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ASSESSING THE RISK OF CHEMICALS TO CHILDREN'S HEALTH: AN OECD-WIDE SURVEY

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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 CO-OPERATION AND DEVELOPMENT
Paris 2013

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or contact:

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

Fax: (33-1) 44 30 61 80

E-mail: ehscont@oecd.org

FOREWORD

This document presents the results of a survey of methodologies and tools used to assess the risk of chemicals to children's health. It compiles currently available methodologies and tools for assessing the risk of chemicals to children's health and also identifies possible needs for additional guidance or tools for assessing the risk of chemicals to children's health. The following areas of risk assessment are covered: the definition of terms, hazard assessment, exposure assessment, risk characterisation, cohort studies and combined exposure to multiple chemicals.

The 47th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology in June 2011 endorsed a proposal for the survey. The online survey was carried out in November 2011. The document of the results was reviewed and approved by the Task Force on Hazard Assessment in June 2012 and the Task Force on Exposure Assessment in October 2012. The Joint Meeting declassified the document on 2 September 2013.

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD.

TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS

Defra	Department for Environment, Food and Rural Affairs (UK)
E FAST	Exposure and Fate Assessment Screening Tool
ECETOC	European Centre of Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EUROPOEM	The European Predictive Operator Exposure Model Database Project
HBM	Human biomonitoring
HESI	Health and Environmental Science Institute
IHCP	Institute for Health and Consumer Protection
ILSE	International Life Sciences Institute
IPCS	International Programme on Chemical Safety
OPPT	Office of Pollution, Prevention and Toxics
PCB	Polychlorinated biphenyl
RIVM	Netherlands National Institute for Public Health
US EPA	United States Environmental Protection Agency
WHO	World Health Organisation

BACKGROUND AND PURPOSE

The 47th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology in June 2011 endorsed a proposal for a survey of methodologies and tools used to assess the risk of chemicals to children's health. It requested that the study should target broadly relevant information to shape the OECD's work beyond 2012. The specific aims of the survey were to:

- identify the existing methodologies and tools for assessing the risk of chemicals to children's health developed and used in OECD member countries and international organisations; and

- identify any needs for additional information or studies in order to develop or harmonise practical risk assessment tools targeting children.

This document is based on the results of a survey of governments, universities, industry and one international organisation (listed below). It was divided into two parts:

1. Part I: Currently available methodologies and tools for assessing the risk of chemicals to children's health, and

2. Part II: Need for additional guidance or tools for assessing the risk of chemicals to children's health.

Respondents were asked to describe whether they currently have methodologies and tools, or need such guidance, in the following areas:

- The definition of terms

- Hazard assessment

- Exposure assessment

- Risk characterisation

- Cohort studies

- Combined exposure to multiple chemicals

SURVEY PARTICIPANTS

The online survey was carried out in November 2011. The following organisations took part:

- Australian Pesticides and Veterinary Medicines Authority, Australia
- Office of Chemical Safety, Department of Health and Ageing, Australia
- NICNAS (National Industrial Chemicals Notification and Assessment Scheme), Australia
- Scientific Institute of Public Health, Belgium
- Health Canada, Pest Management Regulatory Agency (PMRA), Canada
- Health Canada, Safe Environments Directorate, Canada
- Danish EPA (Environmental Protection Agency), Denmark
- ANSES (Agency for Food, Environmental and Occupational Health & Safety), France
- BfR (Federal Institute for Risk Assessment), Germany
- German Environmental Survey for Children (GerES IV), Germany
- University of Modena, Italy
- Environmental Risk Assessment Office, Ministry of the Environment, Japan
- Korea Food and Drug Administration, Korea
- National Institute of Environmental Research, Korea
- COFEPRIS (Federal Commission for the Protection against Sanitary Risk), Mexico
- RIVM (Netherlands National Institute for Public Health), Netherlands
- New Zealand Environmental Protection Agency, New Zealand
- Climate and Pollution Agency, Norway
- Institute of Mother and Child, Department of Pharmacology, Poland
- Nofer Institute of Occupational Medicine, Poland
- Swiss Federal Office for Public Health, Chemicals Department, Switzerland
- North-West University, South Africa
- Ministry of Health, Turkey
- MoEU Turkey (Ministry of Environment and Urbanisation), Turkey
- OCSPP (Office of Chemical Safety and Pollution Prevention), US EPA, US
- US EPA (United States Environmental Protection Agency), US
- ECHA (European Chemical Agency), EU
- WHO (World Health Organisation)
- Cefic (European Chemical Industry Council)
- Albermarle Europe

SUMMARY OF SURVEY RESPONSES

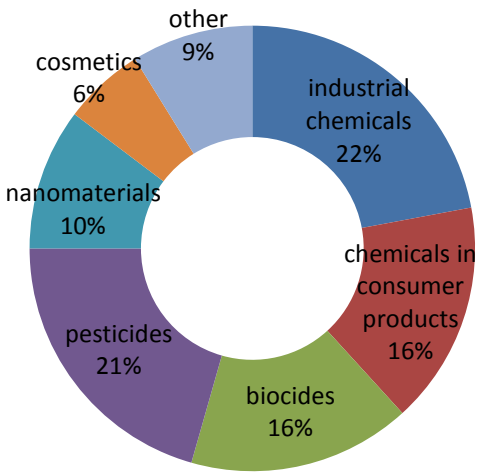
The responses received are summarised below. A compilation of the complete responses can be found in Annex 2.

Part I: Methodologies and tools currently available for assessing the risk of chemicals to children's health

Type of chemical review programme

Respondents were asked to indicate the types of chemicals that are subject to their review programmes. The results can be seen in Figure 1.1. Note that the category labelled "other" included plant protection products (PPP), food additives, environmental chemicals (metals), tobacco, ETS, microbials and semiochemicals, biochemicals/biopolymers (*e.g.* enzymes) and living organisms. In some cases, respondents indicated "all", which means all of the possible chemical types shown in Figure 1.1.

Figure 1.1 Type of chemicals reviewed



[% of total number of respondents]

How the risks for children are assessed

Respondents were asked whether the assessments were done generically, as part of the assessment of consumers and the general public, or focused specifically on the risks to children. The results were as follows:

- 49% of respondents assess the risks generically;
- 45% of respondents assess the risks specifically for children; and
- 6% of respondents do not conduct risk assessments for children or it depends on the chemical being assessed.

Definition of "children"

Respondents were asked whether they have a specific definition of "children," and, if so, to provide a brief description of the definition, including references to documents containing the definition. Fifty-three percent of respondents did not have a definition, while 47% indicated that they did; their definitions can be seen in Table 1.1:

Table 1.1 Definitions of "children"

Definition	Programme/Legislation	Country
Under 15 years	Existing Chemical Program, NICNAS (National Industrial Chemicals Notification and Assessment Scheme in Australia)	Australia
Under 18 years: "children" 2–3 years: "young children"	National Registration Scheme administrated by the Australian Pesticides and Veterinary Medicine Authority	
From conception to adulthood including exposure during pregnancy and from lactation (under 1 year: "infants")	Pesticide Evaluations and Registrations under Pest Control Products Act	Canada
	Assessment of Existing and New Substances under Canadian Environmental Protection Act (CEPA)	
6-11 years for biocides 2-5 years for pesticides 3-5 years for non-food exposure assessment in human health evaluation	Directive 98/8/EC (biocides) and Regulation (EC) No 1107/2009 (pesticides)	Germany
3-14 years	German Environmental Survey for Children (GerES IV)	
Under 18 years (6-24 months: "infants")	German evaluation of dietary exposure in children	
Under 13 years	Risk Assessment of Chemicals in Children's products by National Institute of Environmental Research	Korea
Under 19 years	Korea Food and Drug Administration	
Under 14 years (under 1 year: "infants")	Federal Commission for the Protection against Sanitary Risk (COFEPRIS)	Mexico
Usually under 16 years	North-West University's research projects	South Africa
Different categories driven by the use scenarios or by age categories	Netherlands National Institute for Public Health (RIVM)	The Netherlands
Under 18 years	UN Convention on the Rights of the Child: "child means every human being below the age of eighteen years unless under the law applicable to the child, majority is attained earlier" (UN, 1989)	-

Notes: The COFEPRIS in Mexico answered "Nursing under 1 year," "1-4 years" and "5-14 years."

The United States Environmental Protection Agency (US EPA) suggested in their response that adverse developmental effects may be detected at any point in the lifespan of an organism, and that adverse effects on the developing organism may result from exposure prior to conception (from either parent), during prenatal development, or during postnatal development, up until the time of sexual maturation.

In addition, 68% of respondents indicated that they differentiated age groups of children according to what chemical is being assessed while 32% indicated that they did not; their age groups can be seen in Table 1.2. As seen in the table, the following terms are used for various age groups: "newborn," "infants," "toddlers," "children," "young children," "older children," "teens," "juvenile," "adolescent" and "youth."

Table 1.2 Categories of children by age group

Categories	Programme	Documents referenced	Country
1–6 months ("infants") Under 2 years ("toddlers") Under 12 years ("children")	Existing Chemical Program, National Industrial Chemicals Notification and Assessment Scheme		Australia
Under 18s placed in various age groups depending on the risk assessment, *e.g.* 2–3 years ("young children")	National Registration Scheme administered by the Australian Pesticides and Veterinary Medicines Authority		
For dietary exposures: under 1 year ("infants") 1–2, 3–5 and 6–12 years ("children") 13–19 years ("youth") For non–dietary exposures (depending on scenario): 6–18 months ("infants") 1–2 or 3 years ("toddlers") 3–6 and 6–11 ("children") 10–12 and 11–16 ("youth")	Pesticide Evaluations and Registrations	Pest Control Products Act	Canada
Under 6 months ("infants") 6 months – 4 years ("toddlers") 5–11 years ("children") 12–19 years ("teens")	Assessment of existing and new substances	Canadian Environmental Protection Act (CEPA)	
Differentiated age groups depending on the type of products being investigated	Survey of Chemicals in Consumer Products by the Danish Environmental Protection Agency		Denmark
1–3 years and over 3 years ("children")	The biocides PPP research by the Agency for Food, Environmental and Occupational Health & Safety (Anses)		France
3–5, 6–8 (7–8 for PCBs), 9–11 and 12–14 years ("children")	German Environmental Survey for Children (GerES IV)		Germany
6–24 months ("infants") 2–6, 6–10 and 11–16 years ("children")	Evaluations of dietary exposure in children		
6–12 months ("infants") 6–11 years ("children")	Biocide assessment in human health evaluation	Directive 98/8/EC (biocides)	
In dietary risk assessments: 2–5 years ("children") In non–food exposure assessments: 3–5 years ("children")	Pesticide assessment in human health evaluation	Regulation (EC No 1107/2009)	
0–2 years ("infants and babies") 12–18 years ("juveniles")	Korea Food and Drug Administration		Korea
6–11 months, 2, 6, 10 and 14–16 years	Federal Commission for the Protection against Sanitary Risk		Mexico

	(COFEPRIS)		
1–28 days (“newborns / neonates”) 28 days – 12 months (“infants”) 13–36 months (“small children”)	Nofer Institute of Occupational Medicine		Poland
The following is suggested by the Netherlands National Institute for Public Health (RIVM) with regard to the assessment of chemical substances (especially for regulatory frameworks): “Hazard characterisation is usually based on studies in laboratory animals. In most cases, toxicological studies in which young animals are exposed to the test substance are included (1st and 2nd generation studies of reproductive toxicity, extended one-generation studies of reproductive toxicity and developmental neurotoxicity). These studies may indicate specific critical endpoints for young animals, and differences in sensitivity to toxic effects between young and adult mammals. Generally, data on effects of a substance in adult or young humans are not available.”			Netherlands
The New Zealand Environmental Protection Authority focuses on toddlers or young children when looking at modelling estimates under the Hazardous Substances and New Organisms Act 1996 (HSNO). The age used depends on the circumstances of the substance being assessed. For example, a chemical that will be used domestically by consumers will use a lower age group in modelling than a vertebrate toxic agent (VTA) that is used in forests, where only much older children could potentially be exposed to it.		Hazardous Substances and New Organisms Act 1996 (HSNO)	New Zealand
0–2 years (“infants”) 2–16 years (“children”)	North-West University’s research projects		South Africa
According to the US Environmental Protection Agency (US EPA), different age groups are warranted based on toxicity, exposure, and/or requirements under law, so different age groupings have been used depending on the specific case. Birth to <1 month, 1 to <3 months, 3 to <6 months, 6 to <12 months, 1 to <2 years, 2 to <3 years, 3 to <6 years, 6 to <11 years, 11 to <16 years and 16 to <21 years are recommended by the “Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants” (US EPA, 2006).		“Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants” (US EPA, 2006)	US
The World Health Organisation (WHO) is currently in the process of developing guidance that proposes a globally harmonized set of age bins for chemical risk assessment. WHO provides working definitions of a number of different age groups (see Table 1 in “Principles for Evaluating Health Risks in Children Associated with Exposure to Chemicals”). It contains various stages of pregnancy, as well as 28 days of age to 1 year as infants, young child 1–4 years of age, toddler 2–3 years of age, older child 5–12 years of age, adolescent beginning with the appearance of secondary sexual characteristics to achievement of full maturity (usually 12–18 years of age). In addition, WHO is in the process of developing guidance that proposes a globally harmonised set of age bins for chemical risk assessment.		“EHC 237: Principles for Evaluating Health Risks in Children Associated with Exposure to Chemicals” (WHO, 2006)	

Notes: EPA: Environmental Protection Agency; IPCS: International Programme on Chemical Safety; EHC: Environmental Health Criteria

Hazard assessment

Respondents were asked if they perform specific hazard assessments for children, and, if so, to specify for which hazard endpoints. Five respondents provided total six endpoints: developmental toxicity, carcinogenicity, neurotoxicity, generic alterations, reproductive toxicity and endocrine disruption,
In addition, they were asked if they had any guidance or tools on methodologies for hazard assessment, and, if so, to provide the name of the guidance and references containing the methodology.

Ten respondents reported that they perform specific hazard assessments for children and gave the titles of existing guidance or methodologies (see Table 1.3), as well as suggesting journal papers (listed in Annex 2). Note that some of the guidance is not specific to children.

Additional academic papers are suggested in Annex 2.

Table 1.3. Existing guidance or tools for hazard assessments

Title of the document/tool	Produced by	Other information (date, use, etc.)
"Guidance on information requirements and chemical safety assessment (R7 and R8)" (for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH))	ECHA	
"Guidance for chemical safety assessment (R8.4.3.1) " (for REACH)	ECHA	
TR 96 "Trends in Children's Health and the Role of Chemicals: State of the Science Review"	ECETOC	2005
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	29 July 2008, for pesticides
Regulatory Directive DIR2005-01 "Guidelines for Developing a Toxicological Database for Chemical Pest Control Products"	Health Canada	27 May, 2005, for pesticides
EHC 237 "Principles for Evaluating Health Risks in Children Associated with Exposure to Chemicals"	IPCS	2006
"Guidelines for Developmental Toxicity Risk Assessment"	US EPA	1991
"Guidelines for Reproductive Toxicity Risk Assessment"	US EPA	1996

Notes: ECETOC: European Centre of Ecotoxicology and Toxicology of Chemicals; ECHA: European Chemicals Agency; EPA: Environmental Protection Agency; IPCS: International Programme on Chemical Safety

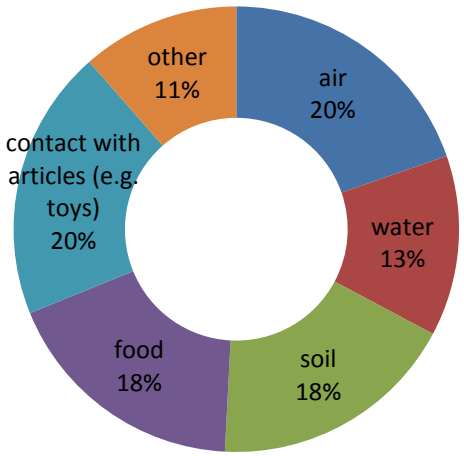
Exposure assessment

Respondents were asked if they perform specific exposure assessments for children and, if so, whether they have developed specific exposure scenarios for children and whether they focus on specific exposure pathways or media (such as air, water, soil, food or contact with articles) in those exposure scenarios. Respondents were also asked to provide the names (and a brief description) of any guidance or tools on methodologies.

