaminant risk assessment.	
Survey on weight loss and dieting among children, and/or changes in perception of body image, especially as these would impact quantity of food consumed relative to body weight.	
Survey on brand loyalty by food commodity, i.e. which foods are more likely to be consumed consistently from one brand, and for what percentage of children.	
Guidance and supporting data on how to estimate oral exposures to residual substances on silicone dishware (e.g. utensils, bowls, plates, cups) as these are popular items for infants and toddlers. Additionally, information on the types of substances may remain on silicone materials, even after rinsing.	

Guidance on child-specific considerations or adjustments with respect to dermal absorption potential. For instance, differences in children's skin pH rendering chemicals to be more or less dermally absorbed.	
Post-application models and inputs for biocides/antimicrobials that include aspects specific to these types of products (e.g., availability of the chemical from the product (e.g., impregnated toys) or from dried surfaces (e.g., paint, floor cleaner)). The US-EPA has a draft SOP for these types of products, however, the approaches are still in development. Ideally, the inputs for the model would be based on data, rather than assumptions, so that the assessment is protective and reflective of real-world exposure, similar to how the inputs for the US-EPA Residential SOP (US EPA, 2012[5]) for pesticides were determined.	
Guidance on dermal absorption.	CH
Guidance on transfer factors from products (e.g. from surface to skin when handling toys).	
Activity patterns of children at home, daycare, schools, after-school recreation, during sports, including contact durations with surfaces and efficiency of the specific contacts.	NL
Guidance on migration from products.	

Finally, the survey provided a chance for the respondents to provide any other comments relevant to the future development of additional guidance or tools at OECD. An overview of the additional comments by the respondents is given below in Table 10.

Table 10. Other comments relevant to the future development of additional guidance or tools at OECD provided by the respondents.

Comment	
As part of the WHO/FAO's Codex Alimentarius programme, various Codex committees include updates from a variety of international organizations as part of their agenda. The OECD may wish to consider providing input to relevant Codex committees (e.g. the Codex Committee on Food Additives, and the Codex Committee on Contaminants in Food) to promote and raise awareness of their publications, guidance and tools among the food safety authorities of Codex member countries.	CA
When considering children's use of personal care products, including cosmetics.	
Guidance on mouthing specific products, such as teething toys and jewellery that are made to be mouthed by children.	
For nanomaterials as a whole (all ages), there is a need to consider exposures at different stages of the lifecycle, including later lifecycle (e.g. sanding of nano coatings/composites, incineration, etc.), and better data to support exposure analysis at these stages. Also, the degree of degradation or transformation of the particle and the form that is actually exposed.	
Please be aware that EU members are expected to follow SCCS Notes of Guidance for cosmetic products (SCCS, 2021[70]), even though this guidance argues that specific exposure calculations for children are, in most cases, not necessary (DK-EPA does not agree with the guideline in this regard).	DK
More details on potential regional variation in the activity parameters, e.g. as related to differences in climate and nature of the built environment.	NZ
The Health Effects Division has identified areas where future research could address data gaps and uncertainty with respect to the various scenarios that are assessed during and following non-occupational pesticidal use. These additional data sources may help further inform either the assumptions used to model behaviour, presence of residue on surfaces or in the air, and/or frequency of exposure. Some common themes are presented here, however, more details relevant to each of the exposure scenarios may be found in the US-EPA Residential SOP (US EPA, 2012[5]). Use survey for pesticide product type-specific application intervals (i.e., how frequently are different pesticide types applied in a residential setting); Studies designed to characterize the air concentrations and deposition of aerosolized pesticides following during and following applications (indoor and outdoor); Studies designed with the intention to distinguish between aerosols, vapours, and dust resuspension (house dust collection); Information to inform take home exposures; Information to inform behavioural patterns in previously treated areas.	US

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Annex A. Survey on exposure parameters for children's health

Introduction

This survey is aimed at gathering information from your chemical review program on the methodology you currently use to determine the level of children's exposure to a chemical and any risks associated with that chemical. The survey is also aimed at gathering information on your programs' needs for any additional parameters that you think must to be included in your exposure assessment methodology for children. This pertains to parameters in exposure assessment methodology, as well as data that would be needed for these parameters. In addition, the survey aims to identify the needs for further guidance documents on specific issues of importance related to the exposure and risk assessment for children.

The survey can be seen as a follow-up of the OECD-wide survey assessing the risk of chemicals to children's health performed in 2011 (reported in 2013 in ENV/JM/MONO(2013)20). As a result of that survey a workshop on children's exposure to chemicals was held in 2013 in Utrecht, the Netherlands with the primary aim to make recommendations on when a child-specific exposure needs to be performed. The 2011 survey and 2013 workshop revealed a relatively high need for improved exposure assessment methodologies for children (ENV/JM/EA/M(2014)1). This has resulted in an OECD document on considerations when assessing children's exposure to chemicals from products (ENV/JM/MONO(2019)29) and an OECD document on estimating mouthing exposure in children providing key considerations and good practices for addressing potential risk from direct object mouthing (ENV/JM/MONO(2019)24).

By the outcome of the present survey we hope to further direct and progress the exposure assessment methodologies for children.

IDENTITY OF THE RESPONDENT

Name:	…
Organisation:	…
Country:	…
Email:	…

CURRENTLY USED METHODOLOGY TO ASSESS CHILDREN'S EXPOSURE AND RISKS TO CHEMICALS

Type of chemical review programme

1. Please provide the name of your chemical review programme

2. At which type of chemical and product is your research programme aimed? *[please check with an X; multiple answers possible]*	
	Industrial chemicals
	Chemical substances in consumer products
	Biocides, including household pesticides
	Plant Protection Products, including pesticides for agricultural use
	Nanomaterials
	Cosmetics
	Food additives, flood flavouring agents
	Food contact materials, food packaging
	Food contaminants
	Environmental contaminants
	Drugs, medicinal products
	Medical devices
	Other, please specify: …

3. In your programme, how do you assess the risks in children? *[please check with an X; multiple answers possible]*	
	in a generic way as part of the assessment of consumers and the general public
	in a specific risk assessment dedicated to the risks to children
	Other, please specify: …

Definition of children

4. In your programme, do you have a definition of children?	*[Yes/No]*
If yes, do you differentiate between different age groups?	*[Yes/No]*
If yes, please provide a brief description of the definition of children including age groups and bodyweights if appropriate (this can include a reference to a document containing the definition): …	

Hazard assessment

5. In your programme, do you perform specific hazard assessments for children?	*[Yes/no]*
If yes, does this hazard assessment include additional, children-specific endpoints (i.e. particularly sensitive for children) for which a hazard assessment is performed?	*[Yes/no]*
If yes, please specify for which additional hazard endpoints a specific assessment is performed: …	
If yes, does the hazard assessment for regular endpoints performed specifically for children includes children specific-dose levels (i.e. from toxicological studies)?	*[Yes/no]*
If yes, are the results from epidemiological studies taken into account?	*[Yes/no]*

6. Do you have guidance or tools on methodology for hazard assessment for children that can be shared (i.e. no need to list internal guidance or tools that cannot be shared)?	*[Yes/no]*
If yes, please provide the name of the guidance or tools, and brief description (this can include a reference to document containing the methodology): …	

Exposure assessment

7. In your programme, do you perform specific exposure assessments for children?	*[Yes/No]*
If yes, do you use specific physiological characteristics of children (e.g. child-specific body weights, skin/body areas, etc.) as parameters in the exposure assessment?	*[Yes/No]*

If yes, do you use specific scenarios or behavioral characteristics for children (e.g. ingestion of craft materials, mouthing behavior, crawling on floors) as parameters in the exposure assessment?	*[Yes/No]*
If yes, please provide further details on the specific scenarios or behavioral characteristics used …	

8. Do you use specific guidance, tools or default values to perform your exposure assessment?	*[Yes/No]*
If Yes, please specify: …	

Risk characterisation

9. In your programme, do you perform specific risk characterisation for children?	*[Yes/no]*
If yes, do you have guidance or tools on methodology for risk characterisation for children?	*[Yes/no]*
If yes, please provide the name of the guidance or tools, and brief description (this can include a reference to document containing the methodology): …	

NEEDS FOR ADDITIONAL PARAMETERS DURING EXPOSURE ASSESMENT FOR CHILDREN

PART A: PARAMETERS IN EXPOSURE ASSESSMENT METHODOLOGY

10. In the methodology currently used for exposure assessment for children, are there exposure parameters which are **not** currently used, which you think need to be included in the exposure assessment methodology?	*[Yes/No]*
If yes, do these include **chemical or product specific** parameters?	*[Yes/No]*
If yes, please specify *[please check with an X; multiple answers possible]*:	

	Vapor pressure of chemicals
	Particle characteristics (e.g. of nanomaterials)
	Emission from products
	Migration from products
	Presence / amount of chemicals in specific places / products

	Other, please specify: …	
If yes, do these include **physiological** parameters?		*[Yes/No]*
If yes, please specify *[please check with an X; multiple answers possible]*:		
	Breathing rate	
	Skin/body surface area(s)	
	Dermal absorption	
	Body weight	
	Higher need/dietary intake of water/calories	
	Other physiological parameters, please specify …	
If yes, do these include **scenario-related or behavioral** parameters?		*[Yes/No]*
If yes, please specify *[please check with an X; multiple answers possible]*:		
	Crawling behavior	
	Mouthing behavior	
	Time spent in specific places (e.g. indoors/outside, or on the grass/floor)	
	Contact scenarios regarding specific activities (e.g. during playing)	
	Contact/use scenarios with specific products (e.g. furniture, floor, toys)	
	Different use scenarios (e.g. use of higher frequency or amount of cosmetics)	
	Time spent as bystander during or after use of specific products (e.g. use of DIY products)	
	Other scenario-related or behavioral parameters, please specify: …	

PART B: DATA FOR PARAMETERS IN EXPOSURE ASSESMENT

11. Regarding the **data/measurements** used as input in your methodology to assess exposure for children, does your methodology need better/more data to support the parameters?	*[Yes/No]*
If yes, do these include **chemical or product specific** data?	*[Yes/No]*
If yes, please specify *[please check with an X; multiple answers possible]*:	

	Product size
	Identity of chemicals
	Particle characteristics (e.g. of nanomaterials)
	Vapor pressure of chemicals
	Molecular weight of chemicals
	log Kow values of chemicals
	Emission from products
	Migration from products
	Presence / amount of chemicals in specific places / products
	Other, please specify: …
If yes, do these include **physiological** data?	*[Yes/No]*
If yes, please specify *[please check with an X; multiple answers possible]*:	
	Breathing rate
	Skin surface area(s)
	Dermal absorption
	Body weight
	Other physiological parameters, please specify: …
If yes, do these include **scenario-related or behavioral** data?	*[Yes/No]*
If yes, please specify *[please check with an X; multiple answers possible]*:	
	Crawling behavior
	Mouthing behavior
	Time spent in specific places (e.g. indoors/outside)
	Contact scenarios regarding specific activities (e.g. during playing)
	Contact/use scenarios with specific products (e.g. furniture, floor, toys)
	Different use scenarios (e.g. higher use of cosmetics)
	Time spent as bystander during or after use of specific products (e.g. use of DIY

	products)
	Other scenario-related or behavioral, please specify: …

NEEDS FOR FURTHER GUIDANCE DOCUMENTS ON SPECIFIC ISSUES OF IMPORTANCE TO THE EXPOSURE AND RISK ASSESSMENT FOR CHILDREN

12. If OECD-WPEA would draft (separate) guidance documents on a specific issue of importance to the exposure and risk assessment for children, which would you rank to be the most important **(rank using a scale from 1 to 10, with 10 being the most important)**. If you have additional topics, please add.	
House dust (definitions; defaults with regard to ingestion)	
Mouthing behavior (defaults with regard to amounts of hand-to-mouth contact and mouthing times)	
Bystander or post-application exposure from use of DIY products	
Time spent on specific places (e.g. indoors/outside)	
Use survey for children and personal care products (amount, frequency; to be used for setting defaults)	
Use survey for children and toys (type, frequency; to be used for setting defaults)	
Review of children specific elements in existing Emission Scenario Documents (ESDs)	
Other: …	
Other: …	
Other: …	

