International Generic Indicators for the use of Highly Hazardous Pesticides

FSC-STD-60-004a

DRAFT 1-0
Content

Introduction

A Objective
B Scope
C Effective and validity date
D References
E Terms and definitions
F. International generic indicators for the use and risk management of highly hazardous pesticides (HHPs)

I. International Generic Indicators that will be incorporated under Criterion 10.7

II. International Generic Indicators that will be incorporated to current FSC-STD-60-004 International Generic Indicators as Annex ‘International Generic Indicators for the use and risk management of Highly Hazardous Pesticides (HHP)

i) INTERNATIONAL GENERIC INDICATORS FOR ALL HHPs
   1. International Generic Indicators for all HHPs

ii) INTERNATIONAL GENERIC INDICATORS FOR HAZARD GROUPS

   Hazard Group Relevant international agreements or conventions
   2. Indicators for HHPs that meet Hazard Criterion 1 (Relevant international agreements or conventions)

   Hazard Group Acute toxicity
   3. Indicators for HHPs that meet Hazard Criterion 2 (Acute toxicity to mammals and birds)

   Hazard Group Chronic toxicity
   4. Indicators for HHPs that meet Hazard Criterion 3 (Carcinogenicity)
   5. Indicators for HHPs that meet Hazard Criterion 4 (Mutagenicity)
   6. Indicators for HHPs that meet Hazard Criterion 5 (Developmental and reproductive toxicity)
   7. Indicators for HHPs that meet Hazard Criterion 6 (Endocrine disruption)

   Hazard Group Environmental toxicity
   8. Indicators for HHPs that meet Hazard Criterion 7 (Acute toxicity to aquatic organisms)
   9. Indicators for HHPs that meet Hazard Criterion 8 (Persistence in soil and water/ biomagnification and bioaccumulation)
Hazard Group Dioxins
10. Indicators for HHPs that meet Hazard Criterion 9
   (Dioxins (residues or emissions))

Hazard Group Heavy metals
11. Indicators for HHPs that meet Hazard Criterion 10
   (Heavy metals (arsenic, cadmium, lead, and mercury))

Appendix 1: Personal Protective Equipment (PPE) and biomonitoring for
Hazard Criteria
Introduction

In line with the objectives of the 2015-2020 FSC Global Strategic Plan the revised FSC Pesticides Policy introduces a risk-based approach, that considers not only the hazard of the active ingredient but also under what circumstances chemical pesticides could be used.

Before any use of pesticides, FSC requires certified Organizations to use integrated pest management (IPM) to avoid, or aim to eliminate, the use of chemical pesticides in management units (MU), and minimize risks to human health and the environment while maintaining economically viable management.

However, in certain circumstances, after having identified and determined likely impacts of a pest, weed or disease and having considered all available pest management strategies, the use of chemical pesticides may be identified as the most suitable control. The FSC Pesticides Policy regulates the use of chemical pesticides in these situations.

As part of the Environmental and Social Risk Assessment (ESRA) framework, the revised policy requires that FSC develops IGI for the use and risk management of HHPs for Hazard Groups.

The IGIs will be the starting point for Standard Development Groups to develop indicators and locally relevant thresholds (conditions) for the use of the relevant FSC Highly Restricted HHPs and FSC Restricted HHPs in the country.

In countries without Standard Development Groups, certification bodies will adopt the IGIs or use the national indicators developed in a country with similar forest and pest problems, upon approval of FSC.

Organizations shall conduct ESRA as part of their IPM systems in accordance with the policy and conform with the applicable international and/or national indicators and thresholds for the use of highly hazardous pesticides.

This document presents a set of International Generic Indicators, derived from the FSC Pesticide Policy FSC-POL-30-001 V3-0 EN, for use in FSC National Standards.

This set of indicators will be incorporated into the existing FSC-STD-60-004 International Generic Indicators.
A. Objective

The objective of this document is to provide a set of IGI’s for the use and risk management of HHPs, which facilitate the implementation of FSC-POL-30-001 V3-0 FSC Pesticides Policy.

This set of indicators will be incorporated into the existing FSC-STD-60-004 International Generic Indicators in two different sections:

a) Under Criterion 10.7, replacing indicator 10.7.2. (See International Generic Indicators under Criterion 10.7 in Section F of this document), which refers to the derogation system in the previous FSC Pesticides Policy.

b) As an Annex into the next version of FSC-STD-60-004 International Generic Indicators (See International Generic Indicators in Annex ‘International Generic Indicators for the use and risk management of Highly Hazardous Pesticides (HHP) in Section F of this document).

The IGIs have been developed considering:

- The exposure elements and variables described in FSC-POL-30-001 V3-0 FSC Pesticides Policy.
- Research into less hazardous alternatives.
- Engagement with interested and/or affected stakeholders.
- Training requirements (FSC Principles and Criteria V5-2, Criteria 2.5 and 4.3).
- Monitoring requirements (FSC Principles and Criteria V5-2, Criteria 8.2).
- Use of personal protective equipment (FSC Principles and Criteria V5-2, Criteria 2.3).

This document also presents instructions for Standard Developer on how to incorporate the IGIs to national standards for implementing the Pesticides Policy.

B. Scope

The IGIs for the use and risk management of Highly Hazardous Pesticides (HHPs) will be mandatory for standards developers to develop national indicators for National Forests Stewardship Standards and Interim National Standards in countries where HHPs are used or likely to be used.

Standard Development Groups shall consider the Instructions for Standard Developers, and all the IGIs, with the option to adopt, adapt, drop or add indicators as appropriate and relevant nationally.

Certification Bodies developing Interim National Standards shall consider the Instructions for Standard Developers, and all the IGIs, with the only option to adopt indicators as appropriate and relevant nationally.

C. Effective and validity date

Approval date XXX
Publication date XXX
Effective date XXX
Period of validity XXX
D. References

The following referenced documents are relevant for the application of this document.

For references without a version number, the latest edition of the referenced document (including any amendments) applies.

- FSC-STD-01-001  FSC Principles and Criteria
- FSC-STD-60-004  International Generic Indicators
- FSC-STD-01-002  FSC Glossary of Terms
- FSC-POL-30-001  FSC Pesticides Policy

E. Terms and definitions

**Allee effect**: a scenario in which populations at low numbers are affected by a positive relationship between population growth rate and density (Source: Courchamp et al. 1999. Trends in Ecology and Evolution: Vol 14, page 405-410) (e.g. goldfish population is growing more rapidly when there are more individuals within the tank).