Twenty-five respondents reported that they perform specific exposure assessments for children, and, of these, 22 reported that they use specific exposure scenarios for children.

The existing exposure assessment programmes reported a relatively balanced distribution of target pathways (such as air, water, soil, food and contact with articles) in exposure assessments for children: around 13% to 20% of the total respondents focused on each pathway (Figure 1.2). More specific exposure pathways that were reported included paints, glazed earthenware, (accidental) contact with biocidal products, residential contact with pesticides ("mouthing" – mouth or tongue contact), house dust, noise, use of household products, contact with pets, grass and foliage, contact with treated surfaces (carpets, bedding), incidental oral digestion, and personal care products.

Figure 1.2 Target pathways in exposure assessment



[% of total number of respondents]

Twenty respondents listed guidance documents or methodologies for assessing exposure to children (Table 1.4).[1]

Table 1.4 Existing guidance/tools/methodologies for exposure assessments

Title of the document/tool	Produced by	Other information (date, use, etc.)
Australian Exposure Assessment Handbook (consultation draft)	Department of Health and Ageing, Commonwealth of Australia; and EnHealth (Environmental Health Council)	2003
"Principles and Practices of Dietary Exposure Assessment for Food	FSANZ (Food	2009. For the use of

[1] Canada reported that it has guidance on the intake parameters used to estimate exposure to children from the environment (air, water, soil and food), and it is developing internal guidance for mouthing scenarios (in which the mouth or tongue makes contact with a substance), defaults used for personal care product scenarios, as well as a scenario on exposure to ink.

Regulatory Purposes"	Standards Australia and New Zealand)	parameters for children in the 'Food Standards Australia and New Zealand' document
Manual of Requirements and Guidelines (MORAG) (an online manual which sets out the requirements and guidelines for registering veterinary and agricultural products in Australia)	Australian government and Australian Pesticides and Veterinary Medicines Authority	
"Revisions to the Residue Chemistry Crop Field Trial Requirements", Regulatory Directive DIR2010-05	Health Canada PMRA (Pest Management Regulatory Agency)	21 December, 2010, for pesticides
"Choosing a Percentile of Acute Dietary Exposure as a Threshold of Concern", Science Policy Notice SPN2003-01	Health Canada PMRA	28 July, 2003, for pesticides
"Residue Chemistry Guidelines", Regulatory Directive DIR98-02	Health Canada PMRA	1 June, 1998, for pesticides
"Estimating the Water Component of a Dietary Exposure Assessment", Science Policy Notice SPN2004-01	Health Canada PMRA	30 April, 2004, for pesticides
"Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probablistic Risk Assessment", Science Policy Notice SPN2003-05	Health Canada PMRA	November 28, 2003, for pesticides
"Assessing Exposure from Pesticides in Food. A User's Guide", Science Policy Notice SPN2003-03	Health Canada PMRA	July 28, 2003, for pesticides
"Assigning Values to Nondetected / Nonquantified Pesticide Residues in Food", Science Policy Notice SPN2003-02	Health Canada PMRA	July 28, 2003, for pesticides
Canadian Environmental Protection Act, 1999 (CEPA)	Government of Canada	1999. For existing substances, upper bounding estimates of daily intake by all age groups are conducted
"Guidance on information requirements and chemical safety assessments: R15" (for REACH)	ECHA (European Chemicals Agency)	2009
Guidance related to EU Cosmetic Directive	EU (European Union)	e.g. Scientific Committee on Consumer Safety's (SCCS's) Notes of Guidance (2010)
Guidance for Post Application Exposure Assessment (EUROPOEM)		
EU Technical Notes for Guidance (TNsG) on Human Exposure (2007)	IHCP JRC (Joint Research Centre)	For biocides
ECETOC Targeted Risk Assessment (TRA)	ECETOC	

German Drinking Water Ordinance	Government of Germany	
Reference and HBM (Human Biomonitoring) Values	German HBM Commission of the Federal Environment Agency	2009
"Guideline Values for Indoor Air"	Federal Environment Agency's Indoor Air Hygiene Commission (IRK) and the Permanent Working Group of the highest State Health Authorities (AOLG), Germany	
RefXP: German Exposure Factors database, derived from GerES IV	Federal Environment Agency, Germany	The database includes the standard approach for deriving exposure factors from survey data including GerES IV
Guidance Document for Harmonised Exposure Assessment (AUH report)	Germany	
ConsExpo	RIVM, Netherlands	Software model for estimating and assessing exposure to substances from consumer products indoors
"Pest Control Products Fact Sheet to assess the risks for consumer"	RIVM, Netherlands	2006
"General Fact Sheet limiting conditions and reliability, ventilation, room size, body surface area" (H.J. Bremmer *et al.*)	RIVM, Netherlands	2006
"Children's Toys Fact Sheet" (Bremmer, H.J *et al.*)	RIVM, Netherlands	2002
"Non-food products – How to assess children's exposure?" (Engelen, J.G.M. van *et al.*)	RIVM, Netherlands	2004
"Cleaning Products Fact Sheet: To assess the risks for the consumer" (L.C.H. Prud'homme de Lodder *et al.*)	RIVM, Netherlands	2006
"Oral exposure of children to chemicals via hand-to-mouth contact" (W. ter Burg *et al.*)	RIVM, Netherlands	2007
"Cosmetics Fact Sheet to assess the risks for the consumer" (H.J. Bremmer *et al.*)	RIVM, Netherlands	2006
BREEAM: environmental assessment method and ratings system for buildings	UK Defra	for biocides
"Child-Specific Exposure Factors Handbook" (interim report)	US EPA	2002
"Guidance on Selecting Age Groups for Monitoring and Assessing	US EPA	2006

Childhood Exposures to Environmental Contaminants"		
"Transition to 1994-96/1998 CSFII and Modification of Age Groups of Regulatory Interest, Health Effects Division"	US EPA	26 September, 2002
"Draft Technical Guidelines: Standard Operating Procedures for Assessing Residential Pesticide Exposure"	US EPA	8 September, 2009
"Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments"	US EPA	18 December, 1997, for pesticides
E-FAST and MCCEM (USEPA/OPPT exposure assessment models, for default exposure factors for children in assessing exposure)	US EPA/OPPT	
IEUBK (Integrated Exposure Uptake Biokinetic Model, for assessing exposure to lead in children)	US EPA	
EHC 210 "Principles for the Assessment of Risks to Human Health from Exposure to Chemicals"	IPCS	1999
EHC 237 "Principles for Evaluation Health Risks in Children Associated with Exposure to Chemicals"	IPCS	2006
"Identifying Important Life Stages for Monitoring and Assessing Risks from Exposures to Environmental Contaminants" (draft guidance)	WHO	

Notes: Defra: Department for environment, food and rural affairs; ECETOC: European Centre of Ecotoxicology and Toxicology of Chemicals; E FAST: Exposure and Fate Assessment Screening Tool; EUROPOEM: The European Predictive Operator Exposure Model Database Project; IHCP: Institute for Health and Consumer Protection; IPCS: International Programme on Chemical Safety; OPPT: Office of Pollution, Prevention and Toxics
Notes: Germany BfR suggested two additional guidance documents: "Technical Guidance Document on Risk Assessment" and "proposal by HEEG on physiological parameters" for Biocides. Swiss Federal Office suggested several documents in German. Korean National Institute of Environment Research suggested "Risk assessment guidelines oral/dermal inhalation exposure scenario"

Additional academic papers were suggested (see Annex 2).

Risk characterisation

Respondents were asked if they perform specific risk characterisation for children and, if so, if they had guidance or tools on methodologies for risk characterisation for children. 19 respondents reported that they perform specific risk characterisations for children and 13 indicated that there are guidance documents or tools on methodologies for risk characterisation for children. These documents and tools are shown in Table 1.5.

Table 1.5 Existing guidance or tools for risk characterisation

Title of the document/tool	Produced by	Other information (date, use, etc.)
"Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes"	FSANZ (Food Standards Australia and	2009. For the use of parameters for

	New Zealand)	children in the "Food Standards Australia and New Zealand" document
"Manual of Requirements and Guidelines" (MORAG) (an online manual which sets out the requirements and guidelines for registering veterinary and agricultural products in Australia)	Government of Australia	
"Assessing Exposure from Pesticides in Food: A User's Guide", Science Policy Notice SPN2003-03	Health Canada PMRA (Pest Management Regulatory Agency)	28 July, 2003, for pesticides
"Choosing a Percentile of Acute Dietary Exposure as a Threshold of Concern", Science Policy Notice SPN2003-01	Health Canada PMRA	28 July, 2003, for pesticides
"Technical Paper - A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency", Science Policy Notice SPN2000-01	Health Canada PMRA	22 December, 2000, for pesticides
"Children and the health risk assessment of existing substances under the Canadian Environmental Protection Act 1999"	Health Canada	1999
"Human Health Risk Assessment for Priority Substances"	Health Canada	1994
"Guidance on information requirements and chemical safety assessment (R8 and part E)" (for REACH)	ECHA	
EU Technical Notes for Guidance (TNsG) on Annex I Inclusion	IHCP EC JRC (Joint Research Centre)	2002, for Biocides
Reference and HBM (Human Biomonitoring) Values, on Federal Environment Agency website	German HBM Commission of the Federal Environment Agency	2009
"Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants"	US EPA	2006
E-FAST and MCCEM (USEPA/OPPT exposure assessment models, for default exposure factors for children in assessing exposure)	US EPA/OPPT	
IEUBK (Integrated Exposure Uptake Biokinetic Model, for assessing exposure to lead in children)	US EPA	
"Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments"	US EPA	18 December, 1997, for pesticides
EHC 237: "Principles for evaluating health risks in children associated with exposure to chemicals"	IPCS	2006
EHC 240: "Principles and methods for the risk assessment of chemicals in food"	IPCSWHO	2009

Additional academic papers were suggested (see Annex 2).

Additional information (cohort study and combined exposure)

Respondents were asked if they perform children *cohort studies* and if they assess the risks to children from combined exposure to multiple chemicals. If they responded 'yes' to either question, they were invited to provide the name of any guidance or tools used.

Nine programmes perform cohort studies of children and seven have existing guidance or tools on performing child cohort studies. These documents and relevant information are shown in Table 1.6.

Table 1.6 Existing guidance/tools for cohort studies

Title of the document/tool	Produced by	Other information (date, use, etc.)
Japan Environment and Children's Study (JECS) – a national birth cohort study on children's health and the environment	Ministry of the Environment, Japan	It has its own study protocol (in Japanese).
International Study of Asthma and Allergies in Childhood (ISAAC), a worldwide epidemiological research programme to investigate asthma, rhinitis and eczema in children	New Zealand	Started 1991
Prevention and Incidence of Asthma and Mite Allergy (PIAMA) birth cohort study	RIVM, Netherlands	
"Special Issue: A Guide to Undertaking a Birth Cohort Study: Purposes, Pitfalls and Practicalities" (J. Golding *et al*.)	WHO[2]	2009
WHO is considering a birth cohort study in Germany, to contribute to health-related environmental monitoring	WHO	

[2] WHO's website, Children's Environmental Health (*www.who.int/ceh/en*) has a broad range of information including on the co-ordination of new large-scale birth cohort studies.

Twelve programmes assess the risks to children from *combined exposure* to multiple chemicals; six have existing guidance or tools on performing risk assessment from combined exposure to multiple chemicals. Four of these documents and relevant information are shown in Table 1.7.

Additional academic papers were suggested (see Annex 2).

Table 1.7 Existing guidance or tools for risk assessments from combined exposure to multiple chemicals

Title of the document/tool	Produced by	Other information (date, use, etc.)
"Guidance for Identifying Pesticides", Science Policy Notice SPN2001-01	Health Canada PMRA	25 January, 2001, (including a common mechanism of toxicity for human health risk assessment)
"General Principles for Performing Aggregate Exposure and Risk Assessments", Science Policy Notice SPN2003-04	Health Canada PMRA	28 July, 2003
"Expert Workshop on Combination Effects of Chemicals" report	Danish EPA	28-30 January, 2009, Hornbæk, Denmark. (note: the principles of dose addition are described)
"Risk Assessment of Combined Exposures to Multiple Chemicals: A WHO/IPCS framework" (M.E. Meek *et al.*)	IPCS	2011

Other guidance or tools relevant to risk assessments for children

Part I of the questionnaire concluded by asking if respondents had any other guidance or tools relevant to risk assessment for children which had not yet been mentioned; eight programmes responded. Besides those mentioned above, the US EPA's *Exposure Factors Handbook* (US EPA, 2011) was suggested, as well as the SPIN Exposure Toolbox (Use Index), a tool on the Danish Environmental Protection Agency's SPIN online database.

Part II: Need for additional guidance or tools on risk assessment for children

In the second part of the questionnaire, respondents were asked to identify for which areas of children's risk assessment additional guidance or tools are needed. The responses for each area are summarised below.[3]

Definition of terms

A total of 11 responses suggested the need for harmonised definitions for assessing the risks of chemicals to children's health.

Hazard assessment

A total of 17 specific responses were provided inputs on hazard assessment (Table 2.1). It should be noted that one response suggested that it is too soon to develop guidance on hazard assessment.

Table 2.1 Need for additional guidance: hazard assessment.

Respondents' comments on what is needed	Number of responses
More information	2
Guidance or methodologies on extrapolation from adults to children including age-dependent adjustment factors	3
Sensitivity guidance or studies related to children's level of development (including one general comment suggesting higher sensitivity for children)	3
Developing markers of outcome assessment for children	1
Tools taking into account developing country scenarios	1
Epidemiological studies to show correlation between human biomonitoring (HBM) and health outcomes	1
Harmonisation of end-points	1
Focus on specific areas: 1) Adult onset effects resulting from early life exposures 2) The effects of chemicals in psychoneuro development and immune development 3) Endocrine modulators as well as low-dose effects 4) Developmental programming and/or epigenetics 5) Markers of outcome assessment for children 6) Prenatal exposure by specific chemicals, such as PCBs	5

Exposure assessment

A total of 20 responses provided inputs on exposure assessment. Based on these responses, it appears that there is a significant need for tools for exposure assessment. But the *types* of need or tools varied by respondents, including:

1) General exposure scenarios for children
2) Specific exposure behaviour or situations for children
3) Exposure scenarios from specific sources
4) Specific exposure factors, data or models

[3] Since some responses contain several suggestions, the number of suggestions outnumbers the total number of responses. In addition, the tables in this section do not list all the comments since some of the responses include general comments or suggest academic papers. The tables list and summarise suggestions related to needs.

A number of responses were provided specific suggestions about exposure scenarios (see Table 2.2).

Table 2.2 Need for additional guidance: exposure scenarios

Respondents' comments on what is needed	Number of responses
An exposure scenario for children. Parameters that would need to be developed for such a scenario include: time of exposure (such as time spent indoors), number of hand-to-mouth events/activities, contact with pets, body weight and inhalation.	3
More specific exposure information related to dietary consumption. This includes consumption data focusing on children eating their meals at home as well as data on meals in day care facilities.	2
More specific data on exposure: 1) standard values for body weight and breathing volume; 2) indoor guide values; and 3) hand-to-mouth behaviours transferred to factor in rubbing-off models.	3
Exposure scenarios for more specific sources such as: 1) exposure scenarios for biocides; 2) children in an agricultural workplace; 3) emissions or exposure from (consumer) products; and 4) dermal and inhalational exposure from insecticides used in domestic environments.	6

Risk characterisation

A total of 9 specific responses were received on the need for tools for risk characterisation (Table 2.3).