13. Please provide any other comments relevant to the future development of additional guidance or tools at OECD: …

Annex B. Compilation of the complete responses to the survey

Currently used methodology to assess children's exposure and risks to chemicals

Type of chemical review programme

1. Please provide the name of your chemical review programme		
1.		
Australian Industrial Chemicals Introduction Scheme (AICIS)	AICIS	AU
-	APVMA	
Consumer goods containing button batteries.	TGA-MDPQD	
MRD of HPRG	TGA-MRD	
EFSA Plant Protection Product (PPP) active substance assessment	FPS	BE
• S-Risk (1) (contaminated soils health risk assessment program) • EFSA (2) (pesticides exposure: Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products)	ISSeP	
Bureau of Chemical Safety, Food Directorate, Health Canada	HC-CHHAD	CA
Existing Substances Risk Assessment Bureau (ESRAB)	HC-ESRAB	
Nanotechnology Section, New Substances Assessment and Control Bureau, Health Canada	HC-NSACB-Nano	
The New Substances Program, jointly administered by Environment and Climate Change Canada and Health Canada (https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances.html)	HC-NSACB	
Health Canada's Pest Management Regulatory Agency (PMRA), which is the national regulatory authority for pesticides (pre-market and re-evaluation)	HC-PMRA	
BPR	FOPH-Bioc	CH
Swiss law on chemicals (Bundesgesetz über den Schutz vor gefährlichen Stoffen und Zubereitungen, Chemikaliengesetz)	FOPH-Chem	
Assessment of occupational exposure.	SECO	
National Poison Center Control	CCSS	CR
Assessment of pesticides (biocides and plant protection products) within the legal framework; BfR is responsible amongst others for the human health risk assessment	BfR-Pest	DE
Chemical substances in articles and mixtures (consumer products) in the scope of the European Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH Regulation) including substances registered in nanoforms	BfR-REACH	
Toys in the scope of the European Toy Safety Directive 2009/48/EG	BfR-Toys	
The national chemical action plan 2018-21 (https://eng.mst.dk/chemicals/chemicals-in-products/consumers-consumer-products/)	DEPA	DK
SPECIMEn study, carried out in the framework of the HBM4EU project	NNK	HU
Initial Environmental Risk Assessment	ERA office	JP
• Comprehensive measures for the protection of children's health(by Environmental Health Act) • Soil Environment Conservation Countermeasures(by Soil Environment Conservation Act)	NIER	KR

Evaluation of biocidal active substances and products under the BPR (Regulation (EU) No. 528/2012)	RIVM-Bioc	NL
Evaluation of plant protection products and active substances under Regulation (EC) No. 1107/2009	RIVM-PPP	
REACH and Biocides	RIVM-REACH	
MCRA 9.1	RIVM-MCRA	
Scientific Committee for Health, Environmental and Emerging Risks	RIVM-SCHEER	
The programme has no specific name but contains different activities with respect consumer exposure to chemicals and nanomaterials.	RIVM-Cons	
Reassessments programme	EPA-NZ	NZ
Environmental, Health and Safety Research in the Risk Assessment of Nanomaterials	DOST-ITDI	PH
-	KEMI-Bioc	SE
Product authorization of biocides and plant protection products	KEMI-Pest	
The Swedish Chemicals Agency are conducting risk assessment specific for children as part of government assignments and within various enforcement projects targeting consumer products	KEMI-Cons	
• Plant protection products and their active substances • Biocidal products and their active substances	CRD-HSE	GB
New Chemicals Program, Existing Chemicals Program	USEPA-OPPT	US
Office of Pesticide Program, Health Effects Division	USEPA-OCSPP	

At which type of chemical and product is your research programme aimed? *[please check with an X; multiple answers possible]*	
2a.	Industrial chemicals
2b.	Chemical substances in consumer products
2c.	Biocides, including household pesticides
2d.	Plant Protection Products, including pesticides for agricultural use
2e.	Nanomaterials
2f.	Cosmetics
2g.	Food additives, flood flavouring agents
2h.	Food contact materials, food packaging
2i.	Food contaminants
2j.	Environmental contaminants
2k.	Drugs, medicinal products
2l.	Medical devices
2m.	Other, please specify: …

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
2a.	X						X	X		X	X			X	X				X
2b.	X		X	X				X		X	X		X		X		X	X	X
2c.		X									X	X		X	X	X			
2d.		X			X	X					X			X	X	X			
2e.	X			X			X		X	X	X		X	X			X		X
2f.	X							X		X					X			X	X
2g.							X	X		X					X				
2h.	X						X	X		X	X								

2i.							X	X			X				X				
2j.						X	X	X							X				X
2k.				X						X					X				
2l.			X	X						X									

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
2a.		X	X			X		X	X	X						X	
2b.	X		X			X		X	X	X				X		X	
2c.	X		X	X		X		X	X	X		X	X		X		X
2d.	X				X		X	X		X			X		X		X
2e.								X	X		X					X	
2f.						X			X	X							
2g.							X										
2h.														X			
2i.							X										
2j.		X	X					X								X	
2k.								X									
2l.								X									

2m.		
Veterinary medicines	APVMA	AU
Allergens	HC-CHHAD	CA
Natural Health Products, non-medicinal ingredients in drugs	HC-ESRAB	
polymers, natural health products and veterinary drugs. The New Substances program also assesses new living organisms (animate products of biotechnology that are micro-organisms and higher organisms like fish, mammals, etc.).	HC-NSACB	
EDCs	FOPH-Chem	CH
EDCs	SECO	
Radiation	RIVM-SCHEER	NL
Biotechnology	USEPA-OPPT	US

In your programme, how do you assess the risks in children? *[please check with an X; multiple answers possible]*	
3a.	in a generic way as part of the assessment of consumers and the general public
3b.	in a specific risk assessment dedicated to the risks to children
3c.	Other, please specify: …

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
3a.	X		X	X	X	X	X	X	X				X		X		X		
3b.	X	X	X	X		X	X			X	X	X	X		X	X	X	X	X

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
3a.		X	X			X	X	X	X	X	X			X	X		X
3b.	X		X				X	X		X		X	X	X	X		X

3c.		
As a vulnerable subpopulation considered individually within the context of a larger risk assessment.	HC-CHHAD	CA
In a generic way as part of the assessment of occupational exposure. No specific approach for adolescent trainees.	SECO	CH
At the Poison Control Center, we receive calls from the 9-1-1 emergency system, calls from home from mothers or other member of the family, calls from hospitals, to report poison with any xenobiotic (chemicals, plants, pesticides, cosmetics, household products). All the information we can take from the calls, is analyze in statistics and annual reports. With that information we can make the necessary interventions (talks to the community, interviews in national TV, in news papers and campaigns) to correct the increase in cases related to specific xenobiotics.	CCSS	CR
Human biomonitoring data will be applied for risk assessment.	NNK	HU
It depends on the product type (PT) under evaluation. When relevant for the product type and relating exposure scenario a specific risk assessment dedicated to the risks to children is conducted. This risk assessment takes into account child specific behaviors such as playing and crawling on floors, touching treated surfaces and hand-to-mouth transfer and object-to-mouth contact.	RIVM-Bioc	NL
It depends on the exposure scenario. • For the residential exposure of children living near fields treated with plant protection products the exposure is assessed by also taking into account specific behaviors such as hand-mouth contact e.g. while playing outside. For the exposure via drinking water it is assessed in a generic way but considering specific body weights and water intake levels. • For the exposure via the diet specific dietary information for children are used to estimate the exposure levels via the diet.	RIVM-PPP	
Children's hazards and exposures s are considered, if applicable, as part of the risk assessment for consumers and the general population.	USEPA-OPPT	US
The HED human health risk assessments are for the US population and children as a subset of said population. Our assessment methodology is protective of all lifestages. We select endpoints that we deem protective of children. We utilize lifestage specific data to inform the exposure assessments. For example, we consider food for the entire US population, but also the subgroups. From a residential perspective, we consider children as engaging in behavior different from adults. Therefore, we assess individual child lifestages as they pertain to the exposure scenarios assessed.	USEPA-OCSPP	

Definition of children

4a. In your programme, do you have a definition of children?	*[Yes/No]*
4b. If yes, do you differentiate between different age groups?	*[Yes/No]*
4c. If yes, please provide a brief description of the definition of children including age groups and bodyweights if appropriate (this can include a reference to a document containing the definition): …	

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
4a.	No	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes
4b.		Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes		Yes	Yes

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
4a.	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	Yes	No	Yes	Yes	Yes
4b.	Yes		No	Yes	Yes	Yes	Yes	Yes	No	Yes		Yes	Yes		Yes	Yes	Yes

4c.		
-	AICIS	AU
We consider children – 1 – 2 year – 11 kg 2 – 3 year old – 15 kg We also consider children up to 12 years in certain risk activities.	APVMA	
-	TGA-MDPQD	
We define children as younger than 18, and depending on the indication of the medicine and the clinical trials conducted, we separate ages/children as <2, 2-6, 6-12, and 12-18.	TGA-MRD	
Age is a discriminant. In all exposure assessments calculations, specific default values (weight, inhalation rate, body part surface area) are assigned to children, based on age. Adolescents (≥ 11-year-old) are generally grouped with adults.	FPS	BE
• (1) 2 age groups: 1 to <6 years and 6 to <15 years for risk assessment. 4 age groups: 1 to <3, 3 to <6; 6 to <10, 10 to <15 for exposure assessment with different exposure parameters (weight, breathing rate, exposure duration…) • (2) One group: 1-3 years	ISSeP	
The BCS does not have a formal definition of children, however, an infant is defined in section B.25.001 the Food and Drug Regulations as "a person who is under the age of one year." Typical age groups considered in current assessments conducted by the BCS are as follows, and are from the Canadian Community Health Survey. There is no specific definition of each group, but some of the wording often used to describe them are provided: • 0–5 mo 'infants' (exclusively breast-fed or formula-fed) • 6–11 mo 'infants' (consume foods in addition to breastmilk or formula) • 1–3 yr 'toddlers' or 'young children' • 4–8 yr 'young children' or 'children' (<9 years of age typically have both sexes together) • 9–13 yr (M/F) 'children' • 14–18 yr (M/F) 'teenagers'	HC-CHHAD	CA
Children are considered to be under 18 years of age. Age group / Body weight (kg) 0 to 5 months: 6.3 6 to 11 months: 9.1 1 yr: 11 2 to 3 yr: 15 4 to 8 yr: 23 9 to 13 yr: 42 14 to 18 yr: 62 For body weights, the reference is: Health Canada. 2015. Food Consumption Table derived from Statistics Canada, Canadian Community Health Survey, Cycle 2.2, Nutrition (2004) A fact sheet with more information on exposure factors is projected to be published on Canada.ca later this year.	HC-ESRAB	
We don't have a legal definition per se in narrative form, but we do define age groups with specific defaults for exposure in line with existing substances assessments conducted under the Canadian Chemicals Management Plan (CMP).	HC-NSACB-Nano	
Children are those 18 years and younger. NSACB is in the process of updating age groups and body weight values but the values currently in use are the following: • Infants (0-0.5 yrs): 7.5 kg • Toddlers (0.5-4 yrs): 15.5 kg • Children (5-11 yrs): 31.0 kg • Teens (12-19 yrs): 59.4 kg • Adults (20-59 yrs): 70.9 kg • Seniors (60+ yrs): 72.0 kg	HC-NSACB	
Children are one of the vulnerable populations included by Health Canada's PMRA in risk assessments. The links included below are for both the consultation and decision documents on the proposed definition of vulnerable populations by Health Canada:	HC-PMRA	