**Buffer zone**: area established to exclude chemical pesticide application to ensure the protection of environmental and cultural values.

**Critical population density**: acceptable maximum density or threshold for a pest population for achieving silvicultural objectives (Source: Based on Food and Agriculture Organization of the United Nations (FAO)). Assessment of critical population density should take into account the historical records of affected area, target population (insects, weeds, pathogens, etc.) and Allee effects* (Source: Based on International Code of Conduct on the Distribution and use of Pesticides 2006).

**Exclusion zone**: an area temporarily demarcated as having no access during the period of re-entry* when there is a risk of contamination for anyone who enters said area.

**Highly hazardous pesticide (HHP)**: chemical pesticides that are acknowledged to present particularly high levels of acute or chronic hazards to health and environment according to internationally accepted classification systems, or are listed in relevant binding international agreements or conventions, or contain dioxins, or heavy metals.

In addition, pesticides that appear to cause severe or irreversible harm to health or the environment under conditions of use in a country may be considered to be and treated as highly hazardous (Source: FSC-POL-30-001 V3-0 FSC Pesticides Policy).

FSC distinguishes between FSC prohibited HHPs, FSC highly restricted HHPs and FSC restricted HHPs:

- **FSC prohibited HHPs**: chemical pesticides that: a) are listed or recommended for listing under Annex A (elimination) of the Stockholm Convention on Persistent Organic Pollutants or Annex III of the Rotterdam Convention on the Prior Informed Consent Procedure, or listed under the Montreal Protocol on Substances that Deplete the Ozone Layer, or b) are acutely toxic and that can induce cancer (carcinogenic and likely to be carcinogenic), or c) contain dioxins or d) contain heavy metals).
- **FSC highly restricted HHPs**: chemical pesticide presenting two or three out of the following hazards: acute toxicity, chronic toxicity and environmental toxicity.

- **FSC restricted HHPs**: chemical pesticide presenting one out of three of the following hazards: acute toxicity, chronic toxicity and environmental toxicity.

**Intervention threshold**: population density level which triggers the use of chemical pesticide for controlling the targeted pest. It is determined in the IPM system and it is usually lower than the *critical population density* level.

**Non-target species**: those species either directly or indirectly exposed to the pesticide and which are not the target of said pesticide. (Source: Based on *FAO and European Food Safety Authority (EFSA) 2009*).

**Over-exposure**: excessive exposure, especially to something harmful.

**Period of re-entry**: time during which there is a risk of contamination.

**Persistent**: continuing to exist or endure over a prolonged period.

**Secondary or latent impact**: further or dormant effects of the Highly Hazardous Pesticide that may present following application.

**Sublethal effect**: biological, physiological, demographic or behavioural effects on individuals or populations that survive exposure to a toxicant at lethal or sublethal dose/concentration. A sublethal dose/concentration is defined as inducing no apparent mortality in the experimental population (Source: Solange et.al. 2016).

**Trigger Value**: value of toxicity exposure ratio above which exposure is considered to be a risk.

NOTE: all categories have a LD/LC50 for each pesticide (acute toxicity value). This is used to calculate the toxicity exposure ratio for each category by dividing it by the dose (measured exposure concentration/dose = TER). The EU developed trigger values for the TER for each category so if the calculated TER is above the trigger value it is a risk, if not it is not a risk (Source: Connon, Geist & Werner, 2012).
F. INTERNATIONAL GENERIC INDICATORS FOR THE USE AND RISK MANAGEMENT OF HIGHLY HAZARDOUS PESTICIDES (HHP)

I. International Generic Indicators that will be incorporated under Criterion 10.7

10.7 The Organization* shall* use integrated pest management and silviculture* systems which avoid, or aim at eliminating, the use of chemical pesticides*. The Organization* shall* not use any chemical pesticides* prohibited by FSC policy. When pesticides* are used, The Organization* shall* prevent, mitigate, and/or repair damage to environmental values* and human health. (C6.6 and C10.7 P&C V4)

<table>
<thead>
<tr>
<th>Existing Instructions and IGIs under 10.7</th>
<th>Proposed Instructions and IGIs under 10.7</th>
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<tr>
<td><strong>INSTRUCTIONS FOR STANDARD DEVELOPERS:</strong> Standard Developers shall* include the relevant aspects of the 'FSC Guide to integrated pest, disease and weed management in FSC certified forests and plantations' (2009) and associated policies, guidelines, advice notes and other FSC normative documents for the development of indicators (Indicator 10.7.1).</td>
<td><strong>INSTRUCTIONS FOR STANDARD DEVELOPERS:</strong> Standard Developers shall* include the relevant aspects of the 'FSC Guide to integrated pest, disease and weed management in FSC certified forests and plantations' (2009) and associated policies, guidelines, advice notes and other FSC normative documents for the development of indicators (Indicator 10.7.1).</td>
</tr>
<tr>
<td>Standard Developers shall* either reference or include the relevant aspects of the ILO document “Safety in the use of chemicals at work” (Geneva, ILO, 1993) or any national interpretation of this document in National Standards and Interim National Standards (Indicator 10.7.4).</td>
<td>Standards Developers shall consider the Annex ‘International Generic Indicators for the use and risk management of Highly Hazardous Pesticides (HHP)’ and develop national indicators for HHP used or likely to be used in the country.</td>
</tr>
<tr>
<td>10.7.1 Integrated pest management, including selection of silviculture* systems, is used to avoid, or aim to eliminate, the frequency, extent and amount of chemical pesticide* applications, and result in non-use or overall reductions in applications.</td>
<td>Standards Developers should consider listing the requirements in FSC-POL-30-001 V3-0 FSC Pesticides Policy Clause 4.12 in National Standards and Interim National Standards.</td>
</tr>
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<td>10.7.2 Chemical pesticides* prohibited by FSC’s Pesticide Policy are not used or stored in the Management Unit* unless FSC has granted derogation.</td>
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<tr>
<td>10.7.3 Records of pesticide* usage are maintained, including trade name, active ingredient, quantity of active ingredient</td>
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FSC-STD-60-004A
INTERNATIONAL GENERIC INDICATORS FOR THE USE OF HIGHLY HAZARDOUS PESTICIDES
2020 – 9 of 43 –
Existing Instructions and IGIs under 10.7

10.7.4 The use of pesticides* complies with the ILO document “Safety in the use of chemicals at work” regarding requirements for the transport, storage, handling, application and emergency procedures for cleanup following accidental spillages.

10.7.5 If pesticides* are used, application methods minimize quantities used, while achieving effective results, and provide effective protection* to surrounding landscapes*.