Table 2.3 Need for additional guidance: risk characterisation

Respondents' comments on what is needed	Number of responses
Harmonisation of risk characterisation methodologies, such as uncertainty factors, to consider specificity of children and/or deviation	6
Identification of people/groups with mixed/multiple exposures	1
Risk characterisation taking into account developing country scenarios	1
More information regarding toxicokinetics and dynamics [4] between children and adults: this may give support to the use of a factor 10 for intraspecies differences, or reason to increase or decrease the assessment factor.	1

Cohort study

Five specific responses were provided concerning cohort studies (Table 2.4).

Table 2.4 Need for additional guidance: cohort studies

Respondents' comments on what is needed	Number of responses
Harmonisation of pregnancy/birth cohorts	1
Development of study tools	1
Harmonisation of exposure and outcome measurement among cohort studies	1
Quality criteria and guidelines	1
Methodology of follow-up of the children	1

[4] Both terms refer to the study of the interaction between a toxic substance and the living organism it enters.

Combined exposure

Twelve specific responses were provided inputs on combined exposure (Table 2.5):

Table 2.5 Need for additional guidance: combined exposures

Respondents' comments on what is needed	Number of responses
Tools/methodologies. Some of the responses suggested that the needs are not only for children but also adults	5
Guidance on combined exposure for all age groups. One response suggested harmonised guidance for cumulative/combined exposure to pesticides, including infants and children	2
Common definitions and common methodology in order to assess combined exposure	1
Guidance for assessment of uncertainty	2
There are other responses addressing the needs for specific information on: 1) co-use scenarios; 2) prenatal exposure of PCBs, and combined exposure; and 3) real-life scenarios in developing countries.	3
Case studies employing the WHO Framework (as recommended by the WHO OECD ILSI/HESI Workshop on the Risk Assessment of Combined Exposures to Multiple Chemicals)	1

Notes: HESI: Health and Environmental Science Institute; ILSE: International Life Sciences Institute

Other comments

Five additional specific responses[5] were provided that were relevant to the future development of additional guidance or tools at OECD (Table 2.6).

Table 2.6 Need for additional guidance or tools: other

Respondents' comments on what is needed	Number of responses
Identification and assessment of other pathways, such as behaviour and lifestyle	1
Harmonised approach for calculating and handling exposures for children when conducting cancer risk assessments, such as-age specific adjustment factors	1
Need to exchange information about factors of exposure measurements and outcome measurements in child health	1
Need for data extrapolating to children for all steps of risk assessment	1
Assessment of risk from engineered and non-engineered nanoparticles which are already dispersed in the environment	1

[5] For this item, results of responses to question 15 on *any other needs for additional guidance or tools* and question 16 on *other comments* are compiled. In addition, as previously mentioned, the tables in this section do not list all the comments since some of the responses include general comments or suggest academic papers. The tables list and summarise suggestions related to needs.

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ANNEX 1

ONLINE QUESTIONNAIRE OF THE SURVEY

IDENTITY OF THE RESPONDENT

Name
Organization
e-mail
telephone

PART I

CURRENTLY AVAILABLE METHODOLOGIES AND TOOLS

Type of chemical review programme

1. Please provide the name of your chemical review programme

2. Type of target chemicals. *(multiple answers)*
- industrial chemicals
- chemicals in consumer products
- biocides
- pesticides
- nanomaterials
- cosmetics
- other, please specify ( )

3. In your programme, how do you assess the risks of children? *(multiple answers)*
- 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, please provide a brief description of the definition.
Please reference(s) of the document(s) containing the definition (document name, URL if available)

5. In your programme, do you differentiate between different age groups?
Yes/no
If yes, please provide a brief description of the age groups.
please provide a reference(s) of the document(s) containing the age groups (document name, URL if available)

Hazard Assessment

6. In your programme, do you perform specific hazard assessments for children?
Yes/no
If yes, please specify for which hazard endpoints a specific assessment is performed.

7. Do you have guidance or tools on methodology for hazard assessment for children?
Yes/no
If yes, please provide the name of the guidance or tools, and brief description.
please provide a reference(s) of the document(s) containing the methodology. (document name, URL if available)

Exposure assessment

8. In your programme, do you perform specific exposure assessments for children?
Yes/no
If yes, have you developed specific exposure scenarios for children?
Yes/no
If yes, do you focus on specific exposure pathway(s)/media in the exposure scenario? (multiple answers if applicable)

Air, water, soil, food, contact with articles (e.g. toys), other please specify ( ).

9. Do you have guidance or tools on methodology for exposure assessment for children?
Yes/no
If yes, please provide the name of the guidance or tools, and brief description.
please provide a reference(s) of the document(s) containing the methodology. (document name, URL if available)

Risk Characterization

10. In your programme, do you perform specific risk characterization for children?
Yes/no

11. Do you have guidance or tools on methodology for risk characterization for children.
Yes/no
If yes, please provide the name of the guidance or tools, and brief description.
please provide a reference(s) of the document(s) containing the methodology. (document name, URL if available)

Additional information

12. Do you perform children cohort study(ies)?
Yes/no
If yes, do you have guidance or tools on performing children cohort study(ies) ?
Yes/no
If yes, please provide the name(s) and a reference(s) of the document(s). (document name, URL if available)

13. In your programme, do you assess the risks to children from the combined exposure to multiple chemicals?
Yes/no
If yes, do you have guidance or tools on performing risk assessment from the combined exposure to multiple chemicals.
Yes/no
If yes, please provide the name(s) and a reference(s) of the document(s). (document name, URL if available)

Other guidance or tools relevant for risk assessment for children

14. Do you have other guidance or tools relevant to risk assessment for children?
Yes/no
If yes, please provide brief description.
please provide a reference(s) of the document(s) containing the guidance or tools. (document name, URL if available)

PART II

NEEDS FOR ADDITIONAL GUIDANCE OR TOOLS ON RISK ASSESSMENT FOR CHILDREN

15. Please identify for which areas of risk assessment there is a need for additional guidance or tools on risk assessment of children.

Please specify the precise needs for each area.

a. Definition of a term(s) (e.g. harmonization or development of definition)

b. Please specify ( )

c. Exposure assessment

d. Please specify ( )

3. Hazard assessment

4. Please specify ( )

5. Risk characterization

6. Please specify ( )

    a. Cohort studies
       Please specify ( )
    b. Combined exposure
       Please specify ( )
    c. Other
       Please specify ( )

16. Please provide any other comments relevant to the future development of additional guidance or tools at OECD. ( )

ANNEX 2

COMPILATION OF RESPONSES TO THE SURVEY

Part I: currently available methodologies and tools

Type of chemical review programme

1. Please provide the name of your chemical review programme

2. Type of target chemicals. *(multiple answers)*
- industrial chemicals
- chemicals in consumer products
- biocides
- pesticides
- nanomaterials
- cosmetics
- other, please specify ( )

Country	Organisation	Name of chemical review programme.	Type of target chemicals.
Australia	Australian Pesticides and Veterinary Medicines Authority	Pesticides Program [NB: this survey has been completed from the standpoint of dietary exposure with input from Food Standards Australia New Zealand. Other exposures to pesticides, e.g. dermal exposure, has been addressed in the survey responses provided by the Australian department of health - Office of chemical safety (OCS)]	Pesticides
Australia	Office of Chemical Safety, Department of Health and Ageing	National Registration Scheme (administered by the Australian Pesticides and Veterinary Medicines Authority)	Pesticides and biocides
Australia	NICNAS	Existing Chemicals Program, National Industrial Chemicals Notification and Assessment Scheme (NICNAS)	Industrial chemicals
Belgium	Institute of Public Health	Involved in evaluation of pesticides, National and European	Pesticides
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Pesticide Evaluations and Registrations under the Pest Control Products Act	Industrial chemicals, chemicals in consumer products, biocides, pesticides, nanomatrials, microbials and semiochemicals (if they have pesticide uses)
Canada	Health Canada - Safe Environments Directorate	Existing and New Substances assessed under the Canadian Environmental Protection Act, 1999	Industrial chemicals, chemicals in consumer products, biocides, pesticides, nanomatrials, biochemicals/biopolymers (e.g. enzyme), living organisms
Denmark	Danish EPA	Surveys of Chemicals in Consumer Products	Chemicals in consumer products
France	ANSES	Biocides PPP Reach	Biocides, PPP, industrial chemicals

Country	Organisation	Name of chemical review programme.	Type of target chemicals.
Germany	BfR	Human health evaluation according to Directive 98/8/EC (biocides) Human health evaluation according to Regulation (EC) No 1107/2009 (pesticides)	Biocides, pesticides
Germany	BfR	Evaluation of dietary exposure in children	Chemicals in food
Germany	German Environmental Survey for Children	German Environmental Survey for children (GerES IV)	Industrial chemicals, chemicals in consumer products, biocides, pesticides, environmental chemicals (metals), tobacco, ETS, mould, PAH, VOCs, Phthalates, POPs
Italy	University of modena	INESE project of nanoecotoxicoly Nanopathology, FP6 EC project	Nanomaterials
Japan	Environmental Risk Assessment Office, Ministry of the Environment	Initial Environmental Risk Assessment	Industrial chemicals
Korea	Korea Food and Drug Administration	Food Safety Evaluation Department	Pesticides
Korea	National Institute of Environmental Research	Risk Assessment of Chemicals in Children's Products	Chemicals in Consumer Products
Mexico	Comision federal para la proteccion contra riesgos sanitarios	It does not have a specific name.	Industrial chemicals, chemicals in consumer products, food additives
Netherlands	RIVM	1. Industrial chemicals: REACH (1907/2007/EC), 2. Consumer Products: EU Directives 88/378/EC,2009/48/EC, 3. Pesticides: Regulation 1107/2009, 4. Biocides: Directive 98/8/EC, 5. Cosmetics: Directive 76/768/EC, Regulation 1223/2009/EC, 6. Veterinary Medicines: Directives 2001/82/EC, 2004/28/EC and 2009/9/EC.	Industrial chemicals
New Zealand	New Zealand Environmental Protection Authority	Hazardous Substances and New Organisms Act 1996 (HSNO). Any hazardous substance that is imported, manufactured or used in NZ must be approved under the HSNo Act.	All above
Norway	Climate and pollution agency	Please see section 14.	
Poland	Nofer Institute of Occupational Medicine	Type of chemical review programme	Pesticides

Country	Organisation	Name of chemical review programme.	Type of target chemicals.
Poland	Institute of Mother and Child, Department of Pharmacology	Safety Assessment of Cosmetics for Children	Cosmetics
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	--	All mentioned above except cosmetics, and indoor air pollutants
South Africa	North-West University	Various research projects	Pesticides
Turkey	MoEU	Programme in accordance with By Law on Inventory and Control of Chemicals	Industrial chemicals
Turkey	Ministry of Health	-	Biocides
US	United States Environmental Protection Agency	Toxic Substances Control Act - new chemical substances	Industrial chemicals, nanomaterials, chemicals in consumer products
US	US EPA/OCSPP	US EPA, Office of Chemical Safety and Pollution prevention, Office of Pollution Prevention and Toxics	Nanomaterials
	ECHA	REACH	Industrial chemicals
	World Health Organization	World Health Organization International Programme on Chemical Safety	All types of chemicals
	Cefic	We do not have a specific chemical review programme; however we have the following programmes of relevance for the topic: - the Long-range Research Programme - www.cefic-lri.org - the Responsible Care - www.cefic.org/Responsible-Care/ - the Global Product Strategy - www.cefic.org/Regulatory-Framework/Voluntary-Initiatives1/Global-Product-Strategy/ These programmes cover some of the issues which questions of this survey refer to. In terms of methodologies and tools for risk assessment of chemicals related to children's health, we can provide the following reference, covering the majority of the questions of the survey: ECETOC Technical Report no.96 (July 2005): Trends in Children's Health and the Role of Chemicals - www.ecetoc.org	All
	Albemarle Europe	OECD HPV, ECETOC JACC, REACH	Industrial chemicals

Type of chemical review programme

3. In your programme, how do you assess the risks of children? *(multiple answers)*
- 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 ( )

Country	Organisation	How do you assess the risks of children?
Australia	Australian Pesticides and Veterinary Medicines Authority	In a specific risk assessment dedicated to the risks to children
Australia	Office of Chemical Safety, Department of Health and Ageing	In a generic way as part of the assessment of consumers and the general public
Australia	NICNAS	In a specific risk assessment dedicated to the risks to children
Belgium	Institute public Health	In a generic way as part of the assessment of consumers and the general public
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	In a specific risk assessment dedicated to the risks to children
Canada	Health Canada - Safe Environments Directorate	In a specific risk assessment dedicated to the risks to children (e.g. for unique scenarios specific to children such as mouthing, object or hand-to-mouth)
Denmark	Danish EPA	In a specific risk assessment dedicated to the risks to children
France	ANSES	In a specific risk assessment dedicated to the risks to children
Germany	BfR (biocides and pesticides)	Both in a generic way as part of the assessment of consumers and the general public, and in a specific risk assessment dedicated to the risks to children
Germany	BfR (dietary exposure)	In a generic way as part of the assessment of consumers and the general public
Germany	German Environmental Survey for Children	In a specific risk assessment dedicated to the risks to children, other modeling daily intake on the basis of HBM-data, comparing with TDI/PTWI/ADI as well as guidance values (drinking water, HBM-Commission, indoor air)
Italy	University of Modena	In a specific risk assessment dedicated to the risks to children
Japan	Environmental Risk Assessment Office, Ministry of the Environment	In a generic way as part of the assessment of consumers and the general public
Korea	Korea Food and Drug Administration	In a generic way as part of the assessment of consumers and the general public
Korea	National Institute of Environmental Research	In a specific risk assessment dedicated to the risks to children
Mexico	Comision federal para la proteccion contra riesgos sanitarios	In a generic way as part of the assessment of consumers and the general public
Netherlands	RIVM	In a generic way as part of the assessment of consumers and the general public
New Zealand	New Zealand Environmental Protection Authority	In a generic way as part of the assessment of consumers and the general public
Norway	Climat- and pollution agency	
Poland	Nofer Institute of Occupational Medicine	In a specific risk assessment dedicated to the risks to children

Country	Organisation	3. How do you assess the risks of children?
Poland	Institute of Mother and Child, Department of Pharmacology	Institute of Mother and Child carries out risk assessment of cosmetics for infants and small children within the framework of "Safety Assessment of Cosmetics for Children". Assessment includes mainly the risk of the ingredients of cosmetic formula (due to their physicochemical properties and toxicological profile) with reference to the children`s age, sensitivity of skin and the type of cosmetic and route of its application. Assessment is based on data and publications found in the medical, toxicological and chemical databases (e.g. The Cochrane Library, MEDLINE, PubMed, EMBASE), publications on safety assessment (e.g. Rogiers V, Pauwels M: Safety Assessment of Cosmetics in Europe. S. Karger AG, Basel, 2008) and opinions of SCCNFP and post-marketing reports sent to the Institute by parents. We don`t study the relationship between the toxic response and the exposure of cosmetic ingredient (dose-response assessment).
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	In a generic way as part of the assessment of consumers and the general public
South Africa	North-West University	In a specific risk assessment dedicated to the risks to children
Turkey	MoEU	We have newly completed prioritisation don't made any assessment
Turkey	Ministry of Health	In a generic way as part of the assessment of consumers and the general public
US	United States Environmental Protection Agency	In a generic way as part of the assessment of consumers and the general public
US	US EPA/OCSPP	We assess all chemicals in a generic way, and have also done risk assessments dedicated to the risks to children. In addition, for compounds like lead or mercury, where specific life stages are important, then risk assessments have focused on those life stage(s).
	ECHA	In a generic way as part of the assessment of consumers and the general public
	World Health Organization	As required, depending on the chemical being assessed
	Cefic	In a generic way as part of the assessment of consumers and the general public and, specifically, if there are certain uses specific only to children
	Albemarle Europe	In a generic way as part of the assessment of consumers and the general public