https://www.canada.ca/en/health-canada/services/chemical-substances/consulting-future-chemicals-management-canada/what-we-heard-defining-vulnerable-populations.html. Children, including infants (< 1 year) and youth (11<16 years), are included in the exposure and risk assessments for pesticides, depending on the potential sources and routes of exposure. Both sex and gender are considered in the risk assessments. This is discussed further in Sex- and Gender-based Considerations in the Scientific Risk Assessment of Pesticides in Canada (Health Canada, 2020[8]) For dietary exposure scenarios, all age groups are included in the assessment. The age-specific groupings for dietary exposure are outlined in Science Policy Note (SPN2002-01): Children's Health Priorities within the Pest Management Regulatory Agency (Health Canada, 2002[9]). For non-dietary exposure scenarios (dermal/inhalation/incidental oral (e.g., hand-to-mouth)), index lifestages (lifestages of highest concern due to unique behavioral characteristics) are included in the assessment to represent exposure for children of all ages. For the index lifestage approach, PMRA follows the US EPA Residential SOPs (2012[5]). Refer to the document link below for more information on the lifestages and body weights used in the assessment. https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide. A summary of the age groups and body weights used by PMRA for dietary and non-dietary assessments are outlined in Science Policy Note (SPN2014-01): General Exposure Factor Inputs for Dietary, Occupational, and Residential Exposure Assessments (Health Canada, 2014[10]). Fetuses and nursing infants are also vulnerable populations. They are considered in the hazard assessment and in risk characterization (PCPA factor). This is discussed further in the hazard assessment question below.		
HEAdhoc Recommendation 14	FOPH-Bioc	CH
Adolescent trainee normally aged of 16 years, with exceptions 15 years. 822.115 Verordnung 5 zum Arbeitsgesetz (Jugendarbeitsschutzverordnung, ArGV 5)	SECO	
• preterm newborn infants • term newborn infants (0 to 27 days) • infants and toddlers (28 days to 23 months) • children (2 to 11 years) • adolescents (12 to 16-18 years (dependent on region)) Reference: Note for guidance on clinical investigation of medicinal products in the paediatric population. (EMEA, 2001[11])	CCSS	CR
Dietary exposure assessment of plant protection products: Currently, German exposure models for pesticide residues differentiate between the general population (14-80 yrs.) and young children (2-4 years) (BfR, 2011[13]). Further consumption data are available for infants/toddlers (0.5-<2 yrs.) and adolescents (8-12 yrs.), but not routinely implemented in the risk assessment process. In addition, the EU model PRIMo provided by EFSA is used including multiple children sub-populations from various countries (https://www.efsa.europa.eu/de/applications/pesticides/tools). **Dietary exposure assessment of biocides:** For non-professional uses of biocides typically a 10 kg toddler is considered as described in Guidance on the BPR: Volume III Parts B+C, section 5 (ECHA, 2017[15]), and Headhoc Opinion 14 (ECHA, 2017[16]). **Non-dietary exposure assessment of plant protection products:** As worst-case exposure scenario for children up to 11 yrs, assessment is performed for a child of 10 kg (< 3 yrs). This body weight default as well as specific breathing rates are specified in the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA, 2014[17]). **Non-dietary exposure assessment of biocides:** In primary and secondary human exposure assessment, 4 different age groups of children are considered. The corresponding default values, such as body weight, body part surface areas as well as inhalation rate of infant (< 1 yr, 8 kg), toddler (1 to < 2 yrs, 10 kg), child (2 to < 6 yrs, 15.6 kg), and child (6 < 12 yrs, 23.9 kg) are defined in Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure (ECHA, 2017[16]).	BfR-Pest	DE
In the scope of the European Toy Safety Directive (TSD) are products designed or intended, whether or not exclusively, for use in play by children under 14 years of age. There are legal limits set for general toys; e.g. the limit values for the release of metal ions and organotin compounds (Annex II No 13 of the TSD) were established based on risk assessments concerning children with a body weight of 7.5 kg (corresponding to the 25th percentile of Dutch infants in the age of 6 – 9 months as reported by RIVM in their General Fact	BfR-Toys	

Sheet). Apart from that, there are specific limits values for chemicals used in toys intended to be used by children under 36 months or in other toys intended to be placed in the mouth (Annex 2 Appendix C). Our own product specific risk assessment takes into account the intended and foreseeable use. Regarding finger paints, for example, we would assume the youngest user to be 1 – 2 years old. In case of toxic effects following a dose-response with a threshold mechanism, older children may be assessed optionally as an additional option, whereas in case of assessments involving the estimation of an additional lifetime cancer risk, all children up to 14 years of age would be considered. Age group information including related body weight data is derived from the RIVM's General Fact Sheet (Te Biesebeek et al., 2014[39]), US EPA's Child Specific Exposure Factors Handbook (2008[53])or other suitable data (e.g. German surveys, WHO data). Where applicable, an established default body weight may be used (e.g. 7.5 kg for infants 6 – 9 months old, 10 kg for toddlers being 1.5 years old).		
We use the definition of children as children under 14 years of age as stated in the Toy Safety Directive https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009L0048-20210521 We mainly use the values found in the report: "Existing Default Values and Recommendations for Exposure Assessment. A Nordic Exposure Group Project 2011" (NCM, 2011[71]). (This report will be updated later this year). We often distinguish between newborn babies, 1-3 year old children, children above the age of 3 and sometimes a separate group representing teenagers are included as well when this is relevant.	DEPA	DK
Children aged between 6-11 years	NNK	HU
In Korea's Environmental Health Act, children are defined as below 13 years old. However, generally children are defined differently according to relative law in Korea.	NIER	KR
Non-dietary exposure The default factors for children to be used in the exposure/risk assessment for biocidal products are provided in Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure (ECHA, 2017[15]): • Infant: <1 year, 8 kg • Toddler: 1 to <2 years, 10 kg • Child: 2-6 years, 15.6 kg • Child (older): 6-12 years, 23.9 kg **Dietary exposure** Where relevant, dietary exposure of children is only estimated for toddlers (10 kg) as they represent the most worst case age group and are considered to cover all other age groups. Infants have the highest food intake on a body weight basis, but as they consume mainly breast milk and formula milk most dietary exposure scenarios do not apply to them. For drinking water there is not yet harmonized approach for biocides with regard to intake volumes for specific age groups. In a recent evaluation the WHO values were used.	RIVM-Bioc	NL
Resident exposure: For the resident exposure of children the following definition is used in the risk assessment: a child with a bodyweight of 10 g which is representative of children around 1 year old. No other age groups are defined as the 10 kg selection is assumed to represent a worst-case scenario for all children. This definition is defined in the EFSA Guidance for the non-dietary risk assessment (EFSA, 2014[17]): **Drinking water:** Although not fully harmonized in the EU in general two children exposure scenario's are included in the drink water risk assessment. A 10 kg toddler drinking 1 L of water a day and a 5 kg bottle-fed infant drinking 0.75 L of water a day. These age groups are considered to represent a worst-case scenario for all children. **Dietary exposure:** For the dietary exposure it depends on the country if the consumption data differentiates between different age groups. For the Netherlands the diets used in the consumer exposure assessment are separated in the general population (age 1-97, weight 65.8 kg), children (age 2-6 years, weight 18.4 kg) and toddlers (age 8-20 months, weight 10.2 kg). More information can be found in Table 4 of the Guidance on the use of EFSA PRIMo revision 2 (EFSA et al., 2018[19]).	RIVM-PPP	
Dependent on the product and its use, different age groups may be considered. Within REACH this is described in guidance R15 on consumer exposure (ECHA, 2016[34]). In biocides HEADhoc recommendation no 14 (see link to biocides framework and exposure related documents: https://echa.europa.eu/nl/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure) The ConsExpo Fact Sheet: General Fact Sheet contains anthropometric data on several age groups including the range of children age groups.	RIVM-REACH	
MCRA uses foodsurveys which provides age and BW per respondent: • Infants: < 12 months old • Toddlers: ≥ 12 months to < 36 months old	RIVM-MCRA	

• Other children: ≥ 36 months to < 10 years old • Adolescents: ≥ 10 years to < 18 years old		
depends on the question and the type of product (e.g. age groups for squishy toys can be quite different from age groups for clays)	RIVM-SCHEER	
For biocidal uses, we differentiate between a toddler (age: 2-3 year; weight: 9 Kg) and an older child (age: 3-4 year; weight: 14 kg)	EPA-NZ	NZ
Guidance document: Biocides Human Health Exposure Methodology Human exposure methodology (ECHA, 2015[18]) infant (based on female 6 to <12 months old); toddler (based on female 1 to <2 years); child (based on female 6 to <11 years)	KEMI-Bioc	SE
Biocides/PPP: see HEAdhoc recommendation 14 (ECHAs homepage)	KEMI-Pest	
We have no specific definition of children. However, we choose age categories most appropriate for the product category we assess. On a case by case basis we differentiate between age group.	KEMI-Cons	
Plant Protection Products Definitions of child age groups are presented in the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA, 2014[17]) Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (wiley.com) **Biocidal Products** Definitions of child age groups are presented in ECHA Guidance document, 'Recommendation no.14 of the BPC Ad hoc Working Group on Human Exposure, Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017)' (ECHA, 2017[16])	CRD-HSE	GB
As appropriate, the risk assessments differentiate between age groups and other factors, as defined in the U.S. EPA's Child-Specific Exposure Factors Handbook (US EPA, 2008[53]).	USEPA-OPPT	US
Residential Exposure Assessment In OPP's Health Effects Division Standard Operating Procedure for Residential Exposure and Risk Assessment for Pesticides (US EPA, 2012[5]), we have defined lifestages for residential exposure assessment. This includes several different lifestages for children, and considers differences between these lifestages (i.e., unique behavioral characteristics and body weights) and how these factors impact exposure. Please see appended to this response document a table which presents all potential adult and child lifestages assessed by EPA based on the 2012 Residential SOPs. The 2012 Residential SOPs employ an exposure scenario-specific approach for each lifestage. Since multiple lifestages could be potentially exposed for a particular exposure scenario, EPA focuses its assessments on the child lifestages which are of the highest concern based on behavioral characteristics which may lead to higher levels of exposure. This "index lifestage" approach (the analysis is presented in Appendix A of the above referenced 2012 Residential SOPs) was performed for each individual Residential SOP and includes the following child lifestages: 6 < 12 months, 1 < 2 years, 2 < 3 years, and 3 < 6 years. Based on analysis of the index lifestage approach, the Agency has determined that the 1 < 2 year old lifestage represents the most appropriate index lifestage for children for most of the residential exposure scenarios. However, there are some exceptions to this selection as presented in the appended table as required based on the likelihood and magnitude of lifestage-specific exposures. **Dietary Exposure Assessment** EPA conducts dietary exposure and risk assessments for the general U.S. population and for child, youth, and adult population subgroups. Child-specific population subgroups for dietary exposure assessment include all infants (<1 year old), children 1-2, children 3-5, and children 6-12 years old. Exposures are calculated using the Dietary Exposure Evaluation Model (DEEM) software with the Food Commodity Intake Database (FCID) (US EPA, 2012[56]). DEEM-FCID includes extensive data on food consumption patterns that are compiled by the U.S. Department of Agriculture (USDA) under the National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The NHANES/WWEIA data are nationally representative. All registered food uses of a pesticide are included in assessments. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant.	USEPA-OCSPP	

Hazard assessment

5a. In your programme, do you perform specific hazard assessments for children?	*[Yes/no]*
5b. If yes, does this hazard assessment include additional, children-specific endpoints (i.e. particularly sensitive for children) for which a hazard assessment is performed?	*[Yes/no]*
5c. If yes, please specify for which additional hazard endpoints a specific assessment is performed: …	

5d. If yes, does the hazard assessment for regular endpoints performed specifically for children includes children specific-dose levels (i.e. from toxicological studies)?	*[Yes/no]*
5e. If yes, are the results from epidemiological studies taken into account?	*[Yes/no]*

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
5a.	Yes	No	No	Yes	No	No	Yes	Yes	Yes	No	Yes	No	No	No	Yes	No		Yes	Yes
5b.	Yes	No		Yes			Yes	Yes	Yes	No	Yes	No			Yes			Yes	Yes
5d.	No			Yes			Yes	Yes	No	No	Yes			No	Yes	No		Yes	
5e.				Yes			Yes	Yes		Yes	Yes				Yes	No		Yes	

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
5a.	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	Yes	No	Yes	Yes
5b.			Yes	Yes	Yes	Yes	No	Yes						Yes		Yes	Yes
5d.			No	No	No	No	No	Yes						No		Yes	No
5e.			Yes	Yes	Yes		No	Yes								Yes	Yes