10.7.6 Damage to environmental values* and human health from pesticide* use is prevented and mitigated or repaired where damage occurs.

10.7.7 When pesticides* are used:

1) The selected pesticide*, application method, timing and pattern of use offers the least risk to humans and non-target species; and
2) Objective evidence demonstrates that the pesticide* is the only effective, practical and cost effective way to control the pest.

Proposed Instructions and IGIs under 10.7

10.7.2 Chemical pesticides* prohibited by FSC’s Pesticide Policy are not used or stored in the Management Unit* unless FSC has granted derogation. Prior to using chemical pesticides*, the requirements of the ESRA framework for Organizations (FSC-POL-30-001 V3-0 FSC Pesticides Policy clause 4.12) are met.

10.7.3 A decision process and rationale are in place for selecting a pest management method that considers economic viability* and effectiveness to determine the lowest risk option(s).

10.7.4 Records of pesticide* usage are maintained, including trade name, active ingredient, quantity of active ingredient used, period of use, number and frequency of applications, location and area of use and reason for use.

10.7.5 The use of pesticides* complies with the ILO document “Safety in the use of chemicals at work” regarding requirements for the transport, storage, handling, application and emergency procedures for cleanup following accidental spillages.

10.7.6 If pesticides* are used, application methods minimize quantities used, while achieving effective results, and provide effective protection* to surrounding landscapes*.

10.7.7 Damage to environmental values* and human health from pesticide* use is prevented and mitigated or repaired where damage occurs.

10.7.8 When pesticides* are used:

1) The selected pesticide*, application method, timing and pattern of use offers
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<td>the least risk to humans and <em>non-target species</em>; and</td>
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<tr>
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<td>2) Objective evidence demonstrates that the <em>pesticide</em> is the only effective, practical and cost effective way to control the pest.</td>
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II. International Generic Indicators that will be incorporated to current FSC-STD-60-004 International Generic Indicators as Annex ‘International Generic Indicators for the use and risk management of Highly Hazardous Pesticides (HHP)’

INSTRUCTIONS FOR STANDARD DEVELOPERS:
Indicators for the use and risk management of specific HHPs are recommended to be compiled into an annex of the National Forest Stewardship Standard (NFSS) or Interim National Standards (INS), but they can be inserted to the body of the national standard. Also, combining these two options is possible.

In case indicators are inserted to the national standard, the need for the HHP indicators should be considered at least for following criteria: C1.3; C1.6; C2.1; C2.3; C2.5; C2.6; C3.1; C3.2; C4.1; C4.2; C4.5; C4.6; C4.7; C5.1; C6.1; C6.2; C6.3; C6.6; C6.7; C7.4; C7.6; C8.2; C8.3; C8.4; C9.1; C9.3; C10.7; C10.8; C10.12. (The list is based on desk studies conducted in South Africa, New Zealand, UK and Brazil. The studies are available from FSC IC by request to forestmanagement@fsc.org).

The IGIs provided below are designed to the option, where the indicators are presented as an Annex to INS or NFSS.

i) INTERNATIONAL GENERIC INDICATORS FOR ALL HHPs

1. International Generic Indicators for all HHPs

INSTRUCTIONS FOR STANDARD DEVELOPERS:

Standard Developers shall* determine, using Best Available Information*, whether critical population density* is an appropriate measure to determine intervention threshold* for a particular pest.

Standard Developers shall* develop indicators to ensure that where mobile HHPs are used and depending on application method, buffer zones* are established to protect environmental and social values.

Exposure elements are types of values that may be negatively affected by chemical pesticide use.

At a minimum the following environmental values, with specific components in brackets, shall be considered to identify and assess the risks of chemical pesticide use:

- Soil (erosion, degradation, biota, carbon storage).
- Water (ground water, surface waters, water supplies).
- Atmosphere (air quality, greenhouse gasses).
- Non-target species (vegetation, wildlife, bees and other pollinators, pets).
- Non-timber forest products (as FSC-STD-01-001 V5-2 FSC Principles and Criteria, criterion 5.1).
- High Conservation Values (particularly HCV 1-4)
- Landscape (aesthetics, cumulative impacts)
- Ecosystem services (water, soil, carbon sequestration, tourism).

At a minimum the following social values, with specific components in brackets, shall be considered to identify and assess the risks of chemical pesticide use.
These social values should be considered with regards to workers, including migrant and seasonal workers, workers’ families, neighbours, local communities, Indigenous Peoples and visitors to the forest.

- High Conservation Values (especially HCV 5-6)
- Health (fertility, reproductive health, respiratory health, dermatologic, neurological and gastrointestinal problems, cancer and hormonal imbalance);
- Welfare;
- Food and water;
- Social infrastructure; (schools and hospitals, recreational infrastructure, infrastructure adjacent to the management unit),
- Economic viability (agriculture, livestock, tourism); and
- Rights (legal and customary).

Standard Developers shall consider total formulations including active ingredient and inert or co-formulants (e.g. surfactant, wetter, adjuvant, additive).

1.1 A documented Integrated Pest Management (IPM) system, consistent with FSC Guide To integrated pest, disease and weed management in FSC certified forests and plantations, is in place.

Note for public consultation
FSC plans to revise and update FSC Guide To integrated pest, disease and weed management in FSC certified forests and plantations in 2020.

1.2 In addition to existing IGI 10.7.3 (proposed IGI 10.7.4) requirements, the following records of HHP usage and IPM implementation are maintained:

a) level of target pest infestation,

b) the decision process and rationale for selecting a Highly Restricted or Restricted HHP over a non HHP or non-chemical pesticide* control method,

c) risk assessment for operator safety, detailing the processes to be followed in carrying out the HHP application, following appropriate legislation or guidelines,

d) assessment of economic impact caused by the pest and the HHP,

e) application methodology,

f) who made the application,

g) total annual volume used,

h) time and date of treatment,

i) the weather conditions at time of application,

j) any disposals or spillage, including action taken to prevent contamination and/or harm,

k) evaluation and monitoring of the effectiveness of treatment,

l) mapped boundaries of treatment area and pest affected area when relevant.

1.3 Control measures are proactively considered and/or implemented before intervention threshold*, and/or critical population densities* of the targeted pest are reached.
1.4 A trend of replacement, reduction and/or removal of HHPs over time is demonstrated and/or otherwise justified.

1.5 Use of HHPs is limited to the minimum effective dose based on the label and \textit{Best Available Information}.

NOTE: In some cases, effective dose range rather than a single dose will need to be determined, depending on the pest.