Definition of children

4. In your programme, do you have a definition of children?
Yes/no
If yes, please provide a brief description of the definition.
Please reference(s) of the document(s) containing the definition (document name, URL if available)

Country	Organisation	4. Definition	A brief description of the definition.	Reference(s)
Australia	Australian Pesticides and Veterinary Medicines Authority	Yes	For puropses of dietary exposure: 2-6 year olds	Food Standards Australia and New Zealand Document: "Principles and practices of dietary exposure assessment for food regulatory purposes" *www.foodstandards.gov.au/scienceandeducation/scienceinfsanz/dietaryexposureassessmentsatfsanz/*
Australia	Office of Chemical Safety, Department of Health and Ageing	Yes	Depending on the risk assessment performed, children can be classified as persons < 18 years."Young children" are classified as between 2-3 years.	Australian Exposure Factor Guidance (draft, 2011).
Australia	NICNAS	Yes	Children defined as up to the age of 15 years. 15 years and onwards is assumed to be an adult	
Belgium	Institute of Public Health	No		
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Yes	From conception to adulthood, including exposure during pregnancy and from lactation.	Science Policy Notice SPN2002-01 Children's Health Priorities within the Pest Management Regulatory Agency *www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2002-01-eng.pdf* 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. 29 July 2008. *www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2008-01-eng.pdf*
Canada	Health Canada - Safe Environments Directorate	Yes	From conception to adulthood, including exposure during pregnancy and from lactation.	Science Policy Notice SPN2002-01 Children's Health Priorities within the Pest Management Regulatory Agency *www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2002-01-eng.pdf*

				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. 29 July 2008. *www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2008-01-eng.pdf*
Denmark	Danish EPA	No		
France	ANSES	No		
Germany	BfR (biocides and pesticides)	No		
Germany	BfR (dietary exposure)	Yes	Age < 18 years.	
Germany	German Environmental Survey for Children	Yes	Child = 3-14 years old	1) German Environmental Survey for Children 2003/06 - GerES IV - Human Biomonitoring, K. Becker; M. Müssig-Zufika; A. Conrad; A. Lüdecke; C. Schulz; M. Seiwert; M. Kolossa-Gehring, Levels of selected substances in blood and urine of children in Germany, WaBoLu-Hefte (Reihe geschlossen) Nr. 01/2008 UBA-FBNr: 001026, FKZ: 202 62 219, 2008 Umweltbundesamt, URL: *www.umweltbundesamt.de/uba-info-medien-e/mysql_medien.php?anfrage=Kennummer&Suchwort=3355* 2) Christine Schulz*, Margarete Seiwert, Wolfgang Babisch, Kerstin Becker, André Conrad, Regine Szewzyk, Marike Kolossa-Gehring: Design of the German Environmental Survey on Children 2003-2006 (GerES IV), accepted: Int. J. Hyg. Environ. Health
Italy	University of Modena	No		185 Antonietta M. Gatti1, Paolo Bosco2, Francesco Rivasi1, Sebastiano Bianca3, Giuseppe Ettore3, Luigi Gaetti4, Stefano Montanari5, Giovanni Bartoloni6, Diego Gazzolo7, Heavy metals nanoparticles in fetal kidney and liver tissues, Frontiers in Bioscience (Elite edition) 2011;3:221-6
Japan	Environmental Risk Assessment Office, Ministry of the Environment	No		
Korea	Korea Food and Drug Administration	Yes	Children : age under 19	Korea National Health and Nutrition Examination Survey
Korea	National Institute of	Yes	Person under the age of 13	Risk assessment guidelines

	Environmental Research			
Mexico	Comision federal para la proteccion contra riesgos sanitarios	Yes	Nursing under 1 year, 1-4 years and 5-14 years.	
Netherlands	RIVM	Yes	In most frameworks, no specific definition is given for children. A division in categories is in many cases driven by the use scenarios or by age categories used in an exposure model. Some definitions: Crom, 1994 < 1 month neonate1-23 months infant 2-12 years child 13-18 years adolescent WHO: <birthbirth-month 1 month-24 months 2 year-6 year 6 year-12 year12 year-18 year	Index Medicus (Crom, 1994) WHO
New Zealand	New Zealand Environmental Protection Authority	No		
Norway	Climat- and pollution agency			
Poland	Nofer Institute of Occupational Medicine	Yes		
Poland	Institute of Mother and Child, Department of Pharmacology	No		
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	No		We define categories according to age in a case by case basis
South Africa	North-West University	No	Usually younger than 16	
Turkey	MoEU	No		
Turkey	Ministry of Health	No		
US	United States Environmental Protection Agency	No		
US	US EPA/OCSPP	Yes	The study of adverse effects on the developing organism that may result	From the US EPA Guidelines for Developmental Toxicity Risk Assessment at

		from exposure prior to conception (either parent), during prenatal development, or postnatally to the time of sexual maturation. Adverse developmental effects may be detected at any point in the lifespanof the organism.	*www.epa.gov/raf/pubyear.htm*
ECHA	No		
World Health Organization	Yes	WHO uses 18 years of age, consistent with the UN Convention on the Rights of the Child, ie "child means every human being below the age of eighteen years unless under the law applicable to the child, majority is attained earlier." This Convention been ratified by 192 countries and is a legally binding international instrument.	UN Convention on the Rights of the Child *www.unicef.org/crc/*
Cefic	No		
Albemarle Europe	No		

Definition of children

5. In your programme, do you differentiate between different age groups?
Yes/no
If yes, please provide a brief description of the age groups.
please provide a reference(s) of the document(s) containing the age groups (document name, URL if available)

Country	Organisation	5. age grouping	A brief description of the age groups.	Reference(s)
Australia	Australian Pesticides and Veterinary Medicines Authority	No		NB - For children we only do dietary risk assessments for 2-6 years olds - above this age is considered as part of the general population assessment.
Australia	Office of Chemical Safety, Department of Health and Ageing	Yes	Depending on the risk assessment performed, children can be classified as persons < 18 years, and can be further defined into narrower age band as necessary. "Young children" are classified as between 2-3 years.	Australian Exposure Factor Guidance (draft, 2011)
Australia	NICNAS	Yes	Exposures to children are estimated for 3 representative age groups: infants (1-6 months), toddlers (2 years) and children (12 years). The children's age groups are selected across several key life stages (infancy, childhood, and adolescence) and take into account the differences in exposure with the life stages.	US EPA (2002) Child-specific exposure factors handbook - interim report *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55145*
Belgium	Institute public Health	No		
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Yes	For dietary exposures, the following populations are considered: the general population (all individuals), infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49 (child-bearing age) and adults 50+ yr old. For non-dietary exposures, depending on the scenario: infants 0.5 - 1.5; toddlers 1-2 or 3; children 6 or 3 to 6; children 6 -11; youths 10 to 12 or 11 - 16; and adults	Health Effects Division, Office of Pesticide Programs, U.S. EPA, Transition to 1994-96/1998 CSFII and Modification of Age Groups of Regulatory Interest (September 26, 2002). Draft. Standard Operationg Procedures (SOPs) for Residential Exposure Assessments. Office of Pesticide Programs, U.S. EPA. December 18, 1997. *www.epa.gov/pesticides/trac/science/trac6a05.pdf* Draft Technical Guidelines. Standard Operating Procedures for Assessing Residential Pesticide Exposure.

			18+ or 16+ yr old.	Submitted to the FIFRA Scientific Advisory Panel for Review and Comment. October 6-9, 2009. Office of Pesticide Programs, U.S. EPA. September 8, 2009
Canada	Health Canada - Safe Environments Directorate	Yes	• Infants (age 0-0.5 years) – Breast fed, formula fed and non-formula fed • Toddlers (age 0.5-4 years old) • Children (age 5-11 years old) • Teens (age 12-19 years old) • Adults (age 20-59 years old) • Senior (age 60-70 years old)	- Exposure Factors for assessing total daily intake of priority substances by the general population of Canada - Bureau of Chemical Hazard, Environmental Health Directorate, Health Canada. 1998. (Unpublished document) - Health Canada - Investigating Human Exposure to Contaminants in the Environment: A Handbook for Exposure Calculations, 1995. (*dsp-psd.pwgsc.gc.ca/Collection/H49-96-1-1995E-1.pdf*);
Denmark	Danish EPA	Yes	The differentiation between the age groups depend on the type of products being investigated	*www.mst.dk/English/Chemicals/Consumer_Products/Surveys-on-chemicals-in-consumer-products.htm*
France	ANSES	Yes	children: 1-3 years children > 3 years	
Germany	BfR (biocides and pesticides)	Yes	Biocides: Infants (6-12 months), children (6-<11 years), adults (20 years and above) Pesticides: Dietary risk assessment: children (in Germany: 2-<5 years; age range differs for each country), adults non-food exposure assessment: children (3-5 years)	Biocides: no reference available at this point, since the age groups are from a proposal on physiological paramters by the Human Exposure Expert Group (HEEG). Pesticdes: Banasiak U et al. Abschatzung der Aufnahme von Pflanzenschutzmittel-Ruckstanden in der Nahrung mit neuen Verzehrsmengen fur Kinder (Estimation of the dietary intake of pesticides residues based on new consumption data for children). Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 2005. 48: 84-93 (German language version available only)
Germany	BfR (dietary exposure)	Yes	Infants (6-24 months), Children (2-6 years)(6-10 years)(11-16 years)	Due to food consumption surveys in Germany (VELS, Eskimo)

Germany	German Environmental Survey for Children	Yes	3-5 years 6-8 y (7-8 for PCB) 9-11 y 12-14 y	See above: 4 1)
Italy	University of Modena	Yes	fetuses	
Japan	Environmental Risk Assessment Office, Ministry of the Environment	No		
Korea	Korea Food and Drug Administration	Yes	infant and baby : 0-2 years juvenile : 12-18 years school children : 7-18 years	Korea National Health and Nutrition Examination survey
Korea	National Institute of Environmental Research	No		
Mexico	Comision federal para la proteccion contra riesgos sanitarios	Yes	6-11 months, 2 years, 6 years, 10 years and 14-16 years.	This is a consumption database originally published by the USFDA. (*www.fda.gov/Food/FoodSafety/FoodCntaminantsAdulteration/TotalDietStudy/ucm184232.htm*)
Netherlands	RIVM	Yes	With regard to the assessment of chemical substances (espicially for regulatory frameworks):Hazard characterization is usually based on studies in laboratory animals. In most cases, toxicological studies in which young animals are exposed to the test substance are included (1- and 2 generation studies of reproductive toxicity, extended one-generation study of reproductive toxicity, developmental neurotoxicity). These studies may indicate specific critical endpoints for young animals, and differences in sensitivity to toxic effects between young and adult mammals. Generally, data on effects of a substance in adult or young humans are not available.	OECD guidelines 415, 416, 421, 422, 426, 443OECD guidance documents
New Zealand	New Zealand Environmental	Yes	When looking at modelling estimates, we focus on	

	Protection Authority		toddlers or young children. The age used depends on the circumstances of the substance being assessed. For example, a chemical that will be used domestically by consumers will use a lower age group in modelling than a VTA that is used in forests and only much older children could potentially be exposed to it.	
Norway	Climat- and pollution agency			
Poland	Nofer Institute of Occupational Medicine	Yes		
Poland	Institute of Mother and Child, Department of Pharmacology	Yes	- Newborns (neonates) - from 1 to 28 days of life;- Infants - the first 12 months of life;- Small children - 13-36 months	Classification used in Polish pediatrics
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	No		Not in a systematic way. only according to exposure route and/or usages
South Africa	North-West University	Yes	Infants (0-2 years)Children (2-16 years)	
Turkey	MoEU			
Turkey	Ministry of Health	No		
US	United States Environmental Protection Agency	No		
US	US EPA/OCSPP	Yes	Different age groups may be warranted based on toxicity, exposure, and/or requirements under law. In each of these cases different age groupings have been used based on the specifics of the case.	EPA does have guidance for selecting age groups for exposure which can be found at *www.epa.gov/raf/publications/guidance-on-selecting-age-groups.htm*
	ECHA	No		
	World Health Organization	Yes	See Table 1, in EHC 237, which provides working definitions of a number of different age groups. *www.who.int/entity/ipcs/publications/ehc/ehc237.pdf* In addition, WHO is in the process of developing guidance that proposes a	*www.who.int/entity/ipcs/publications/ehc/ehc237.pdf* *www.who.int/ipcs/en/*

		globally harmonized set of age bins for chemical risk assessment. The draft is open for comment until 31 January 2012, from the IPCS home page: www.who.int/ipcs/en/
Cefic Albemarle Europe	No	

Hazard Assessment

6. In your programme, do you perform specific hazard assessments for children?
Yes/no
If yes, please specify for which hazard endpoints a specific assessment is performed.

Country	Organisation	6. Specific hazard assessments for children	Hazard endpoints performed in a specific assessment
Australia	Australian Pesticides and Veterinary Medicines Authority	No	
Australia	Office of Chemical Safety, Department of Health and Ageing	No	
Australia	NICNAS	Yes	Developmental hazard endpoint. For other endpoints child specific risk assessments are conducted.
Belgium	Institute public Health	No	
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Yes	All relevant endpoints as per OECD or USEPA protocols of animal toxicity studies of various durations and routes (oral, dermal and inhalation) from single, multiple or lifelong exposures including potential for causing cancer, genetic alterations, neurotoxicity, reproductive effects (including endocrine disruption) and effects on pre- and post-natal development, and sensitivity to the young.
Canada	Health Canada - Safe Environments Directorate	Yes	All relevant endpoints as per OECD or USEPA protocols of animal toxicity studies of various durations and routes (oral, dermal and inhalation) from single, multiple or lifelong exposures including potential for causing cancer, genetic alterations, neurotoxicity, reproductive effects (including endocrine disruption) and effects on pre- and post-natal development, and sensitivity to the young.
Denmark	Danish EPA	Yes	We do not perform hazard assessment for children, but only for the substances. We only assess the risks for children.
France	ANSES	No	
Germany	BfR (biocides and pesticides)	No	-
Germany	BfR (dietary exposure)	-	-
Germany	German Environmental Survey for Children	No	
Italy	University of Modena	Yes	Nanoparticles inhaled or ingested by the mother can be translocated to the fetus and damage it.
Japan	Environmental	No	

	Risk Assessment Office, Ministry of the Environment		
Korea	Korea Food and Drug Administration	No	
Korea	National Institute of Environmental Research	No	
Mexico	Comision federal para la proteccion contra riesgos sanitarios	No	
Netherlands	RIVM	Yes	If yes, please specify for which hazard endpoints a specific assessment is performed. Hazard characterization is usually based on studies in laboratory animals. In most cases, toxicological studies in which young animals are exposed to the test substance are included (1- and 2 generation studies of reproductive toxicity, extended one-generation study of reproductive toxicity, developmental neurotoxicity). These studies may indicate specific critical endpoints for young animals, and differences in sensitivity to toxic effects between young and adult mammals. Generally, data on effects of a substance in adult or young humans are not available.NL is involved in studies of environmental pollutants in children cohorts (in Norway)
New Zealand	New Zealand Environmental Protection Authority	No	
Norway	Climat- and pollution agency		
Poland	Nofer Institute of Occupational Medicine	No	
Poland	Institute of Mother and Child, Department of Pharmacology	Yes	
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,		
South Africa	North-West University	Yes	Exceedance of MRL and ADI Risk of cancer Endocrine disruption
Turkey	MoEU	No	
Turkey	Ministry of Health	No	
US	United States	No	

	Environmental Protection Agency		
US	US EPA/OCSPP	Yes	Potential hazards to children are routinely assessed based on data from a developmental toxicity, or reproductive toxicity, or a screening study like OECD 421/422; the data may be from an analog chemical or the chemical itself. In addition, certain chemicals are known to have specific hazards to children like lead and mercury, and these assessments have focused on neurological endpoints in children. Finally, EPA had a pilot program called the Voluntary Children's Chemical Evaluation Program launched in 2000 which focused on the testing and assessment of 23 chemicals to which children had a high likelihood of being exposed (*www.epa.gov/oppt/vccep/pubs/basic.html*).
	ECHA	No	
	World Health Organization	Yes	The specificity of the assessment is defined by the problem formulation for the chemical concerned.
	Cefic		
	Albemarle Europe	No	

Hazard Assessment

7. Do you have guidance or tools on methodology for hazard assessment for children?
Yes/no
If yes, please provide the name of the guidance or tools, and brief description.
please provide a reference(s) of the document(s) containing the methodology. (document name, URL if available)

Country	Organisation	7. Guidance or tools on hazard assessment for children	Name of the guidance or tools, as well as a brief description.	reference(s)
Australia	Australian Pesticides and Veterinary Medicines Authority	No		
Australia	Office of Chemical Safety, Department of Health and Ageing	No		
Australia	NICNAS	No		
Belgium	Institute public Health	No		
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Yes	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. 29 July 2008. *www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2008-01-eng.pdf* Regulatory Directive DIR2005-01 Guidelines for Developing a Toxicological Database for Chemical Pest Control Products. 27 May 2005. *www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/dir/dir2005-01-eng.pdf*	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. 29 July 2008. *www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2008-01-eng.pdf* Regulatory Directive DIR2005-01 Guidelines for Developing a Toxicological Database for Chemical Pest Control Products. 27 May 2005. *www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/dir/dir2005-01-eng.pdf* plus various OECD Guidance Documents on endpoints from hazard testing.