5c.		
Specific target organ toxicity after repeated exposure, measurement of migration of the chemical into saliva.	AICIS	AU
If the medicine is indicated for children, there are animal studies in young animals, pharmacology studies in children looking at the drug levels in children, and other clinical studies looking at the action of the drug in children. If the drug/medicine is not indicated in children, there may/may not be animal studies in the young. There is no requirement for medicines which are only indicated in animals to have been studied in children.	TGA-MRD	
When the data are available we will assess developmental specific endpoints such as neurodevelopmental toxicity.	HC-CHHAD	CA
Many different substances are assessed under CMP. The amount of data available for each substance and/or grouping varies, with some hazard databases being data rich, while others may require read-across from an appropriate surrogate. Any available animal studies that assess developmental and reproductive endpoints are reviewed (as listed in, but not limited to OECD guidelines 414, 416, 421, 422 and 443). These studies may be guideline studies or studies identified from the literature that incorporate similar testing procedures. If the original studies cannot be located, conclusions from international reviews from trusted partners may be cited instead. When available developmental neurotoxicity (OECD 426) studies and/or endpoints are also considered. In addition, available epidemiological data is reviewed, especially when a developmental or reproductive concern has been identified. Studies examining pregnant women (in utero fetal exposures) and children are considered. For example, the point of departure in the state of the science health assessment for lead was taken from epidemiological data in children, specifically blood lead levels and neurotoxicity data indicative of IQ deficits. Similar approaches may be taken for other substances, when warranted.	HC-ESRAB	
It is case-by-case. If children are likely to be exposed to the substance being assessed, we will consider them in the risk characterization. Even though the hazard data prescribed under the New Substances Notification Regulations (NSNR) are not specific to children, if there is potential for exposure to occur in this group hazard in children would be assessed. In such cases, endpoints considered may extend beyond those prescribed under the regulations, such as for reproductive-developmental effects. Also, as indicated in the NSNR guidance (Government of Canada, 2021[72]), acute and repeated dose toxicity tests are generally not eligible for waivers for polymers intended for use in children's toys.	HC-NSACB-Nano	
Specific hazard assessments are performed if relevant data is available for new substances. If intended	HC-NSACB	

or potential exposure extends to infants/children subgroup, an extra uncertainty factor is applied as appropriate.		
The PMRA's hazard assessment of pesticides includes an evaluation of all lifestages (which includes the developing fetus, the neonate, and young children), and requires toxicology studies that specifically assess effects in, and potential sensitivity of, the young. When children may be exposed from the use of a pesticide, specific toxicology reference values may be established for children if an effect of concern is identified in the young in the toxicology assessment. These reference values are based on toxicology studies, endpoints, and points of departure that are relevant to children (e.g., developmental effects in a developmental neurotoxicity (DNT) study, comparative cholinesterase studies (examine young vs adult sensitivity to toxin)). For risk characterization, in addition to the standard uncertainty factors (10-fold for interspecies extrapolation, 10-fold for intraspecies variability), Health Canada's Pest Control Products Act (PCPA) requires the application of an additional 10-fold factor under certain conditions to provide additional protection for infants and children in the risk assessment. This factor, referred to as the PCPA Factor, is applied to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. The PCPA Factor provides an additional margin of safety for assessing risks to children from pest control products that are used residentially (i.e., in and around homes or schools) as well as from potential pesticide residues in the diet.	HC-PMRA	
With the calls we received, we can keep track of what is going on in certain city, province, even in schools, if is the case of a poison, intoxication with students with opioids, sedatives, or any other xenobiotic. Also, when this is the case the Ministry of Health also receives alerts through unique digital record in health, which the doctors in medical centers do the reports to give an alert. Through toxicovigilance, the possible risk to which the pediatric population is exposed is evaluated, when calls of potentially dangerous xenobiotics are received in the pediatric population, for example: toys, button batteries, possible environmental toxicity, among others	CCSS	CR
developmental toxicity (however, this endpoint is evaluated in every hazard assessment (if the relevant data is available), not only in the ones to be used for risk assessment for children)	BfR-Toys	DE
A specific hazard assessment factor could be used if a chemical is particular hazardous for children e.g. neurotoxic substances. Another reason to adapt the hazard assessment for children is that children are exposed to multiple substances at the same time. Therefor a DNEL/TDI of 10 % is used when it is well know that there are many sources of exposure to the same substance or group of substance.	DEPA	DK
Toxic effects (e.g. toxicities to respiratory system and skin sensory organ system, allergies, etc.) that can be sensitively affected in the child development stages are preferentially reviewed.	NIER	KR
Developmental toxicity and in specific cases also developmental neurotoxicity.	RIVM-Bioc	NL
Developmental toxicity and in specific cases also developmental neurotoxicity.	RIVM-PPP	
Developmental effects mainly.	RIVM-REACH	
this depends on the question asked and the availability of data.	RIVM-SCHEER	
Neurotoxicity	KEMI-Cons	SE
As appropriate, for hazard assessment, we generally use animal studies which include evaluations of developing organisms. If the animal studies show different effects or different responses to the same effect, that information is used. There are also considerations for susceptibility of children to chemicals in general. This is included in our statute (Potentially Exposed Susceptible Subpopulations).	USEPA-OPPT	US
As part of the hazard evaluation, the Office of Pesticide Programs (OPP) evaluates toxicity studies in which endpoints specific to early lifestages are assessed. Data requirements for pesticides in the US include developmental toxicity studies and reproduction toxicity studies. In addition, based on the toxicity profile of the chemical under evaluation, additional studies may be requested that evaluate lifestage differences, such as a comparative cholinesterase assay (for cholinesterase inhibiting chemicals), a comparative thyroid assay (for thyroid toxicants), and developmental neurotoxicity study. Endpoints evaluated that assess lifestage specific endpoints include but are not limited to in utero effects (e.g., malformations and/or variations, fetal weights and viability), birth weight, post-natal development (e.g., pup weight, sexual maturation), and neurodevelopmental effects. The hazard characterization process also considers whether children are expected to be exposed for each anticipated exposure scenario and selects endpoints for human health risk assessment that protect for all effects that are relevant to children for those scenarios. Additionally, we consider the need for a safety factor to protect for the developing young as outlined under the Food Quality Protection Act (Summary of the Food Quality Protection Act | Laws & Regulations | US EPA). https://www.epa.gov/laws-regulations/summary-food-quality-protection-act	USEPA-OCSPP	

6a. Do you have guidance or tools on methodology for hazard assessment for children that can be shared (i.e. no need to list internal guidance or tools	*[Yes/no]*

that cannot be shared)?	
6b. If yes, please provide the name of the guidance or tools, and brief description (this can include a reference to document containing the methodology): …	

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
6a.	No		Yes	No	No	No	No	No	No	No	Yes	No	No	No	Yes	No		No	No

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
6a.	No	No	Yes	No	No	No	No	No	No	No	No			No	No	Yes	Yes

6b.		
EN 60601-1-11:2015 Medical electrical equipment – General requirements for basic safety and essential performance – Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. Australian mandatory standards for consumer goods that contain button batteries (ACCC, 2021[20])	TGA-MDPQD	AU
European Food Safety Authority (EFSA): Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA, 2014[17]).	FPS	BE
Science Policy Note (SPN2002-01): Children's Health Priorities within the Pest Management Regulatory Agency. This document contains an overview of the human health risk assessment for children, including hazard identification and risk characterization (Health Canada, 2002[9]) As noted above, the PCPA factor is a margin of safety intended to provide additional protection for infants and children in the risk assessment. It is detailed in Science Policy Note (SPN2008-01): The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides (Health Canada, 2008[21]) The Guidance document cited below includes a description of the types of toxicology studies generally needed in characterizing the toxicity of a pesticides and the potential hazards it poses to humans, including studies designed to assess effects in the young (e.g. reproduction studies, developmental toxicity studies, refer to Part 4 in the document cited below). Guidance for developing datasets for conventional pest control product applications: data codes for parts 1, 2, 3, 4, 5, 6, 7 and 10. Updated Feb. 2021 (Health Canada, 2021[73]).	HC-PMRA	CA
Each case is registered, with the tools we use Epiinfo® version 3.5.3 2011, where the hazard is evaluated according to severity, frequency, geographic location, age group, among other variables.	CCSS	CR
Guidance on procedures and methods, etc. for risk assessment of hazardous environmental factors (PART 3. Risk assessment of hazardous environmental factors contained in children's products)	NIER	KR
• Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (US EPA, 2005[30]) • Guidelines for Reproductive Toxicity Risk Assessment (US EPA, 1996[27]) • Guidelines for Developmental Toxicity Risk Assessment (US EPA, 1991[74])	USEPA-OPPT	US
The EPA's Human Health Risk Assessment Colloquium developed a framework for risk-based decision making (US EPA, 2014[22]). The following references are provided in that framework and highlight a list of EPA-wide documentation specific to the protection of children: • Policy on Evaluating Health Risks to Children (US EPA, 1995[29]; US EPA, 2013[28]). • Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (US EPA, 2005[30]) • Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants (US EPA, 2005[26]) • A Framework for Assessing Health Risk of Environmental Exposures to Children (US EPA, 2006[24]). • Guide to Considering Children's Health When Developing EPA Actions: Implementing Executive	USEPA-OCSPP	

Order 13045 and EPA's Policy on Evaluating Health Risks to Children (US EPA, 2006[25]). • Exposure Factors Handbook (US EPA, 2011[23]) includes specific sections with child-specific factors). Additionally as noted earlier, FQPA is also applicable (Summary of the Food Quality Protection Act; Summary of the Food Quality Protection Act, Laws & Regulations. US EPA). https://www.epa.gov/laws-regulations/summary-food-quality-protection-act		

Exposure assessment

7a. In your programme, do you perform specific exposure assessments for children?	*[Yes/No]*
7b. If yes, do you use specific physiological characteristics of children (e.g. child-specific body weights, skin/body areas, etc.) as parameters in the exposure assessment?	*[Yes/No]*
7c. If yes, do you use specific scenarios or behavioral characteristics for children (e.g. ingestion of craft materials, mouthing behavior, crawling on floors) as parameters in the exposure assessment?	*[Yes/No]*
7d. If yes, please provide further details on the specific scenarios or behavioral characteristics used …	

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
7a.	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
7b.	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes
7c.	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
7a.	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
7b.	No		Yes	Yes	Yes	Yes	Yes	Yes		Yes		Yes	Yes	Yes	Yes	Yes	Yes
7c.	No		Yes	Yes	Yes	Yes		Yes		Yes		Yes	Yes	Yes	Yes	Yes	Yes