1.6 Directly or potentially affected \textit{stakeholders} are provided with safety information, through \textit{culturally appropriate engagement}, before HHPs are used.
   a) The safety information for the particular HHP is provided in a culturally appropriate and accessible format.
   b) The information complies with World Health Organization in Guidelines for personal protection in handling the pesticides.
   c) An \textit{exclusion zone} is established for the \textit{period of re-entry}, where a HHP and/or application method requires one, as instructed by the label, or other applicable sources, to avoid workers and \textit{affected stakeholders} from being exposed to harm.

1.7 A \textit{buffer zone} is established where a HHP and/or application method requires one to ensure the protection of environmental and cultural values.

1.8 \textit{Free, prior and informed consent} is granted by Indigenous Peoples and local communities prior to HHPs use that affect their rights, resources, \textit{lands and territories}, wherever:
   a) it occurs adjacent to these \textit{lands and territories}, (see definition of local communities)
   b) has a \textit{secondary or latent impact},
   c) has the potential for \textit{sublethal effects} and/or chronic effects.

1.9 In the case of an emergency situation or by governmental order the use of Highly Restricted and Restricted HHPs conforms with the use of FSC prohibited HHPs specified in Annex 3 of FSC-POL-30-001 \textit{FSC Pesticides Policy}.

1.10 When required to use HHPs by government order, the government is informed of the risks, including the requirements of FSC for the use and risk management of HHPs, and requests that non HHPs alternatives are used.
### ii) INTERNATIONAL GENERIC INDICATORS FOR HAZARD GROUPS

<table>
<thead>
<tr>
<th>Hazard Groups</th>
<th>Number</th>
<th>Hazard Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant International Agreements or conventions</td>
<td>1</td>
<td>Relevant International Agreements or conventions</td>
</tr>
<tr>
<td>Acute toxicity</td>
<td>2</td>
<td>Acute toxicity to mammals and birds</td>
</tr>
<tr>
<td>Chronic toxicity</td>
<td>3</td>
<td>Carcinogenicity</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Mutagenicity to mammals</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Developmental and reproductive toxicity</td>
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<tr>
<td></td>
<td>6</td>
<td>Endocrine disrupting chemical (EDC)</td>
</tr>
<tr>
<td>Environmental toxicity</td>
<td>7</td>
<td>Acute toxicity to aquatic organisms</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Persistence in soil or water and soil sorption potential and bio-magnification and bio-accumulation</td>
</tr>
<tr>
<td>Dioxins</td>
<td>9</td>
<td>Dioxins (residues or emissions)</td>
</tr>
<tr>
<td>Heavy metals</td>
<td>10</td>
<td>Heavy metals</td>
</tr>
</tbody>
</table>

Table 1. Hazard Groups and Criteria for the identification of highly hazardous pesticides (Source: FSC-POL-30-001 FSC Pesticides Policy).
Hazard Group Relevant international agreements or conventions

2. Indicators for HHPs that meet Hazard Criterion 1 (Relevant international agreements or conventions)

INSTRUCTIONS FOR STANDARD DEVELOPERS:

Compliance with IGIs is required in Annex 3 of the policy. This instruction is expected to be applied by those Standards Developers that choose to strengthen the requirements for prohibited HHPs.

Standard Developers shall either reference or include the relevant aspects of the following documents or any national interpretation of these documents in National Standards and Interim National Standards.

- FSC POL-30-001a FSC Lists of highly hazardous pesticides.
- The WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification, 2009. World Health Organization (WHO), International Programme on Chemical Safety (IPCS) and Inter-Organization Programme for Sound Management of Chemicals (IOMC). Table 1, Table 6, Table 7.
- International tools for preventing local pesticide problems: A consolidated guide to chemical codes and conventions. European Centre on Sustainable Policies for Human and Environmental Rights (ECSPHR), 2008. Section 3, Section 5.2.1.

NOTE: See Appendix 1 for GHS EDC toxicity category PPE.

Standard Developers shall consider total formulations including active ingredient and inert or co-formulants (e.g. surfactant, wetter, adjuvant, additive).

2.1 When HHPs that meet Hazard Criterion 1 are used:

a) Annex 3. Procedure for the exceptional use of FSC prohibited HHPs in FSC-POL-30-001 FSC Pesticides Policy is applied.

b) Health and safety practices for workers* and affected stakeholders* are developed and implemented in accordance with the GHS toxicity categories chapter 3 and 4.

c) Harm caused to workers* and/or affected stakeholders* by over-exposure* to a HHP that meets Hazard Criterion 1 is treated and/or fair compensation* is provided.
d) Pre-screening and post screening of workers exposed to HHPs listed that meet Hazard Criterion 1 is conducted and appropriate actions are taken to avoid harm. (See Textbox 1)

2.2 When required to use HHPs listed in Hazard Criterion 1 by governmental order, the government is informed of the risks, including the indicators for Hazard Criterion 1 and requests that non prohibited alternatives are used.

**Textbox 1: Biomonitoring for Hazard Criterion 1**

1. For organochlorines:
   1.1 Whole blood test - 1cc anti-coagulated in sodium hepalin (regrigerated). Taken before and after spraying. Analysed by Comet assay (Yusa et al., 2015)
   1.2 Hair test – 50-200mg, cleaned and frozen (Yusa et al., 2015)
2. For organochlorines and POPs
   Breast milk test – 1-5cc, prepared and refrigerated. (Sannolo et al., 1999)
3. For HCH and methyl bromide
   Blood serum and blood plasma tests – 1cc anti-coagulated in sodium hepalin (refrigerated). Tests for body burden. Determined by LC-MS and analysed by Comet assay (Doganlar et al., 2018)

**Hazard Group Acute toxicity**

3. **Indicators for HHPs that meet Hazard Criterion 2 (Acute toxicity to mammals and birds)**

[INSTRUCTIONS FOR STANDARD DEVELOPERS]

Standard Developers *shall* either reference or include the relevant aspects of the following documents or any national interpretation of these documents in National Standards and Interim National Standards.

- Severely Hazardous Pesticides formulations toolkit (sections 4 and 5) (UNEP FAO).
- The WHO Recommended Classification of Pesticides by Hazard and guidelines to classification. 2009. World Health Organization (WHO), International Programme on Chemical Safety (IPCS) and Inter-Organization Programme for Sound Management of Chemicals (IOMC). Tables 1,2, 3 and 7.
• Recognition and management of pesticide Poisonings. 6th Edition. 2013. United States Environmental Protection Agency (EPA), Office of Pesticide Programmes. Section I Chapter 2, Section VI and Section VII. Cross reference with 2.1.3. These are the biomonitoring indicators and signs and symptoms of acute poisoning.