			The first document describes how the PMRA addresses the additional 10-fold margin of safety intended to provide additional protection for infants and children as required under the Pest Control Products Act. The second document outlines toxicological data requirements for pesticides, including many studies which address endpoints related to children's health.	
Canada	Health Canada - Safe Environments Directorate	Yes	Various, including OECD Guidance documents on endpoints from hazard testing.	Various, including OECD Guidance documents on endpoints from hazard testing.
Denmark	Danish EPA	No		
France	ANSES	No		
Germany	BfR (biocides and pesticides)	No	-	-
Germany	BfR (dietary exposure)	-	-	-
Germany	German Environmental Survey for Children	No		
Italy	University of Modena	No		
Japan	Environmental Risk Assessment Office, Ministry of the Environment	No		
Korea	Korea Food and Drug Administration	No		
Korea	National Institute of Environmental Research	Yes	Risk assessment guidelines	
Mexico	Comision federal para la proteccion contra riesgos sanitarios	No		
Netherlands	RIVM	Yes	See answers to earlier question. Furthermore: In the REACH text, it is	*http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r8_en.pdf?vers=16_12_10*

stated (Annex I; article 1.4.1) that "…..¦taking into account the available information and the exposure scenario(s) in Section 9 of the Chemical Safety Report it may be necessary to identify different DNELs for each relevant human population (e.g. workers, consumers and humans liable to exposure indirectly via the environment) and possibly for certain vulnerable sub-populations (e.g. children, pregnant women) and for different routes of exposure…….". This is repeated in the Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health. REACH guidance states that in order to always cover the most sensitive person exposed to any chemical, it would require a very large default assessment factor. That is of course not workable and it is usually assumed that a default assessment factor of 10 is sufficient to protect the larger part of the population, including e.g. children and the elderly. For threshold effects, this factor of 10 is the standard procedure, as a default, when assessing exposure to the general population. It is recognized that there are differences between children and adults in toxicokinetics (especially babies in their first

			months) and toxicodynamics (especially at different stages of development). These differences may render children more or less susceptible to the toxic effects of a substance. A higher intraspecies assessment factor for children should be considered when the following two criteria are both fulfilled: 1. There are indications, obtained from, for example, experiments in adult animals, epidemiological studies, in vitro experiments and/or SARs (structure activity relationships), of effects on organ systems and functions that are especially vulnerable under development and maturation in early life (in particular the nervous, reproductive, endocrine and immune systems and also the metabolic pathways), and 2. There are deficiencies in the database on such effects in young animals.	
New Zealand	New Zealand Environmental Protection Authority	No		
Norway	Climat- and pollution agency			
Poland	Nofer Institute of Occupational Medicine			
Poland	Institute of Mother and Child, Department of Pharmacology	No		
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	No		
South Africa	North-West University	Yes	Calculations based on intake, and or exposure	Bouwman, H., Kylin, H. 2009. Malaria control insecticide residues in breastmilk: The need to consider infant

				health risks. Environmental health perspectives. 117:1477-1480. (Supplementary review online) Bouwman, H., Sereda, B., Meinhardt, R.H. 2006. Simultaneous presence of DDT and pyrethroid residues in human breast milk from a malaria endemic area in South Africa. Environmental pollution. 144:902-917. Eskenazi, B., Chevrier, J., Goldman Rosas, L., Anderson, H.A., Bornman M.S., Bouwman, H., Chen, A., Cohn, B.A., de Jager, C., Henshel, D.S., Leipzig, F., Leipzig, J.S., Lorenz, E.C., Snedeker, S.M., Stapleton, D. 2009. The Pine River Statement: Human health consequences of DDT use. Environmental health perspectives, 117:1359-1367. Quinn, L., Pieters, R., Nieuwhoudt, C., Borgen, A.R., Kylin, H., Bouwman, H. 2009. Distribution profiles of selected organic pollutants in soils and sediments of industrial, residential and agricultural areas of South Africa. Journal of environmental monitoring. 11:1647-1657. Nieuwhoudt, C., Quinn, L.P., Pieters, R., Jordaan, I., Visser, M., Kylin, H., Borgen, A.P., Giesy, J.P., Bouwman, H. 2009. Dioxin-like chemicals in soil and sediment from residential and industrial areas in central South Africa. Chemosphere. 76:774-783.
Turkey	MoEU	No		
Turkey	Ministry of Health	No		
US	United States Environmental Protection Agency	No		
US	US EPA/OCSPP	Yes	Guidelines for Developmental Toxicity Risk Assessment, guidelines for Reproductive Toxicity Risk Assessment, as well as others.	All are available at *www.epa.gov/raf/pubyear.htm*
	ECHA	Yes	REACH Guidance for chemical safety assessment, R.8.4.3.1., deals with assessing the risks of children. It recommends using intraspecies assessment factors to cover the	REACH guidance is available under the following link: *http://guidance.echa.europa.eu/*

		greater sensitivity of children to toxic effects. We quote: “It is recognised that there are differences between children and adults in toxicokinetics (especially babies in their first months) and toxic dynamics (especially at different stages of development). These differences may render children more or less susceptible to the toxic effects of a substance. A higher intraspecies assessment factor for children (US-EPA, 1996, recommends from 10 up to 100 when assessing pesticides in relation to food safety) should be considered when the following two criteria are both fulfilled: - There are indications,…of effects on organ systems and functions that are especially vulnerable under development and maturation in early life (in particular the nervous, reproductive, endocrine and immune systems and also the metabolic pathways), and - There are deficiencies in the database on such effects in young animals.”	
World Health Organization	Yes	EHC 237 Principles for Evaluation Health Risks in Children Associated with Exposure to Chemicals.	*www.who.int/entity/ipcs/publications/ehc/ehc237.pdf*
Cefic Albemarle Europe	Yes	Environmental Genotoxins in Children and Adults (Published August 2006) Mutation Research/Genetic Toxicology and Environmental Mutagenesis 608(2)	*http://guidance.echa.europa.eu/docs/guidance_document/information_requirementswww.ecetoc.org*

Heinrich J. 2011 Influence of indoor factors in dwellings on the development of childhood asthma, International Journal of Hygiene and Environmental Health 214:1-25 (submitted and accepted in 2010)
ECETOC TR 96 Trends in Children's Health and the Role of Chemicals: State of the Science Review (Published June 2005)
REACH guidance on information requirements and chemical safety assessment R7, R8

Exposure assessment

8. In your programme, do you perform specific exposure assessments for children?
Yes/no
If yes, have you developed specific exposure scenarios for children?
Yes/no
If yes, do you focus on specific exposure pathway(s)/media in the exposure scenario? (multiple answers if applicable)
Air, water, soil, food, contact with articles (e.g. toys), other please specify ( ).

Country	Organisation	8. specific exposure assessments for children	specific exposure scenarios for children	specific exposure pathway(s)/media in the exposure scenario
Australia	Australian Pesticides and Veterinary Medicines Authority	Yes	Yes	Food
Australia	Office of Chemical Safety, Department of Health and Ageing	Yes	Yes	residues on turf, domestic floors, pet hair
Australia	NICNAS	Yes	Yes	Soil
Belgium	Institute public Health	Yes	No	soil
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Yes	Yes	air, water, soil, food, contact with articles (e.g. toys), contact with pets, grass and foliage; contact with other treated surfaces (carpets, bedding); ingestion of granules (granular pesticides); personal insect repellents; hand-to-mouth transfer for various scenarios; incidental oral.
Canada	Health Canada - Safe Environments Directorate	Yes	Yes	air, water, soil, food, contact with articles (e.g. toys), exposure from dust and products (e.g. personal care products); direct exposure to cosmetic- and personal care-type products
Denmark	Danish EPA	Yes	Yes	contact with articles (e.g. toys)
France	ANSES	Yes	Yes	all pathways are considered
Germany	BfR (biocides and pesticides)	Yes	Yes	Biocides: food; contact with articles; other: accidental contact with biocidal product. Pesticides: food; residential (mouthing); bystander (same scenario as for adults, but with a different body weight)
Germany	BfR (dietary exposure)	Yes	Yes	Soil, food

Germany	German Environmental Survey for Children	Yes	Yes	air, water, food, housedust, ETS, noise, time-location pattern, use of household products, pesticides
Italy	University of Modena	Yes	Yes	air
Japan	Environmental Risk Assessment Office, Ministry of the Environment	No		
Korea	Korea Food and Drug Administration	Yes	No	food
Korea	National Institute of Environmental Research	Yes	Yes	contact with articles (e.g. toys)
Mexico	Comision federal para la proteccion contra riesgos sanitarios	Yes	Yes	air, water, soil, food, contact with articles, paints and glazed earthenware
Netherlands	RIVM	Yes	Yes	air
New Zealand	New Zealand Environmental Protection Authority	Yes	Yes	Soil, contact/dermal
Norway	Climat- and pollution agency			
Poland	Nofer Institute of Occupational Medicine	Yes	Yes	contact with articles (e.g. toys)
Poland	Institute of Mother and Child, Department of Pharmacology	No		
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	Yes	Yes	air and soil
South Africa	North-West University	Yes	Yes	water
Turkey	MoEU	No	No	
Turkey	Ministry of Health	No		air
US	United States Environmental	No	No	

	Protection Agency			
US	US EPA/OCSPP	Yes	Yes	All except food
	ECHA	Yes	Yes	All mentioned above (screen did not take multiple answers. In the consumer guidance (R15) some exposure assessments are only for children, e.g. oral exposures with plastic articles. All routes/media of exposure apply, depending on the chemical, its uses and whether there is also indirect human exposure to it. So, it is case by case. See also the answer provided to question No.9.
	World Health Organization	Yes	No	
	Cefic	Yes	Yes	contact with articles (e.g. toys)
	Albemarle Europe	Yes	Yes	contact with articles (e.g. toys)

Exposure assessment

9. Do you have guidance or tools on methodology for exposure assessment for children?
Yes/no
If yes, please provide the name of the guidance or tools, and brief description.
please provide a reference(s) of the document(s) containing the methodology. (document name, URL if available)

Country	Organisation	9. Guidance or tools on exposure assessment for children?	Name of the guidance or tools, and a brief description.	Reference(s)
Australia	Australian Pesticides and Veterinary Medicines Authority	No	We use the same methodology as for adults, but just use different parameters detailed in Food Standards Australia and New Zealand Document- "Principles and practices of dietary exposure assessment for food regulatory purposes"	*www.foodstandards.gov.au/scienceandeducation/scienceinfsanz/dietaryexposureassessmentsatfsanz/*
Australia	Office of Chemical Safety, Department of Health and Ageing	Yes	US EPA Child-on-turf exposure model (where appropriate)Manual of Requirements and Guidelines (MORAG) for agricultural/veterinary product registration	*www.epa.gov/oppfead1/trac/science/trac6a05.pdf* *www.apvma.gov.au/registration/morag/index.php*
Australia	NICNAS	Yes	Internationally accepted guidance used such as US EPA (2002) Child-specific exposure factors handbook - interim report *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55145* enHealth (2003) Australian exposure assessment handbook: Consultation draft. Environmental Health Council (enHealth), Department of Health and Ageing, Commonwealth of Australia, Canberra.	
Belgium	Institute public Health	Yes	guidance for post application exposure assessment (Europoem)	guidance for post application exposure assessment (Europoem)
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Yes	Dietary exposure is based on field trials and metabolism studies ("Revisions to the Residue Chemistry Crop Field Trial Requirements","Residue Chemistry Guidelines"). Further guidance on handling dietary exposure data and conducting the risk assessment is available, including special	Health Effects Division, Office of Pesticide Programs, U.S. EPA, Transition to 1994-96/1998 CSFII and Modification of Age Groups of Regulatory Interest (September 26, 2002). Draft. Standard Operationg Procedures (SOPs) for

	consideration of children's dietary habits ("Estimating the Water Component of a Dietary Exposure Assessment","Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probablistic Risk Assessment","Assessing Exposure from Pesticides in Food. A User's Guide","Assigning Values to Nondetected / Nonquantified Pesticide Residues in Food", "Chossing a Percentile of Acute Dietary Exposure as a Threshold of Concern"). "Standard Operationg Procedures (SOPs) for Residential Exposure Assessments" and "Standard Operating Procedures for Assessing Residential Pesticide Exposure" are U.S. EPA guidelines for conducting non-dietary exposure assessments of pesticides used in residential areas. Inputs specific for children are included.	Residential Exposure Assessments. Office of Pesticide Programs, U.S. EPA. December 18, 1997. *www.epa.gov/pesticides/trac/science/trac6a05.pdf* Draft Technical Guidelines. Standard Operating Procedures for Assessing Residential Pesticide Exposure. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment. October 6-9, 2009. Office of Pesticide Programs, U.S. EPA. September 8, 2009 Regulatory Directive DIR2010-05 Revisions to the Residue Chemistry Crop Field Trial Requirements. 21 December 2010. *www.hc-sc.gc.ca/cps-spc/alt_formats/pdf/pubs/pest/pol-guide/dir2010-05/dir2010-05-eng.pdf* Regulatory Directive DIR98-02 Residue Chemistry Guidelines. 1 June 1998. *www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir98-02/index-eng.php* Science Policy Notice SPN2004-01 Estimating the Water Component of a Dietary Exposure Assessment. 30 April 2004. *www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2004-01-eng.pdf* Science Policy Notice SPN2003-05 Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probablistic Risk Assessment. November 28, 2003. *www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2003-05-eng.pdf* Science Policy Notice SPN2003-03 Assessing Exposure from Pesticides in Food. A User's Guide. July 28, 2003.