7d.		
Mouthing behaviour	AICIS	AU
Consider behavioural aspects (crawling, hand to mouth behavior, mouthing activities) Consider child surface area	APVMA	
For medicines regulation, the exposure assessment is known as a PK study. It measures the level of drug in the body, and assess the concentrations reached and time taken to reach those concentration. Numerous other calculations are made in relation to volume of distribution and clearance from the body. The studies take into account the weight, height and age of patients. We do not examine accidental ingestion.	TGA-MRD	
Playing on lawn, hand to mouth exposure, object to mouth exposure	FPS	BE
Hand to mouth and object to mouth exposure	ISSeP	
The food consumption database that we use (a 24-hr recall survey with 1 to 2 days of data for each respondent) includes individual body weight data for respondents 2 years of age and above. These are each associated with that individual's 24-hr recall food consumption records. Those above 2 years of age	HC-CHHAD	CA

who are missing body weight data typically have their body weight imputed from the distribution of body weights in the same stratum (e.g. age, sex, region). For those below 2 years of age, body weights are typically assigned based on age in months from other sources (e.g. U.S. NHANES data, Dietitians of Canada adaptation of the WHO Child Growth Charts). Therefore depending on the assessment, food consumption rates specific to children are employed (which is why 'yes' was highlighted for the 'behaviour scenario' question).		
• Mouthing behavior. Some examples from Canadian assessments are included in the OECD document ENV/JM/MONO(2019)24: DIBP, TCPP and TDCPP, TCEP, triclosan. • Ingestion of craft materials – will refer to SCHER (2016[46]) • Crawling on treated floors (e.g. will often refer to US EPA Residential SOP guidance) • Ingestion of dust and soil (see Exposure Factor Fact Sheet to be published June 2021)	HC-ESRAB	
If children are likely to be exposed to the substance being assessed we will consider them in the exposure assessment. Depending on the notified or potential use and the manufacture/import quantity we will consider different scenarios of exposure in children. Scenarios (e.g. mouthing, ingestion of soil, etc.) considered are in line with Canadian CMP assessments.	HC-NSACB-Nano	
For dietary exposure scenarios, PMRA uses child-specific body weight and food consumption inputs in the assessment through the use of DEEM version 3.18-NHANES Food Consumption and body weight data 2002-2008, as outlined in Science Policy Note (SPN2014-01): General Exposure Factor Inputs for Dietary, Occupational, and Residential Exposure Assessments (link included below). For most non-dietary exposure scenarios (dermal/inhalation/incidental oral) for pesticides, PMRA follows the US EPA residential SOP. This document is published on the US EPA website and outlines various scenarios, index life stages, body weights, body surface areas that are used in the assessment. Excel sheets are also available on the website to support the approaches outlined for each chapter in this SOP. https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide. For biocides/antimicrobials, the US EPA has a separate residential SOP that PMRA often follows. This SOP is still draft and is not available on the US EPA website; however, the models are included in published assessments for specific chemicals. This is an area that is still in development for EPA and PMRA and would benefit from additional data and models. As noted earlier, many of the factors used by PMRA are outlined in Science Policy Note (SPN2014-01): General Exposure Factor Inputs for Dietary, Occupational, and Residential Exposure Assessments (Health Canada, 2014[10])	HC-PMRA	
It depends on the product type and the use of the product but for example where secondary exposure of children is possible, we assess mouthing (e.g. chewing treated playground structures), hand-to-mouth and inhalation of volatilized residue. There are some products which may be directly applied on children such as insect repellents. For these products we assess the relevant exposure routes as is done for adults but using children specific physiological characteristics.	FOPH-Bioc	CH
Mouthing behavior, crawling on floors	FOPH-Chem	
Through toxicovigilance, the possible risk to which the pediatric population is exposed is evaluated, when calls of potentially dangerous xenobiotics are received in the pediatric population, for example: toys, button batteries, possible environmental toxicity, among others. And according to specific times such as vacations, holy weeks, pandemic, natural events such as red tide, among others. Specific behavioral characteristics such as depressed children, victims of bullying, assaults in the home, children who thrive in dysfunctional family environments, where the risk of poisoning from suicide attempts and exposure to toxic substances due to negligence increases. (Intentional and unintentional)	CCSS	CR
Dietary exposure assessment of plant protection products: The dietary exposure for children is based on food consumption/bodyweight ratios on individual level. Normally, default assumptions on bodyweights for sub-populations are avoided. **Dietary exposure assessment of biocides:** Non-professional uses of biocides scenarios are typically calculated for 10 kg toddlers (besides the estimation for adults) as described in Guidance on the BPR: Volume III Parts B+C, section 5 (ECHA, 2017[15]). **Non-dietary exposure assessment of plant protection products:** According to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA, 2014[17]) children are considered as residents or bystanders. Four pathways of exposure are considered: spray drift, vapour, surface deposit, and entry into treated crops. For spray drift, child-specific dermal and inhalation exposure values are available. For vapour, the default children breathing rate of 1.07 m3/day/kg bw is considered. For surface deposits, in addition to dermal exposure, hand to mouth transfer and object to mouth transfer are considered. For entry into treated crops, a factor of 0.3 is applied to the adult TC. Specific models and tools are listed below in point 8. **Non-dietary exposure assessment of biocides:** Depending on the product type and the intended uses of the biocide, all potentially relevant routes of	BfR-Pest	DE

primary and/or secondary exposure are assessed, mostly considering calculations for toddlers as worst-case assumption. These scenarios also include child-specific behavior, such as crawling and playing on relevant surfaces, touching and mouthing of wet/dry residues or increased oral intake. Specific models and tools are listed below in point 8.		
Mouthing behavior & Ingestion - Analytical data, if available for the product-substance combination of the assessed exposure scenario - Observations on object mouthing times, if available for the assessed exposure scenario - Dust/Soil Ingestion defaults: • 100 mg are referenced as a conservative value proposed by Oomen et al., (2008[40]) in Chapter 15.3.4 of the Guidance on Information Requirements and Chemical Safety Assessment Chapter R.15: Consumer exposure assessment (ECHA, 2016[34]) • U.S. EPA. Exposure Factors Handbook Chapter 5 (Update): Soil and Dust Ingestion. (US EPA, 2017[51]) Please note: For Mouthing of toys and ingestion of toy material additional information is given in our questionnaire sheet filled in for "Toys in the scope of the European Toy Safety Directive 2009/48/EG" Child-specific parameter values for exposure assessment (if available for the assessed consumer product), e.g. frequency and duration of use/contact and surface of skin in contact with substance/product; Amount of product used	BfR-REACH	
Mouthing of toys - analytical data in accordance with EN 71-10:2005 may relate to migration from 10 cm² toy surface into 100 mL water for 1 h (head-over heels) - mouthing times observed in European children for general items and specifically for toys are reported in CEN TR 16918 - specific considerations on the EN 71-10 and on mouthing of toys by the European Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) and its successor committees (SCHER, SCHEER) can be found in the following documents: • Assessment of the European Committee for Standardisation (CEN) report on the risk assessment of organic chemicals in toys, (CSTEE, 2003[32]); • Assessment of the European Committee for Standardisation (CEN) report on methods development (CSTEE, 2004[31]); • CEN's response to the opinion of the CSTEE on the assessment of CEN report on the risk assessment of organic chemicals in toys (SCHER, 2007[48]); • Risk from organic CMR substances in toys (SCHER, 2010[47]); • Toxicological reference values for certain organic chemicals emitted from squishy toys with regard to adopting limit values under the Toy Safety Directive 2009/48/EC 'Chemicals in squishy (SCHEER, 2021[45]), **Ingestion of toy material** The following publicly available documents outline approaches established in Europe in relation to the assessment of toy materials ingestion: RIVM, 2008: Chemicals in toys (including erratum from 2015) (van Engelen et al., 2008[43]); Final Opinion on Estimates of the amount of toy materials ingested by children (SCHER, 2016[46]) **Dermal contact with toys** - product- and use-specific exposure estimates - models often used: if information on substance content is available: a) instant and complete availability of a substance in a product for dermal absorption; b) thickness of product layer on the skin as described by the European Chemical Agency (ECHA) in their "Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.15: Consumer exposure assessment, version 3.0, 2016" (ECHA, 2016[34]), however, where available, suitable migration data are preferred for exposure estimation, analytical migration data may be derived applying methods described in EN 71-10 (see above, mainly the same parameters as for estimating mouthing) - point estimates derived on basis of utilizing discrete values; discrete value selection mainly on basis of expert judgement and RIVM's Children's Toys Fact Sheet (2002), sometimes product specific data (product characteristics, use data) may be available from industry associations - when estimating systemic exposure: application of dermal absorption values on basis of literature data (percentage dermal absorption or time-dependent absorption per skin area), adjusted if necessary, taking into account the concentration, contact duration, matrix,…. When such data are not available, conservative defaults may be used. **Inhalation of substances emitting from toys** - only for volatile substances - estimating indoor room concentrations and breathing zone concentration, preferably on the basis of analytical emission data - when estimating systemic exposure: taking into account children's physiology (e.g. respiratory minute volume)	BfR-Toys	
Newborns spending many hours on a madras or play floor Mouthing behavior for toy appealing to kids under the age of three Teenagers/young adults spending many hours in their room each day (e.g. gamers or students) Children do not always wash their hands after play with toys which make the exposure time very long	DEPA	DK
Ingestion of soil, crops, vegetables and groundwater, Soil contact, Inhalation of indoor and outdoor dust/volatiles, Mouthing behavior of children articles	NIER	KR

Body weight (already stated above), body parts surface areas (hands, arms, head, trunk, legs, feet), total body area and short- and long term inhalation rates are provided in Recommendation no. 14 of the BPC Ad hoc Working Group on human exposure (ECHA, 2017[16]). The specific scenarios considered are dependent on the product type and the exposure scenario that occurs. Where relevant, the following child specific scenarios or behavioral characteristics are considered: crawling and playing on treated floors, contact with treated surfaces and hand-to-mouth transfer, object to mouth contact.	RIVM-Bioc	NL
For plant protection products used on lawns a specific exposure assessment is conducted taking into account playing and sport activities conducted by children on those treated lawns. For the resident exposure specific behavioral characteristics of children such as hand-to-mouth and object-to-mouth contact is considered. For the dietary exposure specific information on the diets of children and toddlers are used to estimate the exposure levels through the diet.	RIVM-PPP	
In the ConsExpo Fact Sheets, post-application exposure scenarios often included infants being present after use (or during) crawling over treated surfaces. The rubbing off scenario is tailored to capture this exposure. The general Fact Sheet contains anthropometric data. Hand to mouth contact and mouthing behavior is also quite typical to consider for children.	RIVM-REACH	
MCRA uses individual children consumption over 2 day with at least 3 weeks interval for chronic exposure. For acute both day are considered as separate consumption day Additionally MCRA accounts for individual sampling weights which corrects for 1) the number children per versus the expected number of children per year, 2) social economic/demographic status of the individual child https://mcra.rivm.nl/	RIVM-MCRA	
SCHEER uses as much as is possible guidelines and default values from peer reviewed documents. In some cases data from industry is used after a thorough evaluation	RIVM-SCHEER	
• (1) Agricultural pesticides: Children are considered most sensitive in the bystander exposure modelling. It includes assessment of spray drift and exposures via dermal contact, mouthing activity and soil ingestion. • (2) Biocides: Post application dermal exposure, mouthing behavior, crawling behavior with regard to duration of exposure and frequency of activity.		NZ
A specific scenario was developed for infants and toddlers mouthing textiles based on assumption that volume and weight of the mouthed fabric matters and not surface area. The assumption is that 1.3 g textile are mouthed. This can be found in the assessment report for siler copper zeolite (product type 9) once published here: https://echa.europa.eu/sv/information-on-chemicals/biocidal-active-substances/-/disas/factsheet/1446/PT09 Other scenarios are found in Guidance document: Biocides Human Health Exposure Methodology Human exposure methodology (ECHA, 2015[18])	KEMI-Bioc	SE
Biocides: see no 8	KEMI-Pest	
Data from food diaries from children of different ages was used in exposure assessment of hazardous substances in food contact materials We considered mouthing and chewing in exposure assessment of hazardous substances in textiles and textile toys We used time spent in outdoor playgrounds including contact time (legs, hands) with the surfaces in exposure assessment of PAHs from shock-absorbing tiles.	KEMI-Cons	
Plant Protection Products Definitions of child body weights, skin surface areas and breathing rates are presented in the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA, 2014[17]). Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (wiley.com) For plant protection products we consider the following child-specific situations: • Children's exposure to spray drift and vapour. • Children's exposure to deposits on treated surfaces (direct dermal exposure, hand-to-mouth transfer and object-to-mouth transfer (mouthing behavior)). • Children's exposure from re-entry into treated crops and playing on treated turf. **Biocidal Products** Definitions of child body weights, skin surface areas and breathing rates are presented in ECHA Guidance document, 'Recommendation no.14 of the BPC Ad hoc Working Group on Human Exposure, Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017)' (ECHA, 2017[16]) For biocidal products some of the child-specific situations we consider are: • Children's exposure to spray drift and vapour. • Children's exposure to deposits on treated surfaces (direct dermal exposure, hand-to-mouth transfer and object-to-mouth transfer (mouthing behavior)). • Children's exposure from direct application of biocidal product to skin (topical insect repellents only)	CRD-HSE	GB
As appropriate, the risk assessments may be based on specific scenarios or behavior characteristics	USEPA-	US