NOTE: See Appendix 1 for GHS EDC toxicity category PPE.

Standard Developers shall* consider total formulations including active ingredient and inert or co-formulants (e.g. surfactant, wetter, adjuvant, additive).

Standard Developers shall* prioritize indicators for the identification of the harm and required treatment before looking at compensation when it comes to human health.

3.1 Health and safety practices for workers* and affected stakeholders* are developed and implemented in accordance with the GHS acute toxicity categories (see Textbox 2).

3.2 Harm caused to workers* and/or affected stakeholders* by over-exposure* to a HHP in Hazard Criterion 2 is treated and/or fair compensation* is provided.

3.3 Pre-screening for pesticides persistent* in humans, and regular medical biomonitoring of workers exposed to HHPs in Hazard Criterion 2 is conducted and appropriate actions are taken to avoid harm.

Textbox 2: Biomonitoring for Hazard Criterion 2


Biomonitoring tests for Hazard Criterion 2 include:

1. Urine tests for pyrethroids and neonicotinoids, organophosphate insecticides. <5ml urine sample needed to test for specific metabolite biomarkers as indicates in Yusa et al. 2015. The urine matrix is representative of recent exposure as these are non-persistent pesticides that are rapidly metabolized and eliminated. Spot samples are easily collected, stored and transported. Sample preparation using SPE methods. Analysis is done using QuEChERS method.

2. Erythrocyte acetylcholinesterase (AChE) testing before and after applications using Test-mate Model 400 device (EQM Research Inc)

See also Organisation for Economic Co-operation and Development (OECD) guidance document on acute toxicity testing and biomonitoring Standard Operating Procedures.
**Hazard Group Chronic toxicity**

4. **Indicators for HHPs that meet Hazard Criterion 3 (Carcinogenicity)**

**Instructions for Standard Developers:**

Standard Developers *shall* either reference or include the relevant aspects of the following documents or any national interpretation of these documents in National Standards and Interim National Standards:

- Severely Hazardous Pesticides formulations toolkit (sections 4 and 5) (UNEP FAO).
- FAO HHP protection of children in low to middle income countries (FAO 2015).
- The WHO Recommended Classification of Pesticides by Hazard and guidelines to classification. 2009. World Health Organization (WHO), International Programme on Chemical Safety (IPCS) and Inter-Organization Programme for Sound Management of Chemicals (IO valleys). Tables 1, 2, 3 and 7.
- Understanding the Impacts of Pesticides on Children: A discussion paper. 2018. UNICEF.
- An NGO Guide to SAICM (The Strategic Approach to International Chemicals Management) 2008. Chapters 5.1.4 and 5.1.5 and 5.1.7
- International tools for preventing local pesticide problems: A consolidated guide to chemical codes and conventions. European Centre on Sustainable Policies for Human and Environmental Rights (ECSPHR), 2008. Chapter 3, section 4.2.5, 4.3.5 and Chapter 6.

**NOTE:** See Appendix 1 for GHS EDC toxicity category PPE.

Standard Developers *shall* consider total formulations including active ingredient and inert or co-formulants (e.g. surfactant, wetter, adjuvant, additive).

Standard Developers *shall* consider that children are more vulnerable to the carcinogenic effect of pesticides and need special consideration.
4.1 Health and safety practices for workers* and affected stakeholders* (particularly children*) are developed and implemented.

4.2 Harm caused to workers* and/or affected stakeholders* by over-exposure* to a HHP in Hazard Criterion 3 is treated and/or fair compensation* is provided.

4.3 Regular medical biomonitoring (see Textbox 3) for acute and chronic pesticide indicators based on thresholds levels of workers regularly exposed to HHPs in Hazard Criterion 3 is conducted and appropriate actions are taken to avoid harm.

Textbox 3: Biomonitoring for Hazard Criterion 3

Biomonitoring tests for Hazard Criterion 3 include (Yusa et al. 2015):

1. Urine samples taken for carbamates, pyrethroids. <5ml
2. Urine samples taken for organophosphate insecticides. <5ml
3. Hair samples taken for organophosphate insecticides. 50 -200mg
4. Blood samples taken for organophosphate insecticides. 5cc anti-coagulated with sodium heparin (refrigerate)
5. Breast milk samples taken for organophosphate insecticides. <5ml
6. Meconium samples taken for organophosphate insecticides. Measures prenatal exposure. O.5g dry weight needed
7. Sample analysis done using SPE methods. Analysis done using QuEChERS.

Erythrocyte acetylcholinesterase (AChE) testing before and after applications using Test-mate Model 400 device (EQM Research Inc). – for organophosphates and pyrethroids.

5. Indicators for HHPs that meet Hazard Criterion 4 (Mutagenicity)

Instructions for Standard Developers:

Standard Developers shall* either reference or include the relevant aspects of the following documents or any national interpretation of these documents in National Standards and Interim National Standards:

- Severely Hazardous Pesticides formulations toolkit (sections 4 and 5) (UNEP FAO).
- International tools for preventing local pesticide problems: A consolidated guide to chemical codes and conventions. European Centre on Sustainable Policies for Human and Environmental Rights (ECSPHR), 2008. Chapter 3, section 4.2.5, 4.3.5 and Chapter 6.
• The WHO Recommended Classification of Pesticides by Hazard and guidelines to classification. 2009. World Health Organization (WHO). International Programme on Chemical Safety (IPCS) and Inter-Organization Programme for Sound Management of Chemicals (IOMC). Tables 1, 2, 3 and 7.

NOTE: See Appendix 1 for GHS EDC toxicity category PPE.

Women and their offspring are particularly vulnerable to the mutagenic effect of pesticides and need special consideration.

5.1 **Workers** and **affected stakeholders** are not exposed to and do not handle HHPs in Hazard Criterion 4.

5.2 Health and safety practices for workers and affected stakeholders are developed and implemented (see Textbox 4).

5.3 Harm caused to for workers and/or affected stakeholders by over-exposure to a HHP in Hazard Criterion 4 is treated and/or fair compensation is provided.