				www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2003-03-eng.pdf Science Policy Notice SPN2003-02 Assigning Values to Nondetected / Nonquantified Pesticide Residues in Food. July 28, 2003. *www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2003-02-eng.pdf* Science Policy Notice SPN2003-01 Chossing a Percentile of Acute Dietary Exposure as a Threshold of Concern. July 28, 2003. *www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pol-guide/spn/spn2003-01-eng.pdf*
Canada	Health Canada - Safe Environments Directorate	Yes	We do have guidance on the intake parameters used to estimate exposure to children from the environment (air, water, soil and food). These values are in the document referred to above (Exposure Factors for assessing total daily intake of priority substances by the general population of Canada). We are in the process of developing various guidance and standard operating procedures for exposure assessment in general including methodology for assessing mouthing exposures by children. When child-specific scenarios are needed in an assessment, we use a variety of information sources and models depending on the chemical being assessed and the product or article it is found in. Some of the documents that we use include: • Child-specific exposure factors handbook (US EPA) *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=199243#Download* • ConsExpo Model and Factsheets (RIVM) *www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp* We are developing internal	Exposure and Fate Assessment (E-FAST) Screening Tool Documentation Manual (*www.epa.gov/oppt/exposure/pubs/efast2man.pdf*), EPA Exposure Factors Handbook (*www.epa.gov/ncea/efh/pdfs/efh-complete.pdf*), ConsExpo & Fact Sheets (*www.rivm.nl/*)

			guidance for mouthing scenarios, defaults used for personal care product scenarios as well as ink scenarios.	
Denmark	Danish EPA	Yes	We use:- REACH guidance- US EPA guidance- EU Cosmetics guidance	
France	ANSES	Yes	PPP: BREAM (Defra)biocides: CONSEXPO (RIVM)	
Germany	BfR (biocides and pesticides)	Yes	Biocides: - TNsG on Human Exposure, Technical Guidance Document on Risk Assessment, proposal by HEEG on physiological parameters (not published yet, see also question 5) Pesticides: - Maritin et al., 2008. Guidance for Exposure and Risk Evaluation for Bystanders and Residents exposed to Plant Protection Products during and after Application, J. Verbr. Lebensm. 3, 272- 281. - No specific guidance for dietary risk assessment of children. Dietary risk assessment is performed for children with the same method used for other age groups. If children are the worst-case, their dietary exposure estimate is used to represent the entire population.	Biocides: - TNsG on Human Exposure (2007): *http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/TNsG/TNsG_ON_HUMAN_EXPOSURE/TNsG%20-Human-Exposure-2007.pdf.* - Technical Guidance Document on Risk Assessment: *http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/tgd.*
Germany	BfR (dietary exposure)	Yes	Guidance document for harmonised exposure assessment (AUH-Report)	Arbeitsgemeinschaft der leitenden Medizinalbeamtinnen und -beamten der Lander. Bericht des Ausschusses fur Umwelthygiene (1995) Standards zur Expositiosanbschatzung. Herausgeber: Behorde fur Arbeit, Gesundheit und Soziales, Hamburg
Germany	German Environmental Survey for Children	Yes	1) German drinking water ordinance 2) HBM and reference values of the German HBM Commission of the Federal Environment Agency (UBA) 3) Indoor guide values developed by an ad-hoc working group composed of members of the Federal Environment Agency's Indoor Air Hygiene Commission (IRK) and the Permanent Working Group of the Highest State Health Authorities(AOLG)	1) *www.umweltbundesamt.de/wasser-e/themen/trinkwasser/gesetze.htm* 2) *www.umweltbundesamt.de/gesundheit-e/monitor/definitionen.htm* 3) *www.umweltbundesamt.de/gesundheit-e/innenraumhygiene/richtwerte-irluft.htm*

			4) Database RefXP: contains exposure factors derived from GerES IV, standard approach for deriving exposure factors (e. g. body weight, inhalation rates, etc.) from survey data incl. GerEs IV	4) *www.umweltbundesamt.de/xprob*; Mekel,OCL, Mosbach-Schulz, O; Schümann, M; Okken, P K; Peters, C; Herrmann, J; Hehl, O; Bubbenheim, M; Wintermeier, D; Fehr, R; Timm, J: Distributional exposure reference values for Germany; ISEE/ISEA 2006 Conference Abstracts Supplement: Symposium Abstracts: Abstracts, November 2006 –Volume 17, Issue6, pS474
Italy	University of Modena	No	I see the nanoparticles in the internal organs. That is the exposure they suffered. It can be evaluted as morphology and size of partciles and chemical composition, but not yet as number.The particles can be traced in the environment where the mother lived and the source of nanoparticles sometimes is identified.	
Japan	Environmental Risk Assessment Office, Ministry of the Environment	No		
Korea	Korea Food and Drug Administration	No		
Korea	National Institute of Environmental Research	Yes	Risk assessment guldelines Oral/Dermal/Inhalation exposure Scenario	
Mexico	Comision federal para la proteccion contra riesgos sanitarios	Yes	In most cases using specific methods published by international organisations or agencies of other governments, preferably using validated methods. In the least number of cases we use our own methods based on the available information.	
Netherlands	RIVM	Yes	Additional comments to question 8: In the case of exposure to chemicals from consumer products, mouthing of articles is taken into account. Dermal contact via crawling on floors might be relevant. The intake of house dust might also be relevant (also for adults). In addition the children's small ratio of body size	REACH.Guidance on information requirements and chemical safety assessment Chapter R.15: Consumer exposure estimation. *http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r15_en.pdf?vers=20_08_08*

			to surface area, compared to that of adults, may have a crucial effect on the exposure estimates. To be added: food intake (specific child data especially for assessment of contaminants and pesticides)Additional comments to question 9:REACH.Guidance on information requirements and chemical safety assessment Chapter R.15: Consumer exposure estimation. In this document, exposure scenarios (such as crawling, house dust, hand-mouth contact) are mentioned. Further, some defaults for exposure parameters and references to more information are given to estimate the consumer exposure specific for children.	TNsG/TGD (for biocides, pesticides) CONSEXPO. Consumer exposure model Accompanying factsheets:* H.J. Bremmer, L.C.H. Prud'homme de Lodder, J.G.M. van Engelen. General Fact Sheet Limiting conditions and reliability, ventilation, room size, body surface area. Updated version for ConsExpo 4 RIVM report 320104002/2006* Bremmer, H.J. and M.P. van Veen, 2002 Children's Toys Fact Sheet. Bilthoven, The Netherlands: National Institute for Public Health and the Environment (RIVM). Report no. 612810 012.* Engelen, J.G.M. van, L.C.H. Prud'homme de Lodder, 2004 Non-food products: How to assess children's exposure? Bilthoven, The Netherlands: National Institute for Public Health and the Environment (RIVM). Report 320005001.* H.J. Bremmer, L.C.H. Prud'homme de Lodder, J.G.M. van Engelen Cosmetics Fact Sheet To assess the risks for the consumer. Updated version for ConsExpo 4. RIVM report 320104001/2006* L.C.H. Prud'homme de Lodder, H.J. Bremmer, J.G.M. van Engelen. Cleaning Products Fact Sheet. To assess the risks for the consumer. RIVM report 320104003/2006* Burg W ter, Bremmer HJ, Engelen JGM van. Oral exposure of children to chemicals via hand-to-mouth contact RIVM rapport 320005004/2007
New Zealand	New Zealand Environmental Protection Authority	No		
Norway	Climat- and pollution agency			
Poland	Nofer Institute of Occupational	Yes	The assessment of exposure is based on analysis performed in	Risk characterisation

	Medicine		NIOM laboratory with accredited methods.	
Poland	Institute of Mother and Child, Department of Pharmacology	No		
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	Yes	for calculations of the intake through air either default factor 2 [1] or calculation using Standard ICRP data (ICRP Publ. No.23) / WHO/IPCS EHC 210. In the risk assessment done as a basis for the PCB guideline value for indoor air, we did a short sensitivity analysis by calculating threshold concentrations with using different levels of breathing volumes, with Standard data for 10 year old children and men, women. For the ingestion through house dust, the focus is on playing children. There are different figures on the amount of ingested house dusts [2,3]; as a standard approach we choose 100mg dust per day, but calculate a range of 10 to 100 mg dust per day which we see as a realistic (10) and a high (100) scenario, where as the high scenario includes the higher exposed age group 1-6 years. For pesticides RIVM Factsheet is used to define parameter in Consexpo Tool [4]	[1] Ad-hoc-Arbeitsgruppe aus Mitgliedern der Innenraumlufthygiene-Kommission (IRK) des Umweltbundesamtes und des Ausschusses fur Umwelthygiene der AGLMB. Richtwerte fur die Innenraumluft: Basisschema. Bundesgesundheitsblatt 39 (1996) S. 422-425[2] Butte W. and Heinzow, B. Pollutants in House Dust as Indicators of Indoor Contamination. Rev Environ Contam Toxicol. 2002;175:1-46.[3] Seifert B. Die Untersuchung von Hausstaub im Hnblick auf Expositionsabschatzungen[4] RIVM report 320005002/2006 Pest Control Products Fact Sheet To assess the risks for the consumer Updated version for ConsExpo 4
South Africa	North-West University	Yes	Total Homestead Environment Approach (THEA)	van Dyk, J.C., Bouwman, H., Barnhoorn I.E.J., Bornman, M.S. 2010. DDT contamination from indoor residual spraying for malaria control. Science of the total environment. 408:2745-2752.
Turkey	MoEU	No		
Turkey	Ministry of Health	No		
US	United States Environmental Protection Agency	No		
US	US EPA/OCSPP	Yes	Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants; Exposure Factors Handbook; Also, U.S. EPA/OPPT exposure assessment models such as E-FAST and MCCEM	*www.epa.gov/raf/publications/guidance-on-selecting-age-groups.htm*; *http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252#Download*; *www.epa.gov/oppt/exposure/*; *www.epa.gov/superfund/lead/p*

		(*www.epa.gov/oppt/exposure/*) can be used with default exposure factors for children in assessing exposure. Other models such as IEUBK (*www.epa.gov/superfund/lead/products.htm#ieubk*) are specifically tailored for use in assessing children's exposures.	*roducts.htm#ieubk*
ECHA	Yes	In order just to give an outline of principles of exposure assessment: When children can be exposed (even in case of foreseeable misuse) to a substance e.g. in some consumer products that can be accessible to children, the registrant under REACH is assumed to prepare a respective exposure scenario. In that scenario the level of exposure, the precautions (and risk management measures) taken, need to the addressed/included. When doses per kilogram of body weight are calculated (for the exposure scenario) the relatively high intake of children, who have lower body weights, is taken into account in risk characterisation. Further reference is given to the following tools: ECETOC TRA; Cons Expo tools	REACH guidance is available under the following link: *http://guidance.echa.europa.eu/*
World Health Organization	Yes	EHC 237 Principles for Evaluation Health Risks in Children Associated with Exposure to Chemicals. In addition, as mentioned in earlier responses in this survey, WHO has developed draft guidance on Identifying Important Life Stages for Monitoring and Assessing Risks from Exposures to Environmental Contaminants, now available for public comment, and to be finalized during 2012.	*www.who.int/entity/ipcs/publications/ehc/ehc237.pdf*
Cefic			
Albemarle Europe	Yes	Biomarkers in Children and Adults (Published July 2007)Toxicology Letters 172(1-2) REACH guidance on information requirements R15	*http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r8_en.pdf?vers=16_12_10* *www.ecetoc.org*

Risk Characterization

10. In your programme, do you perform specific risk characterization for children?
Yes/no

11. Do you have guidance or tools on methodology for risk characterization for children.
Yes/no
If yes, please provide the name of the guidance or tools, and brief description.
please provide a reference(s) of the document(s) containing the methodology. (document name, URL if available)

Country	Organisation	10. Specific risk characterisation for children?	11. guidance or tools on risk characterisation for children?	Name of the guidance or tools, as well as a brief description.	Reference(s)
Australia	Australian Pesticides and Veterinary Medicines Authority	Yes	No	We use the same methodology as for adults, but just use different parameters detailed in Food Standards Australia and New Zealand Document- "Principles and practices of dietary exposure assessment for food regulatory purposes"	*www.foodstandards.gov.au/scienceandeducation/scienceinfsanz/dietaryexposureassessmentsatfsanz/*
Australia	Office of Chemical Safety, Department of Health and Ageing	Yes	Yes	US EPA Child-on-turf exposure model (where appropriate)Manual of Requirements and Guidelines (MORAG) for agricultural/veterinary product registration	*www.epa.gov/oppfead1/trac/science/trac6a05.pdf www.apvma.gov.au/registration/morag/index.php*
Australia	NICNAS	Yes	No	No specific inhouse guidance developed, however, internationally accepted guidance or tools utilised.	
Belgium	Institute public Health	No	No		
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Yes	Yes	See references 11, 13, 14. Reference 14 is an overall document describing health risk assessment and characterization at PMRA. References 11 and 13 focus on the	

				dietary risk assessment and characterization.	
Canada	Health Canada - Safe Environments Directorate	Yes	Yes	The following documents may provide more information on this topic: • Children and the health risk assessment of Existing Substances under the Canadian Environmental Protection Act, 1999: *www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/contaminants/existsub/children_health_risk.pdf* • Human health risk assessment of priority substances: *www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/contaminants/approach/approach-eng.pdf*	
Denmark	Danish EPA	Yes	No		
France	ANSES	Yes	No		
Germany	BfR (biocides and pesticides)	Yes	Yes	Biocides: TNsG on Annex I Inclusion (Chapter 4.1 - see revised version) The method for risk characterisation is the same as for adults, but exposure estimates derived from the specific exposure scenarios for children are used.	Biocides: TNsG on Annex I Inclusion (Chapter 4.1 - revised version): *http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/TNsG/TNsG_ANNEX_I_INCLUSION/Revision_TNsG_Annex_I_Inclusion_Chapter_4.1_2009.pdf*
Germany	BfR (dietary exposure)	-	-	-	-
Germany	German Environmental Survey for Children	Yes	Yes	HBM and reference values of the German HBM Commission of the Federal Environment Agency (UBA)	*www.umweltbundesamt.de/gesundheit-e/monitor/definitionen.htm*
Italy	University of Modena	No	No		
Japan	Environmental Risk Assessmen	No			

	t Office, Ministry of the Environment			
Korea	Korea Food and Drug Administration	No	No	
Korea	National Institute of Environmental Research	No	No	
Mexico	Comision federal para la proteccion contra riesgos sanitarios	Yes	Yes	In most cases using specific methods published by international organisations or agencies of other governments, preferably using validated methods. In the least number of cases we use our own methods based on the available information.
Netherlands	RIVM	Yes	Yes	EHC 237 Principles for evaluating health risks in children associated with exposure to chemicals EHC 240 Principles and methods for the risk assessment of chemicals in food.
New Zealand	New Zealand Environmental Protection Authority	Yes		
Norway	Climat- and pollution agency			
Poland	Nofer Institute of Occupational Medicine	Yes	Yes	Based on detailed questionnaire with mothers and biomonitoring
Poland	Institute of Mother and Child, Departmen	Yes		

	t of Pharmacology				
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	No			
South Africa	North-West University	Yes	Yes	Calculations based on ADI and MRL	Bouwman, H., Kylin, H. 2009. Malaria control insecticide residues in breastmilk: The need to consider infant health risks. Environmental health perspectives. 117:1477-1480. (Supplementary review online) Bouwman, H., Sereda, B., Meinhardt, R.H. 2006. Simultaneous presence of DDT and pyrethroid residues in human breast milk from a malaria endemic area in South Africa. Environmental pollution. 144:902-917. Eskenazi, B., Chevrier, J., Goldman Rosas, L., Anderson, H.A., Bornman M.S., Bouwman, H., Chen, A., Cohn, B.A., de Jager, C., Henshel, D.S., Leipzig, F., Leipzig, J.S., Lorenz, E.C., Snedeker, S.M., Stapleton, D. 2009. The Pine River Statement: Human health consequences of DDT use. Environmental health perspectives, 117:1359-1367. Quinn, L., Pieters, R., Nieuwhoudt, C., Borgen, A.R., Kylin, H., Bouwman, H. 2009. Distribution profiles of selected organic pollutants in soils and sediments of industrial, residential and agricultural areas of South Africa. Journal of environmental monitoring. 11:1647-1657. Nieuwhoudt, C., Quinn, L.P., Pieters, R., Jordaan, I., Visser, M., Kylin, H., Borgen, A.P., Giesy, J.P., Bouwman, H. 2009. Dioxin-like chemicals in soil and sediment from residential and industrial areas in central South Africa. Chemosphere. 76:774-783.