informed by the U.S. EPA's Child-Specific Exposure Factors Handbook (US EPA, 2008[53])	OPPT	
Specific information can be found in the Health Effects Division Standard Operating Procedure for Residential Exposure and Risk Assessment for Pesticides (US EPA, 2012[5]), which identifies the appropriate behavioral and physiological characteristics by lifestage and scenario . As described in the response to question 4 above, OPP's 2012 Residential SOPs uses an "index lifestage" approach. This approach requires that children's exposures assessments focus on child lifestages of the highest potential concern based on behavioral characteristics which may lead to higher levels of exposure. This index lifestage evaluation includes consideration of the exposure rates of activities specific to the exposure scenarios assessed (e.g., exposures rates are quantified using exposure studies conducted with adults performing typical activities on residential turf or carpet and these exposure rates are scaled to child body surface areas). Child dermal, inhalation, and non-dietary exposure routes were taken into account for all potential exposure scenarios/SOPs. Non-dietary incidental oral exposures occur from children contacting treated surfaces and putting their hands in their mouth (i.e., "hand-to-mouth" exposure) and exposure resulting from children putting objects or other toys in their mouth that had been in contact with treated surfaces (i.e., "object-to-mouth" exposure). More specifically, OPP considered child lifestage-specific surface area adjustment factors, developmental milestones relevant to potential child dermal and oral exposures, hand-to-mouth and object-to-mouth event hourly activity data, body weights, and inhalation rates. The appended table presents all potential adult and child exposures scenarios as assessed by EPA based on the 2012 Residential SOPs. The table identifies the routes of exposure anticipated and assessed for each potential exposure scenario/SOP to include dermal, incidental oral (i.e., hand-to-mouth, object-to-mouth), and inhalation exposures. For example, a child contacting an animal (pet) treated with a pesticide is expected to be exposed through the dermal route, as well as from incidental oral (i.e., hand-to-mouth) exposures from contacting the treated pet and then the child subsequently placing his or her hands in their mouth. **Dietary Exposure Assessment** For dietary exposure assessment, bodyweights are incorporated into the DEEM-FCID model that is used for dietary exposure assessment. DEEM-FCID includes extensive data on food consumption patterns that are compiled by the U.S. Department of Agriculture (USDA) under the National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). All of the demographic information associated with respondents, as collected by CSFII (previous dietary consumption survey) or NHANES, such as socio-economic status, age, race/ethnicity, etc. and other information such as body weight and other anthropometric measurements is also retained with that record. Additional details can be found at https://fcid.foodrisk.org/faq/.	USEPA-OCSPP	

8a. Do you use specific guidance, tools or default values to perform your exposure assessment?	*[Yes/No]*
8b. If Yes, please specify: …	

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
8a.	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
8a.	Yes	No	Yes	Yes	Yes	No	Yes		No	Yes			Yes	Yes	Yes	Yes	Yes

8b.		
• US EPA (2017[75]), Indoor Exposure Product Testing Protocols Version 2.0, Office of Chemical Safety and Pollution Prevention – Document #740-S1-7002, Washington DC • Simoneau, C. et al. (2001[36]), Validation of methodologies for the release of di-isononylphthalate (DINP) in saliva simulant from toys, European Commission DG-Joint Research Center, Food Products Unit, Institute for health and Consumer Protection, I-2102 • SCCS (Scientific Committee on Consumer Safety), SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 10th revision, 24-25 October 2018, SCCS/1602/18	AICIS	AU
US EPA residential SOPs.	APVMA	
In our guidance, we have some reference weights which we use if it is required: child of 2 years = 12 kg, 6 years = 20 kg, 10 years = 35 kg, 12 years = 40 kg. In general, we use international scientific guidance documents which describe how PK studies are performed for different ages, and medicines and biological products. https://www.tga.gov.au/ws-sg-index	TGA-MRD	
European Food Safety Authority (EFSA): Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA, 2014[17]).	FPS	BE
• (1) Skin areas, body weights, exposure duration, etc.. • (2) default values included in the xlsx calculator EFSA	ISSeP	
Our exposure assessments are typically carried out in a tiered assessment approach as described in EHC 240: Principles and methods for the risk assessment of chemicals in food (WHO, 2008[59]). Chapter 6 "Dietary Exposure Assessment of Chemicals in Food" is presently undergoing revisions to which our group has provided input (https://www.who.int/docs/default-source/food-safety/publications/chapter6-dietary-exposure.pdf?sfvrsn=26d37b15_6). In cases where a ballpark exposure calculation is being performed as an early tier, mean or median body weight for each age group (e.g. Food Consumption Table (Health Canada, 2022[4]), see Body Weights - FCT) is often used when estimating exposure in a conservative, deterministic assessment. Consideration is also given to potential vulnerable subpopulations depending on the food or beverage under consideration, especially if it a food intended for or frequently consumed by infants and children. If there is evidence that exposure might be of concern, then this is progressively refined to use individual consumption data and body weights as part of a more in-depth exposure assessment where warranted. Such an assessment could be partial probabilistic (individual food consumption records and body weights directly matched with fixed chemical concentrations or summary statistics thereof in foods) or full probabilistic (individually food consumption records and body weights probabilistically matched with a full distribution of chemical concentrations in foods via Monte Carlo simulation). More straightforward exposure calculations are typically conducted in MS Excel, and more in-depth exposure assessments are carried out in SAS.	HC-CHHAD	CA
Some examples: • Consexpo Fact Sheets (RIVM, 2011[76]) • Selection of Body Weights Values for Use in Human Health Risk Assessment (HHRA) Conducted by Health Canada (Health Canada, 2019[77]) • Exposure Factor Fact Sheet to be published June 2021	HC-ESRAB	
This question does not seem to be specific to children so we will address exposure assessment in general. For nanomaterials we refer to tools and models included under the OECD WPMN SG8. There is ongoing work to develop and eventually publish a Canadian Risk Assessment Framework for the assessment and management of nanomaterials under the Canadian Environmental Protection Act (CEPA).	HC-NSACB-Nano	
Internal tools In-house produced spreadsheets may be used for estimating indirect exposure through drinking water and direct exposure to cosmetics and personal care products. EPI Suite may be used for estimating physical-chemical parameters. ConsExpo and E-FAST are used for exposure modelling.	HC-NSACB	
These are outlined in the response to question 7	HC-PMRA	
We use Headhoc Recommendations and opinions (such as Recommendation 5 & 14. Also the biocides human health exposure methodology and the ConsExpo Fact Sheets are used.	FOPH-Bioc	C H
Various literature (open, EU guidance etc), nothing specific, would be good to have defined reference values	FOPH-Chem	
The tool to perform exposure assessment is call EDUS (unique digital record in health): where certain important cases are consulted according to the danger, verifying the evolution of the patient	CCSS	C R
See models cited above. • Guidance: https://www.who.int/foodsafety/publications/chem/en/pesticide_en.pdf?ua=1 Progress on acute dietary intake estimation – International Estimate of Short Term Intake (IESTI), FAO Plant Protection and Protection Paper 153, 1999, FAO, Rome • Guidance on the BPR: Volume III Parts B+C, section 5 (ECHA, 2017[15])	BfR-Pest	DE

Relevant models, guidance and tools for non-dietary exposure assessment: **Plant Protection Products:** • EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA, 2014[17]). **Biocides:** • ECHA Biocides Human Health Exposure Methodology • BPR Guidance Volume III Human health Part B+C • Recommendations of the BPC Ad hoc Working Group on Human Exposure • ConsExpo Web (RIVM, 2011[44]) and corresponding Fact Sheets for e.g. disinfectants, paints and pest control products (RIVM, 2011[76])		
Guidance Guidance on information Requirements and Chemical Safety Assessment Chapter R.15: Consumer exposure assessment (Version 3; July 2016) (ECHA, 2016[34]) **Tools & Defaults** Regularly used tools include ECETOC´s Targeted Risk Assessment Tool (ECETOC, n.d.[33]) and ConsExpo web (RIVM, 2011[44]) and the corresponding RIVM's fact sheets (RIVM, 2011[76]) e.g. General Fact Sheet (Te Biesebeek et al., 2014[39]) Children's Toys Fact Sheet (Bremmer and van Veen, 2002[42]) US EPA's Child-specific Exposure Factors Handbook (US EPA, 2008[53]) And others defaults mentioned above	BfR-REACH	
RIVM's fact sheets (General Fact Sheet, Children's Toys Fact Sheet) opinions of CSTEE and its successor committees (SCHER, SCHEER) US EPA's Child-specific Exposure Factors Handbook (US EPA, 2008[53]) Others as mentioned above	BfR-Toys	
Among others; Existing Default Values and Recommendations for Exposure Assessment. A Nordic Exposure Group Project 2011". (NCM, 2011[71]) (This report will be updated later this year). REACH-guidance are used for exposure assessment (ECHA, 2016[34]) General default parameters for estimating consumer exposure - Updated version 2014, RIVM (Te Biesebeek et al., 2014[39]) For phthalates in toys: Risk assessment guidance on phthalates in toys for notifications under the Rapid Alert System For cosmetics: Notes of Guidance 11th revision (SCCS, 2021[70])	DEPA	DK
• Guideline for Risk Assessment of Soil Contaminants • Guidance on procedures and methods, etc. for risk assessment of hazardous environmental factors (PART 3. Risk assessment of hazardous environmental factors contained in children's products) • Korean Exposure Factors Handbook for Children	NIER	KR
The specific tools or default values to be used are dependent on the product type under evaluation. Specific recommendations and guidances can be found in: • The Recommendations of the Ad hoc Working Group on Human Exposure (https://echa.europa.eu/nl/view-article/-/journal_content/title/recommendations-of-the-ad-hoc-working-group-on-human-exposure), • the Opinions of the Human Exposure Expert Group (HEEG) (https://echa.europa.eu/nl/view-article/-/journal_content/title/support-biocides-heeg-opinions), • the BPR Guidance Volume III Human health part B (ECHA, 2017[15]) and: • the Biocides Human Health Exposure Methodology (ECHA, 2015[18]).	RIVM-Bioc	NL
Default values are set for among others body weight, breathing rate and body surfaces. All defaults can be found in the EFSA OPEX guidance for the non-dietary risk assessment (EFSA, 2014[17]) For the dietary exposure assessment the EFSA PRIMo (Pesticide Residue Intake Model) version 3 is used. This model includes food consumption data for children. A detailed description of the tool is available in a guidance document (EFSA et al., 2018[19])	RIVM-PPP	
Assessing risks of substances includes children, but I am unaware of specific guidance to assess risks to children, although RIVM reports have been written to assess the risk of children as a target group. Guidance for risk assessment of chemicals for children (Wolterink, van Engelen and van Raaij, 2007[41])	RIVM-REACH	
Pesticides: tier 1, tier 2, EC 2018 tier I and EC 2018 tier II Contaminants: non-detects handled according LB, MB and UB: EFSA (European Food Safety Authority), 2010b. Management of left-censored data in dietary exposure assessment of chemical substances. EFSA Journal 2010;8(3):1557, 96 pp. doi:10.2903/j.efsa.2010.1557 Additives: MPL scenario's, UL scenarios and brand loyalty scenario's	RIVM-MCRA	
SCHEER uses guidelines and default values from peer reviewed documents	RIVM-SCHEER	
EPA Risk assessment Methodology for Hazardous substances (2020). Additionally, we also refer- ConsExpo Fact Sheets, Technical notes for guidance-human exposure to biocidal products (TNsG 2002 & 2007), Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation	EPA-NZ	NZ