---

**Textbox 4: Biomonitoring for Hazard Criterion 4**

Biomonitoring tests for Hazard Criterion 4 include:

1. Erythrocyte acetylcholinesterase (AChE) testing before and after applications using Test-mate Model 400 device (EQM Research Inc)
2. The urine matrix is representative of recent exposure as these are non-persistent pesticides that are rapidly metabolized and eliminated. Spot samples are easily collected, stored and transported. Sample preparation using SPE methods. Analysis is done using QuEChERS method. 5ml fresh samples required and refrigerated. (Yusa et al. 2015)
3. Serum levels of Mullerian hormone in women measured using spot hormone test (Burns & Pastoor, 2018)
6. Indicators for HHPs that meet Hazard Criterion 5 (Developmental and reproductive toxicity)

INSTRUCTIONS FOR STANDARD DEVELOPERS:

Standard Developers shall either reference or include the relevant aspects of the following documents or any national interpretation of these documents in National Standards and Interim National Standards:

Note: Post 2018 product label will conform to GHS harmonized system of classification and labelling of chemicals (2019)

- Severely Hazardous Pesticides formulations toolkit (sections 4 and 5) (UNEP FAO).
- The WHO Recommended Classification of Pesticides by Hazard and guidelines to classification. 2009. World Health Organization (WHO), International Programme on Chemical Safety (IPCS) and Inter-Organization Programme for Sound Management of Chemicals (IOMC). Tables 1.2, 3 and 7.

Standard Developers shall consider total formulations including active ingredient and inert or co-formulants (e.g. surfactant, wetter, adjuvant, additive).

Standard Developers shall prioritize indicators for the identification of the harm and required treatment before looking at compensation when it comes to human health.

NOTE: See Appendix 1 for GHS EDC toxicity category PPE.

6.1 Health and safety practices for workers* and affected stakeholders* are developed and implemented in accordance with the GHS reproductive toxicity categories.

6.2 Pregnant women are not exposed to and do not handle HHPs that meets Hazard Criterion 5.
6.3 Harm caused to workers* and/or affected stakeholders* by over-exposure* to a HHP that meets Hazard Criterion 5 is treated* and/or fair compensation* is provided.

6.4 Pre-screening for HHPs persistent* in humans, and regular medical biomonitoring of workers exposed to HHPs that meet Hazard Criterion 5 is conducted and appropriate actions are taken to avoid harm (see Textbox 5).

**Textbox 5: Biomonitoring for Hazard Criterion 5**

Biomonitoring tests for Hazard Criterion 5 include:

2. Breast milk test – 1-5cc, prepared and refrigerated.
3. AChE tests done regularly with Test-Mate Model 400 device.

7. Indicators for HHPs that meet Hazard Criterion 6 (Endocrine disruption)

**INSTRUCTIONS FOR STANDARD DEVELOPERS:**

Standard Developers shall* either reference or include the relevant aspects of the following documents or any national interpretation of these documents in National Standards and Interim National Standards:

- Severely Hazardous Pesticides formulations toolkit (sections 4 and 5) (UNEP FAO).
- The WHO Recommended Classification of Pesticides by Hazard and guidelines to classification. 2009. World Health Organization (WHO), International Programme on Chemical Safety (IPCS) and Inter-Organization Programme for Sound Management of Chemicals (IOMC). Tables 1, 2, 3, 4 and 7.
• IPCS International Program of Chemical Safety (WHO) - Integrated Risk Assessment document.

NOTE: See Appendix 1 for GHS EDC toxicity category PPE.

Standard Developers shall* consider total formulations including active ingredient and inert or co-formulants (e.g. surfactant, wetter, adjuvant, additive).

Standard Developers shall* prioritize indicators for the identification of the harm and required treatment before looking at compensation when it comes to human health.

7.1 Health and safety practices for workers* and affected stakeholders* are developed and implemented in accordance with the GHS EDC toxicity categories

7.2 Harm caused to workers* and/or affected stakeholders* by over-exposure* to a HHP in Hazard Criterion 6 is treated and/or fair compensation* is provided.

7.3 Pre-screening for pesticides persistent* in humans, and regular medical biomonitoring (see Textbox 6) of workers exposed to HHPs in Hazard Criterion 6 is conducted and appropriate actions are taken to avoid harm.

Textbox 6: Biomonitoring for Hazard Criterion 6

Biomonitoring for Hazard Criterion 6 includes ((Yusa et al, 2015, Estaban & Castano, 2009):

1. Organophosphates, carbamates and pyrethroids: Meconium samples taken from mother. Measures prenatal exposure. 0.5g dry weight needed.
2. Sample analysis done using SPE methods. Analysis done using QuEChERS.
3. AChE tests done with Test-Mate model 400 device before and after spraying (Vikkey et al., 2017). This can be used to test all groups, including pregnant and lactating women.
Hazard Group Environmental toxicity

8. Indicators for HHPs that meet Hazard Criterion 7 (Acute toxicity to aquatic organisms)

INSTRUCTIONS FOR STANDARD DEVELOPERS:

Standard Developers *shall* either reference or include the relevant aspects of the following documents or any national interpretation of these documents in National Standards and Interim National Standards:

- Acute toxicity risk of pesticides in Hazard Criterion 7, as indicated in the table below:

<table>
<thead>
<tr>
<th>Category</th>
<th>Insecticides</th>
<th>Organophosphate</th>
<th>Carbamate</th>
<th>Pyrethroid</th>
<th>Phenyl parazol es</th>
<th>Herbicide</th>
<th>Integrated Growth Regulators</th>
<th>Fungicide</th>
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</thead>
<tbody>
<tr>
<td>Algae</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Mod</td>
<td>High</td>
<td>Low</td>
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<tr>
<td>Aquatic invertebrates</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Mod</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Aquatic plants</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Fish</td>
<td>Mod</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Mod-high</td>
<td>High</td>
<td>Low</td>
<td>Low-high</td>
</tr>
<tr>
<td>Non target arthropods</td>
<td>Mod</td>
<td>Mod-high</td>
<td>No-mod</td>
<td>Mod-high</td>
<td>Mod-high</td>
<td>Low-mod</td>
<td>Low-high</td>
<td>Low-mod</td>
</tr>
<tr>
<td>Earthworms</td>
<td>Low-high</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Low-high</td>
<td>Mod</td>
<td>Low-high</td>
</tr>
<tr>
<td>Birds</td>
<td>Low-mod</td>
<td>Low-high</td>
<td>No-high</td>
<td>No-low</td>
<td>No-high</td>
<td>No-low</td>
<td>No</td>
<td>No-mod</td>
</tr>
<tr>
<td>Mammals</td>
<td>Mod</td>
<td>Low-high</td>
<td>No-high</td>
<td>Low</td>
<td>No-high</td>
<td>No-low</td>
<td>No</td>
<td>No-mod</td>
</tr>
<tr>
<td>Bees</td>
<td>Low-high</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Low-high</td>
<td>Mod</td>
<td>Low-high</td>
<td>Mod</td>
</tr>
</tbody>
</table>

Table 2. Acute toxicity risk of pesticides in Hazard Criterion 7

Standard Developers *shall* consider total formulations including active ingredient and inert or co-formulants (e.g. surfactant, wetter, adjuvant, additive).
8.1 The relevant *trigger values* are identified (see Textbox 7) to avoid harm to aquatic organisms.