Turkey	MoEU	No	No		
Turkey	Ministry of Health	No	No		
US	United States Environmental Protection Agency	No	No		
US	US EPA/OCSPP	Yes	Yes	Same as stated above in 6-9.	Same as stated above in 6-9.
	ECHA	Yes	Yes	Registrants perform risk characterisation for children as part of their Chemical Safety Assessment. Further see answer to question 9	see answer to question 9
	World Health Organization	Yes	Yes	EHC 237 Principles for Evaluation Health Risks in Children Associated with Exposure to Chemicals.	*www.who.int/entity/ipcs/publications/ehc/ehc237.pdf*
	Cefic				
	Albemarle Europe	Yes	Yes	REACH guidance on information requirements R8 and chapter E	*http://guidance.echa.europa.eu/guidance_en*

Additional information

12. Do you perform children cohort study(ies)?
Yes/no
If yes, do you have guidance or tools on performing children cohort study(ies) ?
Yes/no
If yes, please provide the name(s) and a reference(s) of the document(s). (document name, URL if available)

Country	Organisation	12. cohort studies	guidance or tools on children cohort studies	Reference(s)
Australia	Australian Pesticides and Veterinary Medicines Authority	No		
Australia	Office of Chemical Safety, Department of Health and Ageing	No	No	
Australia	NICNAS	No	No	
Belgium	Institute public Health	No	No	
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	No	No	
Canada	Health Canada - Safe Environments Directorate	No	No	
Denmark	Danish EPA	No		
France	ANSES	No		
Germany	BfR (biocides and pesticides)	No	-	-
Germany	BfR (dietary exposure)	No	-	-
Germany	German Environmental Survey for Children	Yes	Yes	1) Concept of a birth cohort study as contribution to the health related environmental monitoring in Germany 2) WHO: Coordination of the next generation of birth cohort studies
Italy	University of Modena	Yes	Yes	We selected babies with malformations who died after the birth.
Japan	Environmental Risk Assessment Office, Ministry of the Environment	Yes	Yes	Japan Environment and Children's Study *www.env.go.jp/en/chemi/hs/jecs/Study Protocol* (Japanese) *www.env.go.jp/chemi/ceh/outline/data/kenkyukeikaku112.pdf*
Korea	Korea Food and Drug	No	No	

	Administration			
Korea	National Institute of Environmental Research	Yes	No	
Mexico	Comision federal para la proteccion contra riesgos sanitarios	Yes	Yes	Specifically for students and specially for measuring the assessment of health the reference document is the ISAAC study (*http://isaac.auckland.ac.nz/#*)
Netherlands	RIVM	Yes	Yes	PIAMA Birth Cohort The PIAMA study is a multi center birth cohort study conducted in the Netherlands since 1996. PIAMA stands for "Prevention and Incidence of Asthma and Mite Allergy." The study has two aims, one is to evaluate the effectiveness of mite impermeable mattress and pillow covers to reduce exposure to mite allergens, and to reduce incidence of allergic sensitization and asthma. The other is to study the natural history of allergy and asthma in childhood, in relation to nutrition, familial factors, day care, pet ownership, air pollution, gas cooking, genetics etc *http://piama.iras.uu.nl/en/ http://piama.iras.uu.nl/piama_project_overzicht.php#opzet Guidance in Dutch*
New Zealand	New Zealand Environmental Protection Authority	No	No	
Norway	Climat- and pollution agency			
Poland	Nofer Institute of Occupational Medicine	Yes	Yes	Information about Polish Mother and Child Cohort can be found on: *www.repropl.com*
Poland	Institute of Mother and Child, Department of Pharmacology	No	No	
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	Yes	No	
South Africa	North-West University	No	No	
Turkey	MoEU	No	No	
Turkey	Ministry of Health	No		
US	United States Environmental Protection Agency	No	No	
US	US EPA/OCSPP	No		
	ECHA	No		
	World Health Organization	Yes	Yes	WHO does not perform cohort studies ourselves, but we provide coordination and harmonization of countries' efforts to develop and conduct cohort studies. WHO has developed the

			following guidance: Golding J, Birmingham K, and Jones R. (2009) Special Issue: A Guide to Undertaking a Birth Cohort Study: Purposes, Pitfalls and Practicalities. Pediatric and Prenatal Epidemiology. 23 (Suppl 1): 1-236. *http://onlinelibrary.wiley.com/doi/10.1111/ppe.2009.23.issue-s1/issuetoc*
Cefic Albemarle Europe	No	No	

Additional information

13. In your programme, do you assess the risks to children from the combined exposure to multiple chemicals?

Yes/no

If yes, do you have guidance or tools on performing risk assessment from the combined exposure to multiple chemicals.

Yes/no

If yes, please provide the name(s) and a reference(s) of the document(s). (document name, URL if available)

Country	Organisation	13. Assessing risks to children from the combined exposure to multiple chemicals?	guidance or tools on combined exposure to multiple chemicals	Reference(s)
Australia	Australian Pesticides and Veterinary Medicines Authority	No		
Australia	Office of Chemical Safety, Department of Health and Ageing	No		
Australia	NICNAS	Yes		
Belgium	Institute public Health	No	No	
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Yes		
Canada	Health Canada - Safe Environments Directorate	Yes		
Denmark	Danish EPA	Yes	Yes	We use the principles of dose addition described in: Expert workshop on combination effects of chemicals, 28-30 January 2009, Hornbaek, Denmark
France	ANSES	Yes	Yes	work in progress for biocides and pesticides
Germany	BfR (biocides and pesticides)	No	-	-
Germany	BfR (dietary exposure)	No	-	

Germany	German Environmental Survey for Children	Yes	No	
Italy	University of Modena		No	
Japan	Environmental Risk Assessment Office, Ministry of the Environment	No		
Korea	Korea Food and Drug Administration	No	No	
Korea	National Institute of Environmental Research	No	No	
Mexico	Comision federal para la proteccion contra riesgos sanitarios	Yes	Yes	Derived from the measurement of chemicals and metals contents in water and soil.
Netherlands	RIVM	Yes	Yes	Combined exposure to multiple chemicals is performed on a case by case basis.
New Zealand	New Zealand Environmental Protection Authority	No	No	
Norway	Climate and pollution agency			
Poland	Nofer Institute of Occupational Medicine	Yes	Yes	Within the study there are the protocols developed for biological sample collection, storage, transportation and analysis. The assessment of exposure is based on analysis performed in NIOM laboratory with accredited methodology. Information about Polish Mother and Child Cohort can be found on: *www.repropl.com*
Poland	Institute of Mother and Child, Department of Pharmacology	No	No	
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	Yes	No	
South Africa	North-West University	Yes	No	Strong need motivated in Bouwman, H., Sereda B, Meinhardt H.R. & Kylin, H. 2006. DDT and pyrethroid residues in human breast milk from

				KwaZulu-Natal, South Africa. Organohalogen Compounds. 68:1623-1626AndBouwman, H., Kylin, H. 2009. Malaria control insecticide residues in breastmilk: The need to consider infant health risks. Environmental health perspectives. 117:1477-1480. (Supplementary review online)
Turkey	MoEU	No	No	
Turkey	Ministry of Health	No	No	
US	United States Environmental Protection Agency	No	No	
US	US EPA/OCSPP	No		
	ECHA	No		
	World Health Organization	Yes	Yes	WHO Framework for Risk Assessment of Combined Exposures to Multiple Chemicals (2011) *http://dx.doi.org/10.1016/j.yrtph.2011.03.010*
	Cefic			"Maximum Cumulative Ratio (MCR), a tool for assessing the value of cumulative risk assessments", Int. J. Environ. Res. Public Health 2011, 8(6), 2212-2225
	Albemarle Europe	No	No	

Other guidance or tools relevant for risk assessment for children

14. Do you have other guidance or tools relevant to risk assessment for children?
Yes/no
If yes, please provide brief description.
please provide a reference(s) of the document(s) containing the guidance or tools. (document name, URL if available)

Country	Organisation	14. Other relevant guidance or tools	Brief description.	reference(s)
Australia	Australian Pesticides and Veterinary Medicines Authority	No	Use same methodology as for adults.	
Australia	Office of Chemical Safety, Department of Health and Ageing	Yes	IPCS EHC 237 (2006)	*http://www.who.int/ipcs/publications/ehc/ehc237.pdf*
Australia	NICNAS	No		
Belgium	Institute public Health	No		
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	No		
Canada	Health Canada - Safe Environments Directorate	No		
Denmark	Danish EPA	Yes	We use:- REACH guidance- US EPA guidance- EU Cosmetics guidance	
France	ANSES	Yes	Biocides: exposure factor handbook EPA	
Germany	BfR (biocides and pesticides)	Yes	-	Biocides: - Cons Expo and its Fact Sheets: *www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp.* - EPA Child-Specific Exposure Factors Handbook: *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=199243.* - Nordic Exposure Group project (only draft report currently available).
Germany	BfR (dietary exposure)	No	-	-
Germany	German	No		

	Environmental Survey for Children			
Italy	University of Modena	No		
Japan	Environmental Risk Assessment Office, Ministry of the Environment	No		
Korea	Korea Food and Drug Administration	No		
Korea	National Institute of Environmental Research	No		
Mexico	Comision federal para la proteccion contra riesgos sanitarios	Yes	The one used for general risk assessment but adjusted by age groups.	
Netherlands	RIVM			
New Zealand	New Zealand Environmental Protection Authority	Yes		See example in email
Norway	Climate and pollution agency	Yes	SPIN Exposure Toolbox - Use Index. This is not just for children, but it may be of interest. The tool makes it possible to search for a general indicative exposure of human beings and environment from different chemical uses. It is based on the extensive information stored in the Nordic product registers.	please see *www.spin2000.net*
Poland	Nofer Institute of Occupational Medicine	No		
Poland	Institute of Mother and Child, Department of Pharmacology	No		
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	No		
South Africa	North-West University	No	We need tools better directed at situations in developing countries	
Turkey	MoEU	No		

Turkey	Ministry of Health	No		*http://mevzuat.basbakanlik.gov.tr/Metin.Aspx?MevzuatKod=7.5.13672&MevzuatIliski=0&sourceXmlSearch=biyosidal* Turkish legislation document for Biocides
US	United States Environmental Protection Agency	No		
US	US EPA/OCSPP	No		
	ECHA	No		
	World Health Organization	Yes	In addition to EHC 237, a number of other endpoint specific guidance materials reference information about children where available and appropriate.	
	Cefic			
	Albemarle Europe	No		

Part II: Needs for additional Guidance or tools on risk assessment for children

15. Please identify for which areas of risk assessment there is a need for additional guidance or tools on risk assessment of children.

Please specify the precise needs for each area.

a. Definition of a term(s) (e.g. harmonization or development of definition)
   Please specify ( )
b. Exposure assessment
   Please specify ( )
c. Hazard assessment
   Please specify ( )
d. Risk characterization
   Please specify ( )
e. Cohort studies
   Please specify ( )
f. Combined exposure
   Please specify ( )
g. Other
   Please specify ( )

a. Definition of a term(s) (e.g. harmonization or development of definition)
   Please specify ( )

Country	Organisation	Definition of term(s) (e.g. harmonisation or development of definition)
Australia	Australian Pesticides and Veterinary Medicines Authority	
Australia	Office of Chemical Safety, Department of Health and Ageing	Harmonisation of terms and definitions at an international level
Australia	NICNAS	
Belgium	Institute public Health	
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	No
Canada	Health Canada - Safe Environments Directorate	harmonization of standards (exposure factors such as body weight and inhalation rate)
Denmark	Danish EPA	
France	ANSES	development of definition term and age categories

Germany	BfR (biocides and pesticides)	Biocides: we would welcome a harmonised definition for infants and children.
Germany	BfR (dietary exposure)	-
Germany	German Environmental Survey for Children	Develop SES definition Definition of Vulnerable phase Definition of Migration status
Italy	University of Modena	We verified that in some food inorganic nanosized particles are present. We do not know if they are engineered or not. In a chewingum there are nanopartciles of titania and silica. They are not biodegradable, not biocompatible and they are biopersistent. I a homogenized food we found titania.
Japan	Environmental Risk Assessment Office, Ministry of the Environment	
Korea	Korea Food and Drug Administration	
Korea	National Institute of Environmental Research	Harmonization
Mexico	Comision federal para la proteccion contra riesgos sanitarios	
Netherlands	RIVM	early exposure, later in life effects
New Zealand	New Zealand Environmental Protection Authority	
Norway	Climate and pollution agency	
Poland	Nofer Institute of Occupational Medicine	
Poland	Institute of Mother and Child, Department of Pharmacology	
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	internationally harmonized definitions of different age groups
South Africa	North-West University	
Turkey	MoEU	
Turkey	Ministry of	

	Health	
US	United States Environmental Protection Agency	would just need common agreed upon terms for risk assessment of children
US	US EPA/OCSPP	None
	ECHA	
	World Health Organization	
	Cefic	harmonisation of definitions
	Albemarle Europe	

16. Please identify for which areas of risk assessment there is a need for additional guidance or tools on risk assessment of children.

b. Exposure assessment
Please specify ( )

Country	Organisation	Exposure assessment
Australia	Australian Pesticides and Veterinary Medicines Authority	
Australia	Office of Chemical Safety, Department of Health and Ageing	Guidance required on calculating dermal and inhalational exposure to children from insecticides used in domestic environments
Australia	NICNAS	Standard guidance on adjustment of exposure assessment to take into account child specific exposure factors
Belgium	Institute public Health	
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Yes, such as better dietary consumption data for infants and children, including on-farm consumption; children's activity patterns (e.g. time spent indoors, number of hand-to-mouth events, contact with pets) and exposure from consumer products. Also data to assess child farm workers, farm children, and non-working children brought to the agricultural workplace by their parents.
Canada	Health Canada - Safe Environments Directorate	- Guidance and/or tools to harmonize approaches for dietary exposure intake values (including introduction of solids, formula and nursing, appropriate timescales, etc.) for children under 3 years, especially infants; - Guidance on assessing exposure for infants, children and adolescents and potential approaches/defaults for substances in consumer products including frequency of use and amounts used; harmonized body weights, surface areas, inhalation rates and general exposure defaults; - harmonized approaches for object & hand-to-mouth exposure scenarios for various consumer products including textiles, paper, plastics, rubber, etc. and standardized saliva extraction efficiencies.
Denmark	Danish EPA	Harmonised guidance on methodologies and exposure factors (e.g. time of exposure).Product emission factors (e.g. migration, evaporation) related to different "standard" materials. IT-models
France	ANSES	data on for hand to mouth behaviours transfer factor for rubbing off models
Germany	BfR (biocides and pesticides)	Biocides: experimental or observational data to fill data gaps for a number of parameters in the exposure scenarios (in particular regarding children's behaviour) would be of great value. Pesticides: consumption data focus on children eating their meals at home. Data on children consuming meals in day care facilities would be useful.
Germany	BfR (dietary exposure)	-
Germany	German Environmental Survey for Children	Need for more HBM values (assessment values) Need for more procedures for chemical analyses Need for more indoor guide values Need for more and current exposure factors based on survey data

Italy	University of Modena	Difficult to say since it should be necessary to verify all the baby food.
Japan	Environmental Risk Assessment Office, Ministry of the Environment	To develop the factors of exposure assessment To develop the markers of exposure assessment To build and promote the biomarker banking system
Korea	Korea Food and Drug Administration	Guideline needed to develop exposure scenario on children
Korea	National Institute of Environmental Research	Development of Exposure algorithm
Mexico	Comision federal para la proteccion contra riesgos sanitarios	
Netherlands	RIVM	Regarding consumer products, specific information on use frequency, use duration, but also product amount used, weight fraction of the substance in the product, percentage of products on the market containing the substance, etcetera is in most cases missing. For adults as well as for children.
New Zealand	New Zealand Environmental Protection Authority	More information on this would be good. Our exposure assessment doesn't do much on veterinary medicines or VTAs. There are some tool available but not used routinely. They are pretty simplistic and precautionary. More realistic models would be very useful.
Norway	Climate and pollution agency	
Poland	Nofer Institute of Occupational Medicine	
Poland	Institute of Mother and Child, Department of Pharmacology	
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	Standard values for body weight, breathing volume,...
South Africa	North-West University	Tools taking into account developing country scenarios
Turkey	MoEU	
Turkey	Ministry of Health	
US	United States Environmental Protection Agency	extrapolating available data to children
US	US EPA/OCSPP	Might be an area to pursue to internationalize and expand existing guidance.
	ECHA	
	World Health Organization	Exposure scenarios

Cefic	
Albemarle	Representative data on children’s behaviour for different ages and regions.
Europe	Model tools developed from the above.