(Parts B+C) (V4.0; 2017)		
Guidance document: Biocides Human Health Exposure Methodology (ECHA, 2015[18])	KEMI-Bioc	SE
Biocides: Biocides Human Health Exposure Methodology/Heeg opinions/HEADhoc recommendations (all available on ECHAs homepage), ConsExpo (+ Fact Sheets)	KEMI-Pest	
US EPA Exposure Factors Handbook REACH Guidance on Information Requirements and Chemical Safety Assessment, R15	KEMI-Cons	
For plant protection products, guidance and default values for the child-specific exposure assessment is described in the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA, 2014[17]). The exposure tool (model) used is the EFSA Calculator https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2014.3874&file=3874Ax1-sup-0001.zip For biocidal products, guidance is available at: • Recommendations of the Ad hoc Working Group on Human Exposure (https://echa.europa.eu/view-article/-/journal_content/title/recommendations-of-the-ad-hoc-working-group-on-human-exposure), in particular Recommendation No.'s 5, 6, 11, 14 • Biocides Human Health Exposure Methodology (ECHA, 2015[18])	CRD-HSE	G B
The following guidance documents, tools and/or default values may be used to perform child-specific exposure assessments: a. Guidelines for Exposure Assessment (US EPA, 1992[78]) b. Guidelines for Human Exposure Assessment (US EPA, 2019[50]) c. A Framework for Assessing Health Risk of Environmental Exposures to Children (US EPA, 2006[24]) d. Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants (US EPA, 2005[26]) e. Child-Specific Exposure Scenarios Examples (Final Report) (US EPA, 2008[53]) f. and other Agency-specific guidance (US EPA, 2021[54])	USEPA-OPPT	US
Guidance and default values for different exposure assumptions have been established for our exposure assessments. Different values may be considered based on the lifestage, exposure scenario, route of exposure, etc. Details can be found in the 2012 Health Effects Division Standard Operating Procedure for Residential Exposure and Risk Assessment for Pesticides (US EPA, 2012[5]) The DEEM-FCID model used for dietary exposure and risk assessment can be downloaded at the US EPA website (US EPA, 2012[56]). Additionally, U.S. EPA's What We Eat in America - Food Commodity Intake Database (FCID), 2005-2010 can be found at https://fcid.foodrisk.org/. The FAQ page (https://fcid.foodrisk.org/faq/) includes topics such as a discussion of how the database was developed, how demographic information, including bodyweights, are retained, and how multiple survey cycles can be combined to increase the sample size of infant and child age groups.	USEPA-OCSPP	

Risk characterisation

9a. In your programme, do you perform specific risk characterisation for children?	*[Yes/no]*
9b. If yes, do you have guidance or tools on methodology for risk characterisation for children?	*[Yes/no]*
9c. If yes, please provide the name of the guidance or tools, and brief description (this can include a reference to document containing the methodology): …	

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
9a.	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes			Yes	Yes
9b.	No	Yes	Yes	No		Yes	No	Yes	No	No	Yes	No	No		Yes			Yes	Yes

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
9a.	No	No	Yes	Yes	No	Yes	Yes	Yes	No	No	No		Yes	No	No	Yes	Yes
9b.			Yes			Yes	No	No					No		No	Yes	Yes

9c.		
US EPA residential SOPs, using hazard based endpoints from tox evaluations conducted on the active constituents	APVMA	AU
Australian mandatory standards for consumer goods that contain button batteries (ACCC, 2021[20])	TGA-MDPQD	
All applications for prescription medicines have a risk management plan. This addresses whether studies have been performed in children or not. If there are no studies in children, this is usually an area of missing data and sponsors are requested to provide data. We have special labelling and packaging requirements for highly toxic substances to avoid accidental ingestions The product information includes information about the extent of studies in children	TGA-MRD	
EFSA Guidance PPP (2014) (EFSA, 2014[17]) Technical guidance document for S-Risk (VITO, 2017[79])	ISSeP	BE
Fact sheets available online about Government of Canada assessments (REF) • Chemicals and Children's Health (Health Canada, n.d.[64]) • Assessing exposure of Canadians and the environment to substances in products (Health Canada, 2022[63]) • Consideration of endocrine-related effects in risk assessment (Health Canada, 2022[65]) • Uses of human biomonitoring data in risk assessment (Health Canada, 2022[66]) • Considerations of vulnerable populations in risk assessment (Health Canada, 2022[80])	HC-ESRAB	CA
As noted earlier, for scenarios where children may be exposed, the PMRA identifies toxicology reference values specific for children and estimates their exposure using child-specific inputs. The determination of whether dietary exposure is acceptable is made by comparing the estimated exposure to the dietary toxicology reference values (ARfD and ADI). Exposures that fall below the reference value are considered to provide sufficient margins of safety and therefore do not present health risks of concern. For non-dietary exposure scenarios (dermal/inhalation/incidental oral), exposure estimates are compared to the appropriate toxicology reference values (e.g., NOAEL) to calculate a margin of exposure. If the calculated margin of exposure is equal to, or greater than the target margin of exposure, risks are considered acceptable. The target margin of exposure includes the PCPA factor, which is discussed previously. This approach is further discussed in the following documents: • PMRA Guidance Document, A Framework for Risk Assessment and Risk Management of Pest Control Products. 27 January 2021 (Health Canada, 2021[62]) • Science Policy Note (SPN2008-01): The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides (Health Canada, 2008[21])	HC-PMRA	
We do not have knowledge of specific methodology for risk charaterisation of children. We use the children specific exposure scenarios and in case of unacceptable use there are risk mitigation measures that might apply which have already been assessed for similar biocidal products such as "keep children away".	FOPH-Bioc	CH
We have guidance and tool on methodology for risk characterization for children, we can count with literature based on toxicologic emergencies, we use a date base IBM Micromedex ® (©Copyright IBM 2021). The Micromedex is a tool that evaluates the toxicity of each xenobiotics (hydrocarbons, chemicals, drugs, cosmetics, plants, medications) and shows toxic doses, symptoms and signs of poisoning, treatment, observations necessary for the recovery of the patient, and with this tool we can evaluate the risk in each case in particular.	CCSS	CR
For genotoxic carcinogens: - Estimating additional lifetime cancer risk under consideration of age-dependent adjustment factors as suggested by the US EPA in their "Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens", (US EPA, 2005[30]). - Deriving a "virtually safe dose" corresponding to an additional lifetime cancer risk of 10-6 as exemplified by SCHER for chromium (VI) migration from toy materials (SCHER, 2015[67]): Opinion on Chromium VI in toys, https://ec.europa.eu/health/sites/	BfR-Toys	DE
REACH-guidance are used for risk assessment (ECHA, 2016[61]): A basic guideline aimed for manufacturers, importers and distributors.	DEPA	DK

"Chemical safety assessment of toys. Guidance and inspiration for manufacturers, importers and distributors" (Danish EPA, 2019[60]) https://mst.dk/media/183564/chemical-safety-assessment-of-toys_uk.pdf Assessment of phthalates in toys: Risk assessment phthalates Excel calculation sheet.		
Guidance on procedures and methods, etc. for risk assessment of hazardous environmental factors (PART 3. Risk assessment of hazardous environmental factors contained in children's products) • According to the guidance, toxicity reference values for children, if any, would be preferentially applied to calculate risks	NIER	KR
See the aforementioned report. However, I feel this is an integral part of risk assessment nowadays	RIVM-REACH	NL
https://mcra.rivm.nl/	RIVM-MCRA	
SCHEER develop a WoE methodology to come to conclusions on exposure, hazard and risk.	RIVM-SCHEER	
This Guidance provides technical advice on how to perform the hazard and exposure assessment and risk characterisation for biocidal active substances and products with respect to human health risk assessment and evaluation (ECHA, 2017[15]).	KEMI-Bioc	SE
Risk characterization is generally performed in keeping with the U.S. EPA's Risk Characterization Handbook (US EPA, 2001[68]).	USEPA-OPPT	US
A document explaining EPA's general principles for performing aggregate exposure and risk assessments for pesticides, including aggregate exposure assessments for children, can be found in (US EPA, 2001[69]). Additionally the Framework for risk-based decision making includes consideration of children (US EPA, 2014[22]). The 2012 Residential SOP document, includes methodology and exposure assumptions for how to assess and characterize risk to children. Details can be found in the Health Effects Division Standard Operating Procedure for Residential Exposure and Risk Assessment for Pesticides (US EPA, 2012[5])	USEPA-OCSPP	

Needs for additional parameters during exposure assessment for children

Part A: Parameters in exposure assessment methodology

10a. In the methodology currently used for exposure assessment for children, are there exposure parameters which are **not** currently used, which you think need to be included in the exposure assessment methodology?	*[Yes/No]*
10b. If yes, do these include **chemical or product specific** parameters?	*[Yes/No]*
If yes, please specify *[please check with an X; multiple answers possible]*:	
10c.	Vapor pressure of chemicals
10d.	Particle characteristics (e.g. of nanomaterials)
10e.	Emission from products
10f.	Migration from products
10g.	Presence / amount of chemicals in specific places / products
10h.	Other, please specify: …

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
10a.	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	No	Yes	Yes	Yes
10b.		No	Yes	Yes		Yes	Yes	Yes	Yes	Yes			Yes	No			Yes	No	No
10c.				X		X													

10d.													X						
10e.										X			X						
10f.			X	X				X		X									
10g.			X				X	X		X									

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
10a.	No	No	Yes	Yes	Yes	Yes	No	No		Yes	No	No	Yes	No	No	No	No
10b.			Yes	Yes	No	Yes				Yes			No				
10c.																	
10d.			X														
10e.																	
10f.										X							
10g.																	

10h.		
Half-life in air, water, soil (for contaminated soils health risk assessment program)	ISSeP	BE
Often there is limited information on the use pattern for certain products used by children (e.g. hand sanitizer, hair products, make up, glues, toys). Additional information such as product amount used, frequency and duration on products used or intended to be used by children.	HC-ESRAB	CA
How are nanomaterials dispersed/embedded in products (e.g. nanomaterials in plastic toys). This is also relevant to products for which other age groups may be exposed as well.	HC-NSACB-Nano	
The parameters identified for this question are considered by PMRA in exposure and risk assessments for children, as applicable, depending on the scenario assessed. Chemical-specific data (e.g., migration from products, dermal absorption) are not available for all chemicals; when these data are not available, there are often high-end standard values that can be used as surrogate in the assessment. The sources of values for these parameters are referenced in the responses to the questions above and to question 11 below.	HC-PMRA	
Products matrix composition (may influence phys.-chem. behavior of chemicals)	BfR-REACH	DE
Relative weight compared to air. If substances in vapour or gas form are heavier than air, children may be higher exposed.	RIVM-Bioc	NL
Relative weight compared to air. If substances in vapour or gas form are heavier than air, children may be higher exposed. Also manipulation of the product by the child is not always considered. Release upon breaking products or sucking on products (so active release rather than passive emission or migration)	RIVM-REACH	

10i. If yes, do these include **physiological** parameters?	*[Yes/No]*
If yes, please specify *[please check with an X; multiple answers possible]*:	
10j.	Breathing rate
10k.	Skin/body surface area(s)
10l.	Dermal absorption
10m.	Body weight
10n.	Higher need/dietary intake of water/calories
10o.	Other physiological parameters, please specify …

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA

	AU				BE		CA					CH			CR	DE			DK
10i.		No	Yes	Yes		No	Yes	Yes	No	Yes			Yes	Yes			No	Yes	No
10j.														X					
10k.			X	X										X					
10l.			X	X						X			X	X					
10m.				X			X							X					
10n.							X	X						X					

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
10i.			No	No	No	Yes				No			Yes				
10j.																	
10k.													X				
10l.													X				
10m.													X				
10n.																	