8.2 Protection measures are implemented to avoid exceeding *trigger values*.

8.3 A monitoring program is implemented to ensure *trigger values* are not exceeded and has sufficient scope, detail and frequency to detect changes, relative to the initial assessment and status of the *trigger values*.

**Textbox 7: Calculating the trigger values* for Hazard Criterion 7 & 8**

The Toxicity Exposure ratio (TER) is a risk indicator for a risk assessment of pesticides and other plant protection products. The TER indicates the ratio of harmful concentration of a pesticide (acute toxicity value) to the estimated concentration of exposure (PEC) for an organism (acute or chronic). The former generally used the EC50 or NOEC while the latter uses the PEC (predicted environmental exposure). The predicted no effect concentration (PNEC) indicates the safe concentration of the pesticide for the aquatic environment. The Exposure Toxicity Ratio (ETR) is the inverse of this. The TER is also sometimes referred to as the risk quotient (RQ).

\[
\text{TER} = \frac{\text{Acute toxicity (PNEC)}}{\text{exposure (PEC)}}
\]

\[
\text{ETR} = \frac{\text{Exposure (PEC)}}{\text{Toxicity (PNEC)}}
\]

If the ETR >100 there is an acute risk (RED), if the ETR is 100> ETR>1 then there is a medium risk (YELLOW) and if the ETR is <1 then the ETR is low (GREEN).

<table>
<thead>
<tr>
<th>Category</th>
<th>Acute PEC trigger values</th>
<th>EU TER trigger value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae</td>
<td>&lt;0.1</td>
<td>100</td>
</tr>
<tr>
<td>Aquatic invertebrates</td>
<td>&lt;0.01</td>
<td>10</td>
</tr>
<tr>
<td>Fish</td>
<td>&lt;0.01</td>
<td>100</td>
</tr>
</tbody>
</table>

The extrapolation for tropical environments is generally by a factor of 10 for each category.

9. **Indicators for HHPs that meet Hazard Criterion 8 (Persistence in soil and water/biomagnification and bioaccumulation)**

**INSTRUCTIONS FOR STANDARD DEVELOPERS:**

Standard Developers *shall* either reference or include the relevant aspects of the following documents or any national interpretation of these documents in National Standards and Interim National Standards:

- Metabolites, Ex) Non – target arthropods and pollinators
  - Ecological monitoring methods for the assessment of pesticides impacts (Grant and Tingle, DFID).
  - Considerations of assessing the risks of combined exposures to multiple chemicals. Series on testing and assessment. No 296. OECD, 2018
The European soil database v2.0.

Standard Developers shall consider total formulations including active ingredient and inert or co-formulants (e.g. surfactant, wetter, adjuvant, additive).

9.1 The relevant trigger values are identified to detect persistence in soil and water/biomagnification and bioaccumulation (see Textbox 7).

9.2 Protection measures are implemented to avoid exceeding trigger values.

9.3 A monitoring program is implemented to ensure trigger values are not exceeded and has sufficient scope, detail and frequency to detect changes, relative to the initial assessment and status of the trigger values.

Hazard Group Dioxins

10. Indicators for HHPs that meet Hazard Criterion 9 (Dioxins (residues or emissions))

INSTRUCTIONS FOR STANDARD DEVELOPERS:

Standard Developers shall either reference or include the relevant aspects of the following documents or any national interpretation of these documents in National Standards and Interim National Standards:

- Severely Hazardous Pesticides formulations toolkit (sections 4 and 5) (UNEP FAO).
- ILO Safety in the use of chemicals at work
- IPCS International Program of Chemical Safety (WHO) -Integrated Risk Assessment document
- International Code of Practice for use of pesticides (WHO)
- Strategic Approach to International Chemicals management (UNEP)

Standard Developers shall consider total formulations including active ingredient and inert or co-formulants (e.g. surfactant, wetter, adjuvant, additive).

10.1 When HHPs that meet Hazard Criterion 9 are used:

a) Annex 3. Procedure for the exceptional use of FSC prohibited HHPs in FSC-POL-30-001 FSC Pesticides Policy is applied.
b) Health and safety practices for workers* and affected stakeholders* are developed and implemented in accordance with the GHS toxicity categories chapter 3 and 4.

c) Harm caused to workers* and/or affected stakeholders* by over-exposure* to a HHP that meets Hazard Criterion 9 is treated and/or fair compensation* is provided.

d) Pre-screening and post screening of workers exposed to HHPs listed that meet Hazard Criterion 9 is conducted and appropriate actions are taken to avoid harm.

10.2 When required to use HHPs listed in Hazard Criterion 9 by governmental order, the government is informed of the risks, including the indicators for Hazard Criterion 9 and requests that non prohibited alternatives are used.

Hazard Group Heavy metals

11. Indicators for HHPs that meet Hazard Criterion 10 (Heavy metals (arsenic, cadmium, lead, and mercury))

INSTRUCTIONS FOR STANDARD DEVELOPERS:

Standard Developers shall* either reference or include the relevant aspects of the following documents or any national interpretation of these documents in National Standards and Interim National Standards:

- ILO Safety in the use of chemicals at work
- IPCS International Program of Chemical Safety (WHO) Integrated Risk Assessment document
- International Code of Practice for use of pesticides (WHO)
- Strategic Approach to International Chemicals management (UNEP)
- The European soil database v2.0.

Standard Developers shall* consider total formulations including active ingredient and inert or co-formulants (e.g. surfactant, wetter, adjuvant, additive).

11.1 When HHPs that meet Hazard Criterion 10 are used:

a) Annex 3. Procedure for the exceptional use of FSC prohibited HHPs in FSC-POL-30-001 FSC Pesticides Policy is applied.
b) Health and safety practices for *workers* and *affected stakeholders* are developed and implemented in accordance with the GHS toxicity categories chapter 3 and 4.

c) Harm caused to *workers* and/or *affected stakeholders* by *over-exposure* to a HHP that meets Hazard Criterion 10 is treated and/or *fair compensation* is provided.

d) Pre-screening and post screening of workers exposed to HHPs listed that meet Hazard Criterion 9 is conducted and appropriate actions are taken to avoid harm.