17. Please identify for which areas of risk assessment there is a need for additional guidance or tools on risk assessment of children.

c. Hazard assessment
Please specify ( )

Country	Organisation	Hazard assessment
Australia	Australian Pesticides and Veterinary Medicines Authority	
Australia	Office of Chemical Safety, Department of Health and Ageing	Guidance on the appropriate use of age-dependent adjustment (safety) factors
Australia	NICNAS	Guidance on extrapolating from adult animal studies to other life stages
Belgium	Institute public Health	
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Yes, adult onset effects resulting from early life exposures.
Canada	Health Canada - Safe Environments Directorate	Guidance and/or harmonized approach for endocrine modulators as well as low-dose effects.
Denmark	Danish EPA	Specific sensitivity guidance related to children's level of development.
France	ANSES	
Germany	BfR (biocides and pesticides)	-
Germany	BfR (dietary exposure)	-
Germany	German Environmental Survey for Children	Epidemiological studies to show correlation between HBM and health outcomes
Italy	University of Modena	not known
Japan	Environmental Risk Assessment Office, Ministry of the Environment	To promote the studies on the effects of chemicals in the psychoneuro development and immune development To promote the studies on the sensitivity to chemicals in children's growth and development To develop the markers of outcome assessment for children
Korea	Korea Food	

	and Drug Administration	
Korea	National Institute of Environmental Research	Harmonization of end-points
Mexico	Comision federal para la proteccion contra riesgos sanitarios	It is important to have more information on specific effects in children or, recognised ways to extrapolate the information from adults to children. It would also be important to have information on prenatal exposure, such as PCBs, and combined exposures.
Netherlands	RIVM	The OECD TG 416 (2-gen) and 443 (EOGRTS) include the entire reproductive cycle as regards exposure duration. They are therefore expected to cover at least part of possible hazards for childhood. EOGRTS includes parameter sets for developmental immunetox and developmental neurotox, which are relatively new parameters incorporated in OECD guidelines. These parameters have been efined in technical meetings preparing the guideline. The developmental neurotoxicity guideline (OECD TG 426) also includes neurotox parameters but its exposure duration is shorter. Recent database analyses (Piersma et al, 2011, Rorije et al., 2011) have provided justification for replacing the OECD416 with the OECD443 which would also significantly enhance effect assessment power and reduce animal use. Novel developments include scientific work towards defining a juvenile toxicity protocol in which early postnatal exposure (e.g. PND 10-50) is followed by immune and neurotox parameter assessment. There is no guideline for this protocol as yet, but scientific research (e.g. Tonk et al, 2011) shows that at least functional immune parameters (such as the response to KLH challenge) can be orders of magnitude more sensitive than classical developmental parameters in such a study design. New studies are emerging presently, and evidence is mounting towards the need for such an approach. These parameters are relevant in view of increasing prevalences in the human population of early onset diseases of the immune system (asthma, allergies, autoimmune diseases etc) and the neural system (adhd, schyzophrenia, autism etc.). The NL is preparing an initiative towards an spsf for preparing a survey or DRP to map the field and define possible steps forward towards a test guideline. An important regulatory question is whether a safety factor of 100 (10x for intra- and 10x for interspecies variation) is sufficient to protect sensitive populations such as children from carcinogen exposure. In the Netherlands, additional safety factors are always considered on a case-by-case basis. In the U.S.A., the U.S. Environmental Protection Agency (EPA) apply age-dependent potency adjustment factors (ADAF) if a carcinogen is found to have a genotoxic mode of action. The ADAF is an additional 10x safety factor for children from birth to < 2 years and an additional 3x safety factor for children from 2 years of age to < 16 years. Current research performed by RIVM focuses on the question whether children are more susceptible to carcinogenic compounds than adults and if so, whether age-related potency adjustment factors (safety factors) should be implemented. An additional area for risk assessment on children that still needs to be explored is developmental programming and/or epigenetics. To date, it is still unknown to what extent exposures to chemicals induce epigenetic changes that may result in adverse health effects.
New Zealand	New Zealand Environmental Protection Authority	More information here is also useful. Should we be assessing differently for children? Example: a domestic veterinary medicine applied to a household pet could easily lead to exposure for a child. Should we take a more precautionary approach in these cases? But is the amount given to pet low enough that any exposure would have minimal effect? How frequently could the child be exposed? These are issues we have to grapple with.
Norway	Climate and	

	pollution agency	
Poland	Nofer Institute of Occupational Medicine	
Poland	Institute of Mother and Child, Department of Pharmacology	
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	the higher sensibility of children should be integrated and should oriented the assessment toward the most significant risk
South Africa	North-West University	Tools taking into account developing country scenarios
Turkey	MoEU	
Turkey	Ministry of Health	
US	United States Environmental Protection Agency	extrapolating available data to children
US	US EPA/OCSPP	Probably too soon to develop guidance, but need to begin thinking how to use new approaches through comptox etc.
	ECHA	
	World Health Organization	
	Cefic	
	Albemarle Europe	

18. Please identify for which areas of risk assessment there is a need for additional guidance or tools on risk assessment of children.

d. Risk characterization
Please specify ( )

Country	Organisation	Risk characterisation
Australia	Australian Pesticides and Veterinary Medicines Authority	
Australia	Office of Chemical Safety, Department of Health and Ageing	Harmonised approach to selection of endpoints and safety factors for risk assessment for children
Australia	NICNAS	Guidance on use of safety factors specific for children particularly when extrapolating from adult life stage studies
Belgium	Institute public Health	
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	No
Canada	Health Canada - Safe Environments Directorate	No
Denmark	Danish EPA	Guidance related to Uncertainty and deviation
France	ANSES	
Germany	BfR (biocides and pesticides)	-
Germany	BfR (dietary exposure)	-
Germany	German Environmental Survey for Children	Identification of people/groups with mixed/multiple exposure
Italy	University of Modena	The risk can be identified by analyses of baby food by means of scanning electron microscopy and Energy dispersive spectroscopy (Nanopathology: the health impact of nanopartciles. Pan Stanford Publisher, Singapore 2008. 1-231.
Japan	Environmental Risk Assessment Office, Ministry of the	

	Environment	
Korea	Korea Food and Drug Administration	
Korea	National Institute of Environmental Research	Harmonization of safety factors for children
Mexico	Comision federal para la proteccion contra riesgos sanitarios	It is essential to harmonise the way to consider this assessment in children, for example, additional uncertainty factors.
Netherlands	RIVM	More information regarding toxicokinetic and dynamics between children and adults might give some more basis to support the similar use of a factor 10 for intraspecies differences or reason to enlarge or decrease the assessment factor. This is probably difficult to do it in a more general way, but substance specific it could be possible.
New Zealand	New Zealand Environmental Protection Authority	
Norway	Climate and pollution agency	
Poland	Nofer Institute of Occupational Medicine	
Poland	Institute of Mother and Child, Department of Pharmacology	
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	the specificity of the behaviour of children must be taken into account
South Africa	North-West University	Tools taking into account developing country scenarios
Turkey	MoEU	
Turkey	Ministry of Health	
US	United States Environmental Protection Agency	extrapolating available data to children
US	US EPA/OCSPP	None
	ECHA	
	World Health Organization	
	Cefic	
	Albemarle Europe	

19. Please identify for which areas of risk assessment there is a need for additional guidance or tools on risk assessment of children.

e. Cohort studies
Please specify ( )

Country	Organisation	Cohort studies
Australia	Australian Pesticides and Veterinary Medicines Authority	
Australia	Office of Chemical Safety, Department of Health and Ageing	N/A
Australia	NICNAS	
Belgium	Institute public Health	
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Not applicable
Canada	Health Canada - Safe Environments Directorate	Not applicable
Denmark	Danish EPA	
France	ANSES	
Germany	BfR (biocides and pesticides)	-
Germany	BfR (dietary exposure)	-
Germany	German Environmental Survey for Children	Harmonisation of pregnancy/birth cohorts
Italy	University of Modena	
Japan	Environmental Risk Assessment Office, Ministry of the Environment	Harmonization of exposure and outcome measurement among cohort studies
Korea	Korea Food and Drug Administration	
Korea	National Institute of Environmental Research	Development of study tools
Mexico	Comision federal para la proteccion contra riesgos sanitarios	
Netherlands	RIVM	
New Zealand	New Zealand Environmental Protection Authority	
Norway	Climate and pollution agency	
Poland	Nofer Institute of Occupational Medicine	Methodology of follow-up of the children
Poland	Institute of Mother and Child, Department of Pharmacology	
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	
South Africa	North-West University	
Turkey	MoEU	
Turkey	Ministry of Health	
US	United States Environmental Protection Agency	
US	US EPA/OCSPP	None
	ECHA	
	World Health Organization	
	Cefic	quality criteria and guidelines
	Albemarle Europe	

20. Please identify for which areas of risk assessment there is a need for additional guidance or tools on risk assessment of children.

f. Combined exposure
Please specify ( )

Country	Organisation	Combined exposure
Australia	Australian Pesticides and Veterinary Medicines Authority	
Australia	Office of Chemical Safety, Department of Health and Ageing	Additional harmonised guidance (e.g. OECD) for cumulative/combined exposure to pesticides, including infants and children
Australia	NICNAS	Practical methodology guidance that is easy to use like a tool kit
Belgium	Institute public Health	
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Yes, for addressing lack of adequate data and uncertainties
Canada	Health Canada - Safe Environments Directorate	Yes, for addressing lack of adequate data and uncertainties
Denmark	Danish EPA	There is a need for a common definition and common methodology in order to assess combined exposure
France	ANSES	Development of guidance on combined exposure for adults and children.
Germany	BfR (biocides and pesticides)	Guidance on combined exposure is needed for all age groups.
Germany	BfR (dietary exposure)	-
Germany	German Environmental Survey for Children	Need for tools/methodologies
Italy	University of Modena	
Japan	Environmental Risk Assessment Office, Ministry of the Environment	
Korea	Korea Food and Drug Administration	
Korea	National Institute of Environmental Research	Development of study tools
Mexico	Comision federal para la proteccion contra riesgos sanitarios	
Netherlands	RIVM	Information on co-use scenarios.
New Zealand	New Zealand	This is always very complex and more information on how to assess

	Environmental Protection Authority	combined exposures would be appreciated.
Norway	Climate and pollution agency	
Poland	Nofer Institute of Occupational Medicine	
Poland	Institute of Mother and Child, Department of Pharmacology	
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	harmonized methodology (but it this is not a specific problem for children)
South Africa	North-West University	Real-life scenarios in developing countries
Turkey	MoEU	
Turkey	Ministry of Health	
US	United States Environmental Protection Agency	extrapolating available data to children
US	US EPA/OCSPP	None
	ECHA	
	World Health Organization	Case studies employing the WHO Framework (as recommended by the WHO OECD ILSI/HESI Workshop on the Risk Assessment of Combined Exposures to Multiple Chemicals. This would inform development of further tools.
	Cefic	
	Albemarle Europe	

21. Please identify for which areas of risk assessment there is a need for additional guidance or tools on risk assessment of children.

g. Other
Please specify ( )

Country	Organisation	Other
Australia	Australian Pesticides and Veterinary Medicines Authority	
Australia	Office of Chemical Safety, Department of Health and Ageing	N/A
Australia	NICNAS	
Belgium	Institute of Public Health	
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Not applicable
Canada	Health Canada - Safe Environments Directorate	Harmonized approach for calculating and handling exposures for 'children' when conducting cancer risk assessments such as age specific adjustment factors.
Denmark	Danish EPA	
France	ANSES	
Germany	BfR (biocides and pesticides)	-
Germany	BfR (dietary exposure)	-
Germany	German Environmental Survey for Children	Other pathways: behaviour, lifestyle, etc. (identification and assessment)
Italy	University of Modena	
Japan	Environmental Risk Assessment Office, Ministry of the Environment	
Korea	Korea Food and Drug Administration	
Korea	National Institute of Environmental Research	
Mexico	Comision federal para la proteccion contra riesgos sanitarios	
Netherlands	RIVM	
New Zealand	New Zealand Environmental Protection Authority	
Norway	Climat- and pollution agency	
Poland	Nofer Institute of Occupational Medicine	
Poland	Institute of Mother and Child, Department of Pharmacology	
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	
South Africa	North-West University	

Turkey	MoEU
Turkey	Ministry of Health
US	United States Environmental Protection Agency
US	US EPA/OCSPP
	ECHA
	World Health Organization
	Cefic
	Albemarle Europe

22. Please provide any other comments relevant to the future development of additional guidance or tools at OECD. ( )

Country	Organisation	16. Other comments relevant to additional guidance or tools.
Australia	Australian Pesticides and Veterinary Medicines Authority	
Australia	Office of Chemical Safety, Department of Health and Ageing	N/A
Australia	NICNAS	
Belgium	Institute public Health	
Canada	Health Canada, Pest Management Regulatory Agency (PMRA)	Not applicable
Canada	Health Canada - Safe Environments Directorate	Not applicable
Denmark	Danish EPA	
France	ANSES	
Germany	BfR (biocides and pesticides)	-
Germany	BfR (dietary exposure)	-
Germany	German Environmental Survey for Children	
Italy	University of Modena	Children must be protected for food and air contamination. Engineered and not engineered nanopartciles are already dispersed in the environment. It is necessary a specific monitoring of food and air.
Japan	Environmental Risk Assessment Office, Ministry of the Environment	We expect to exchange information about factors of exposure measurements and outcome measurements in child health
Korea	Korea Food and Drug Administration	
Korea	National Institute of Environmental	

	Research	
Mexico	Comision federal para la proteccion contra riesgos sanitarios	
Netherlands	RIVM	Developmental immunotoxicity of di-n-octyl tin dichloride(DOTC) in an extended one-generation reproductive toxicity study. Tonk ECM, de Groot DME, Penninks AH, Waalkens-Berendsen IH , Wolterbeek APM, Piersma AH, Van Loveren H. Toxicology, 2011, in press,StÃ¸levik SB, Nygaard UC, Namork E, Haugen M, Engelstad Kvalem H, Meltzer HM, Alexander J, Van Delft JHM, Van Loveren H, LÃ¸vik M, Granum B. Prenatal exposure to polychlorinated biphenyls and dioxins is associated with increased risk of wheeze and infections in infants. Food and Chemical Toxicology, 2011, in Press Tonk ECM, De Groot DMG, Penninks AH, Waalkens-Berendsen DH, Wolterbeek APM, Slob W, Piersma AH, Van Loveren H. Developmental Immunotoxicity of Methylmercury: The Relative Sensitivity of Developmental and Immune Parameters. Tox Sci 2010, 117, 325-335.
New Zealand	New Zealand Environmental Protection Authority	I've provided further information in an email to the Secretariat. If this needs to be sent elsewhere, please email me for it.
Norway	Climate and pollution agency	
Poland	Nofer Institute of Occupational Medicine	
Poland	Institute of Mother and Child, Department of Pharmacology	
Switzerland	Swiss Federal Office for Public Health, Chemicals Dept,	
South Africa	North-West University	
Turkey	MoEU	
Turkey	Ministry of Health	
US	United States Environmental Protection Agency	
US	US EPA/OCSPP	
	ECHA	
	World Health Organization	Work of OECD and WHO should be complementary and avoid duplication of effort.
	Cefic	
	Albemarle Europe	