10o.		
Specialized dietary restrictions (e.g. vegetarian, low carb); Food allergies and intolerances (e.g. milk allergy, gluten intolerance); Depending if these are for medical reasons or by individual or family choice, some of these may fall under behavioural patterns, but the main point would be to identify sub groups of children whose diets may be Different from others in their age group. Body weight: used if available, but not always available, especially for children < 2 years of age. Higher need/dietary intake of water/calories: e.g. indication of how typical a given consumption record is for the respondent	HC-CHHAD	CA
Higher need/dietary intake of water/calories: Often there is limited dietary intake data for infants and toddlers which limits exposure estimates from food for these specific sub-populations.	HC-ESRAB	
Toxicokinetic data of children, i.e. metabolic capacity	BfR-Toys	DE
The toxicokinetic differences between adults and children are not well understand for the majority of substances (perhaps most known in field of medicine) with respect to ADME. The other listed above are generally considered (to my knowledge).	RIVM-REACH	NL
The system for detoxification and excretion of toxic substances is not fully developed at birth, e.g., for many substances the half-life is much longer in children < 1 y than in adults. This could affect the risk. Skin/body surface area(s)/Body weight: Default value for newborns. The default values for infants (<12 months; HEAdhoc recommendation 14) are based on data on infants 6-12 months. This means that the skin surface/body weight are not adapted for newborns. Exposure assessment of newborns could be relevant e.g. for repellents against mosquitos. Dermal absorption: The skin of small children is thinner and has higher permeability than the skin of adults, which also means that the dermal absorption probably is higher. Normally, the same dermal absorption value is used for all age categories which means that there is a risk that the exposure of small children will be underestimated.	KEMI-Pest	SE

10p. If yes, do these include **scenario-related or behavioral** parameters?	*[Yes/No]*
If yes, please specify *[please check with an X; multiple answers possible]*:	
10q.	Crawling behavior
10r.	Mouthing behavior
10s.	Time spent in specific places (e.g. indoors/outside, or on the grass/floor)
10t.	Contact scenarios regarding specific activities (e.g. during playing)
10u.	Contact/use scenarios with specific products (e.g. furniture, floor, toys)

10v.	Different use scenarios (e.g. use of higher frequency or amount of cosmetics)
10w.	Time spent as bystander during or after use of specific products (e.g. use of DIY products)
10x.	Other scenario-related or behavioral parameters, please specify: …

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
10p		Yes	No	Yes		Yes	No	Yes	Yes	Yes			Yes	No			No	No	Yes
10q						X							X						
10r						X				X			X						X
10s		X		X									X						
10t		X		X									X						
10u				X									X						
10v				X				X		X			X						X
10w									X										

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
10p			Yes	Yes	Yes	Yes				No			No				
10q			X			X											
10r						X											
10s						X											
10t			X														
10u																	
10v																	
10w						X											

10x		
Incidental ingestion – e.g. swallowing water while swimming (higher on a relative basis for children than adults).	HC-NSACB-Nano	CA
Cleaning behavior or avoidance behavior. We often assume the worst, but actually have limited information about whether children will clean themselves or actively avoid bad smell or bad taste.	RIVM-Bioc	NL
Exposure through contact with house dust containing plant protection residues and information on under which activities (crawling, playing) such exposure might occur.	RIVM-PPP	
cleaning behavior or avoidance behavior. We often assume the worst, but actually have limited information about whether children will clean themselves or actively avoid bad smell or bad taste.	RIVM-REACH	

Part B: Data for parameters in exposure assessment

11a. Regarding the **data/measurements** used as input in your methodology to assess exposure for children, does your methodology need better/more data to support the parameters?	*[Yes/No]*
I11b. f yes, do these include **chemical or product specific** data?	*[Yes/No]*
If yes, please specify *[please check with an X; multiple answers possible]*:	

11c.	Product size
11d.	Identity of chemicals
11e.	Particle characteristics (e.g. of nanomaterials)
11f.	Vapor pressure of chemicals
11g.	Molecular weight of chemicals
11h.	log Kow values of chemicals
11i.	Emission from products
11j.	Migration from products
11k.	Presence / amount of chemicals in specific places / products
11l.	Other, please specify: …

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
11a	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
11b	Yes		Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
11c			X	X				X		X	X						X		
11d	X		X	X				X	X	X					X		X		X
11e	X			X					X	X	X		X				X		X
11f	X					X													X
11g	X			X															
11h	X			X				X											
11i	X		X					X	X	X	X		X			X	X	X	X
11j	X			X				X	X	X	X	X	X			X	X	X	X
11k	X						X	X	X	X	X		X				X		X

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
11a	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes
11b			Yes	No	No	Yes		Yes	Yes	Yes				Yes		Yes	Yes
11c																X	X
11d			X						X					X		X	
11e						X			X							X	X
11f			X						X							X	
11g			X													X	
11h			X													X	
11i			X			X		X	X					X		X	X
11j			X			X		X	X	X				X		X	X
11k			X			X		X	X					X		X	X

11L		
Chemical specific data including levels in products.	AICIS	AU
For nanoparticles relevant phys-chem properties include size, shape, surface chemistry, aspect ratio	HC-NSACB-	CA

(for fibres), dissolution rate/dispersion stability, degree of agglomeration/aggregation. Currently there are no strict requirements under the New Substances Notification Regulations for chemicals & polymers (NSNR C&P) for particle characteristics or release, emission or migration from products, but exposure assessment methodology currently tries to model or make assumptions about these parameters based on available tools and information to the degree possible.	Nano	
The parameters above are identified primarily for assessments related to consumer products containing biocides/antimicrobial products. For typical pesticide uses/products, these aspects are generally well characterized.	HC-PMRA	
Under the BPR most parameters of the chemical are known due to the requirements of the product dossier. We have certain assumptions that can be made for emission and migration parameters. However, we expect that in the future more data on leaching is necessary especially for the use of the biocidal products in treated articles. The leaching studies should be specific to the active substance and the media (saliva, sweat).	FOPH-Bioc	CH
Product design (spray, powder, fluid)	BfR-REACH	DE
product use data. Amounts, frequency of use	RIVM-REACH	NL
While EPA's exposure assessment methodologies are unlikely to change given the parameters outlined above for Question 10, additional exposure study data, use and usage survey data, or other information can be used to inform the inputs applied for our current methods. On occasion, the size of the pesticide product being assessed is not clearly defined on the registered product labeling. In this instance, EPA will assume that a larger size product is being used to result in a more protective assessment. More clearly defined product size information could lead to a more refined assessment. The migration of pesticides is of particular concern as related to the active ingredient volatility and the potential for inhalation exposures. Emission information from treated indoor and outdoor surfaces could further inform OPP's risk assessments relating to the potential for inhalation exposures. Finally, the migration of pesticide active ingredients from the treated surface to the exposed individual is a potential exposure pathway for which additional data could refine many of the Residential SOPs. For example, OPP is currently working with an industry task force to develop exposure data which could inform our understanding of the potential for exposures with treated animals (pets) from typical behaviors/interactions.	USEPA-OCSPP	US

11m. If yes, do these include **physiological** data?	*[Yes/No]*
If yes, please specify *[please check with an X; multiple answers possible]*:	
11n.	Breathing rate
11o.	Skin surface area(s)
11p.	Dermal absorption
11q.	Body weight
11r.	Other physiological parameters, please specify: …

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
11m	YES		YES	YES		No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes
11n	X			X										X					
11o	X			X										X			X	X	
11p	X		X	X				X		X			X	X			X	X	X
11q	X			X			X							X	X				

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	

11m			Yes	No	No	No		No	Yes	No				Yes		No	No
11n			X						X								
11o			X						X								
11p			X						X					X			
11q			X						X								

11r		
Not just a mean or median body weight, but specific focus on those who are small for their age, e.g. lower percentiles of body weight. In addition, a more quantitative and high sample size data set of body weights for infants and young children would be helpful when calculating exposure from breast milk, infant formula, and baby foods. Food Frequency information for infrequently consumed foods. Many of our available tools focus on quantifying amount consumed (e.g. 24-hr recall surveys) but there is little available regarding food frequency (e.g. FFQ) such as the number of times per month that certain fish, vegetables, and other products are consumed. Brand Loyalty information. How likely are parents or children to stick to a very specific brand of infant formula, baby food, breakfast cereal, granola bar. This could also include things like type of juice, flavour of pudding, etc. At present we have little capacity to quantify this. What proportion of families change brand or type based on sale pricing vs. keep to the same because of taste preference, etc.	HC-CHHAD	CA
Nano-specific pharmacokinetic data is useful, e.g. broncheoalvaeolar lavage (BAL) test for inhalation of poorly soluble nanoparticles.	HC-NSACB-Nano	
Volume of urine excreted per day or grams of creatinine excreted in urine per day. These are used to extrapolate urine spot samples from biomonitoring studies to estimate full day values. Most of the physiological data used by PMRA is from the US EPA Residential SOPs (2012[5])and the US EPA Exposure Factors Handbook (2011[23])or, in the case of dermal absorption, from chemical-specific studies.	HC-PMRA	
Skin surface area(s): product/use specific contact area. Dermal absorption: matrix specific, skin contact area specific	BfR-Toys	DE

11s. If yes, do these include **scenario-related or behavioral** data?	*[Yes/No]*
If yes, please specify *[please check with an X; multiple answers possible]*:	
11t.	Crawling behavior
11u.	Mouthing behavior
11v.	Time spent in specific places (e.g. indoors/outside)
11w.	Contact scenarios regarding specific activities (e.g. during playing)
11x.	Contact/use scenarios with specific products (e.g. furniture, floor, toys)
11y.	Different use scenarios (e.g. higher use of cosmetics)
11z.	Time spent as bystander during or after use of specific products (e.g. use of DIY products)
11aa.	Other scenario-related or behavioral, please specify: …

	AICIS	APVMA	TGA-MDPQD	TGA-MRD	FPS	ISSeP	HC-CHHAD	HC-ESRAB	HC-NSACB-Nano	HC-NSACB	HC-PMRA	FOPH-Bioc	FOPH-Chem	SECO	CCSS	BfR-Pest	BfR-REACH	BfR-Toys	DEPA
	AU				BE		CA					CH			CR	DE			DK
11s.	Yes		No	Yes		No	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes
11t.	X												X						
11u.	X									X			X		X				
11v.				X							X		X		X				
11w.	X			X				X		X	X		X		X		X	X	X
11x.	X			X				X		X	X		X		X		X	X	
11y.	X			X				X		X			X		X		X	X	X
11z.	X			X				X			X				X				

	NNK	ERA office	NIER	RIVM-Bioc	RIVM-PPP	RIVM-REACH	RIVM-MCRA	RIVM-SCHEER	RIVM-Cons	EPA-NZ	DOST-ITDI	KEMI-Bioc	KEMI-Pest	KEMI-Cons	CRD-HSE	USEPA-OPPT	USEPA-OCSPP
	HU	JP	KR	NL						NZ	PH	SE			GB	US	
11s.			Yes	Yes	Yes	Yes		Yes	Yes	No				Yes		Yes	Yes
11t.						X			X							X	
11u.			X						X					X		X	
11v.			X	X		X		X	X					X		X	X
11w.			X	X		X		X	X					X		X	X
11x.			X	X		X		X	X					X		X	X
11y.						X		X	X							X	
11z.				X		X		X	X							X	X

11aa.		
Time spent outdoors, in contact with dermal and inhalation antigens (for allergies) and/or in contact with solar UV radiation.	TGA-MRD	AU
For bystanders and DIY products- for pesticide products, there is a good amount of data in the US EPA Residential SOPs (2012[5]) and US EPA Exposure Factors Handbook (2011[23]). However, there is limited data available for products containing a biocide/antimicrobial product. Time spent in specific places (e.g. indoors/outside): There is data available for the time spent in various places (e.g. US EPA Exposure Factors Handbook and US EPA Residential SOPs); however, the parameters determined from this data could be improved with additional data that is more specific to the scenario that is assessed (e.g. time spent in contact with carpets/hardwood flooring inside a home). In addition, Canadian specific data would be most relevant.	HC-PMRA	CA
Under the BPR we use the parameters and scenarios specified for example in the ConsExpo Fact Sheets. These Parameters are usually based on experimental data or in some cases on expert opinions. The parameters can of course always be improved if better data becomes available.	FOPH-Bioc	CH
Data on exposure levels in house dust. Better/more spray drift data for children. Exposure of children due to pesticide use by non-professionals. More information on how often and which combination of plant protection products are used to allow for a cumulative non-dietary risk assessment.	RIVM-PPP	NL
Mouthing behavior: Specific materials, e.g. textile. Time spent in specific places (e.g. indoors/outside): Playgrounds, indoor play areas.	KEMI-Cons	SE
Again, while EPA's exposure assessment methodologies are unlikely to change given the parameters outlined above for Question 10, additional usage survey data relating to the time spent conducting specific activities, the duration of these activities, and the frequency of contact with areas treated with pesticide products are helpful. Such information is often useful for the characterization for both adults and children's residential exposure assessment. In the absence of specific data, it is HED's standard approach to use conservative assumptions.	USEPA-OCSPP	US