11.2 When required to use HHPs listed in Hazard Criterion 10 by governmental order, the government is informed of the risks, including the indicators for Hazard Criterion 10 and requests that non prohibited alternatives are use
## Appendix 1: Personal Protective Equipment (PPE) and biomonitoring for Hazard Criteria

This table provides the Personal Protective Equipment (PPE), with their classification and compiles the biomonitoring with their references for all Hazard Groups and criteria.

<table>
<thead>
<tr>
<th>Hazard group</th>
<th>N o.</th>
<th>Hazard Criterion</th>
<th>Personal Protective Equipment (PPE)</th>
<th>Classification</th>
<th>Lab Biomonitoring</th>
<th>Lab Classification</th>
<th>Medical Biomonitoring</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant international Agreements or conventions</td>
<td>1</td>
<td>Relevant international Agreements or conventions</td>
<td>GHS06 DANGER H300, H301, H310, H311, H330, H331</td>
<td>EN 374:2016</td>
<td>Lab</td>
<td>EN 14605:2005,</td>
<td>Organochlorines: 1. Whole blood test – 1cc anticoagulated in sodium heparin (refrigerated). Taken before and after spraying. Analysed by Comet assay 2. Blood serum and plasma tests – 1cc anticoagulated in sodium heparin (refrigerated). Tests for body burden of HCH and methyl bromide. Determined by LC-MS and</td>
<td>Yusa et al., 2015 (<a href="http://dx.doi.org/10.1016/j.aca.2015.05.032">http://dx.doi.org/10.1016/j.aca.2015.05.032</a>)</td>
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<td>Lab</td>
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<td>Doganlar et al., 2018 (<a href="https://doi.org/10.1007/s00244-018-0545-7">https://doi.org/10.1007/s00244-018-0545-7</a>)</td>
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<td>Hazard group No.</td>
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<td>Classification</td>
<td>Lab Biomonitoring</td>
<td>Lab Classification</td>
<td>Medical Biomonitoring</td>
<td>Reference</td>
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<td>Warning Ozone depleting H420</td>
<td>Type 6 protective clothing (Chemical splash)</td>
<td></td>
<td>EN 13034</td>
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<td>analysed by Comet assay.</td>
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<td></td>
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<td>Full face respirators for vapours and gases</td>
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<td>EN 141: 2000</td>
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<td>This test used for organochlorine s and POP's</td>
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<tr>
<td></td>
<td></td>
<td>5. Particulate air filters for respirator s</td>
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<td>Hazard group</td>
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<td>Hazard Criterion</td>
<td>Personal Protective Equipment (PPE)</td>
<td>Classication</td>
<td>Lab Biomonitorin g</td>
<td>Lab Classification</td>
<td>Medical Biomonitoring</td>
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</tr>
</tbody>
</table>
| Acute Toxicity | 2 | Acute toxicity to mammals and birds | 1. Chemically resistant nitrile gloves  
2. Type 3 and 4 protective clothing  
3. Safety boots  
4. Face and eye protection (safety goggles) | P95, P99, P100  
EN 467: 1995 | 1. Fish Acute toxicity test  
2. Earthworm acute toxicity test  
3. Mammal acute toxicity test | OECD 203  
OECD 207  
OECD 237 | PhA herbicides, Neonicotinoids, Pyrethroids, Organophosphate insecticides:  
1. Urine test – 5cc fresh urine sample refrigerated. Regularly taken. Tested using ELISA test  
2. AChE tests done regularly with Test-Mate model 400 device | Yusa et al., 2015 (http://dx.doi.org/10.1016/j.aca.2015.05.032) |
<table>
<thead>
<tr>
<th>Hazard group</th>
<th>N o.</th>
<th>Hazard Criterion</th>
<th>Personal Protective Equipment (PPE)</th>
<th>Classification</th>
<th>Lab Biomonitoring</th>
<th>Lab Classification</th>
<th>Medical Biomonitoring</th>
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<td>Warning H335, H336</td>
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<td>3. Face and eye protection (safety goggles)</td>
<td>EN 345:1993 EN ISO 20345</td>
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<td>4. Half-face respirators</td>
<td>EN 140, EN 149 EN 143: 2000 R95, R99, R100</td>
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<td>Doganlar et al., 2018 (<a href="https://doi.org/10.1007/s00244-018-0545-7">https://doi.org/10.1007/s00244-018-0545-7</a>)</td>
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<td>EN 14605:2005,</td>
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<td>Classificaton</td>
<td>Lab Biomonitorin g</td>
<td>Lab Classificaton</td>
<td>Medical Biomonitoring</td>
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<td>2. Herschberger assay</td>
<td>OECD TG 441, OECD TG 414 OECD TG 451-453 OECD TG 426</td>
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1. EN 166; 2001
2. EN 140, EN 149, EN 143: 2000
3. P95, P99, P100
4. EN 467: 1995
5. EN 374:2016
6. EN 14605:2005
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References:
- Angerer, Ewers & Wilhelm, 2007 ([https://doi.org/10.1016/j.ijheh.2007.01.024](https://doi.org/10.1016/j.ijheh.2007.01.024))
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**Warning:** H400, H410, H411, H412, H413

4. Full face respirators
   - Full face respirators for vapours and gases
5. Particulate air filters for respirators
6. Apron

**EN 136 EN 141:**

- **P95, P99, P100**
- **EN 476:**
  - **1995**

**Heavy metals GHS06, GHS08**

1. Hair testing – 50-200mg, cleaned, dried and frozen
2. Breast milk testing - 1-5cc, prepared and refrigerated
3. Meconium testing – 0.5g dry weight needed for testing

[https://doi.org/10.1016/j.envint.2008.09.003]
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**Note:**
- **Type 5 protective clothing**
- **BS EN ISO 13982:2004**
- **EN 345:1993 EN ISO 20345**
- **4. Full face respirators**
- **EN 136 EN 141:2000**
- **5. Particulate air filters**
- **EH 467:1995**
- **6. Apron**
- **EN 136 EN 141:2000**
- **P95, P99, P100**
- **EH 467:1995**
- **EN 136 EN 141:2000**
- **P95, P99, P100**
- **EH 467:1995**
- **4. Urine testing - 5cc fresh urine sample refrigerated. Regularly taken.**