

A person wearing a white protective suit, a respirator mask with a large filter, and gloves is working with a large blue container. The person is holding a white cloth or filter over the container's opening. The background is a bright blue sky.

CropLife
INTERNATIONAL



Chemical Exposure Assessment and Control during the Manufacturing Process

Practical Guidance

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1. Introduction

This CropLife International guidance document is intended to provide guidance to agrochemical companies and share best practices of performing an exposure and risk assessment for hazardous chemicals (including active ingredients).

The goal of this guidance document is to prevent harm to employee's health when working with chemicals. This document describes how to anticipate, recognize, evaluate and control potential chemical exposures in the workplace. The exposure assessment strategy described in this document is designed to demonstrate with a high degree of confidence that workers are unlikely to be exposed to concentrations above the exposure standard.

Procedures and tools are described which, if followed, should ensure that workplace exposures are adequately controlled. Guidance is provided to assure the right combination of short and long-term controls and it enables the prioritization of control efforts and effective use of resources. It should be noted that local laws and regulations that are more stringent or conflict with this procedure take precedence.

2. Definitions

A.I.: Active Ingredient.

AIHA: American Industrial Hygiene Association.

CMR: chemicals that are defined according to the Globally Harmonized System as carcinogenic, mutagenic or as toxic to reproduction.

COSHH: the Control of Substances Hazardous to Health Regulations 2002, as amended is a United Kingdom Statutory Instrument that states general requirements for employers to protect workers and other persons from the hazards of substances used at work by risk assessment, control of exposure, health surveillance and incident planning.

CPC: Chemical Protective Clothing.

DNEL: Derived No Effect Level, is the level of exposure to a substance above which humans should not be exposed.

ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals.

ECHA: European Chemicals Agency.

EHS: Environment, Health and Safety

Exposure monitoring: to monitor (sample) workers' exposure to chemicals or other hazardous substances.

Exposure monitoring strategy: the exposure monitoring process that is designed to demonstrate with a high degree of confidence that workers are unlikely to be exposed to concentrations above the OES.

Exposure Scenario: the task, or combination of multiple tasks or activities of workers that result in potential exposure to chemicals given the control measures in place. The (predicted or measured) exposure level for an exposure scenario is a combination of properties of the chemical, the frequency and duration of exposure during activities as well as the type and effectiveness of controls in place at the workplace.

Hazard: a potential source of harm or adverse health effect on a person or persons

ILO: International Labour Organization.

IOHA: International Occupational Hygiene Association.

LOQ: Limit of Quantification, the lowest concentration at which a substance analyte can not only be detected but with predefined confidence level, so that goals for bias and imprecision are met.

NIOSH: National Institute of Occupational Safety and Health.

NOAEL: No Observed Adverse Effect Level, the highest experimental dose level that is without adverse effect in experimental test system, e.g. animal.

OEB: Occupational Exposure Bands are airborne concentration ranges for products without an OES but with a similar hazard profile. These exposure bands are intended to reflect the range of full-shift exposure limit values that would be expected for a chemical with a similar hazard profile.

OEL: Occupational Exposure Limit, is the maximum permissible concentration of a given gas, vapor, fiber or dust in the air in the workplace. It is intended to be the level at or below which a given substance can be present in the air in the workplace without harming the health of employees and their offspring, based on current knowledge. This should be the case even if exposure to the substance at that level occurs repeatedly or over a long period of time, even an employee's entire working life.

OES: Occupational Exposure Standard, comparable to an OEL. In this document OES is used as the generic term for atmospheric exposure limits set either by a regulatory body or by internally derived company values.

OECD: Organisation for Economic Co-operation and Development.

OSHA: Occupational Safety and Health Risk Assessment.

PPE: Personal Protective Equipment, is equipment which is designed to be worn or held by the worker to protect against one or more hazards (harmful effects of chemical, physical, biological, climatic or others) likely to endanger safety and health, and any additional accessories designed to meet this objective. This includes respiratory as well as skin protection (e.g. gloves, chemical resistant clothing) and eye protection.

REACH: REACH is the Regulation (EC) No 1907/2006 of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals.

Risk: combination of the likelihood of an occurrence of a hazardous event or exposure(s) and severity of injury or ill health that can be caused by the event or exposure(s).

Risk of chemical exposures: the potential harm to workers' health given the workers exposure level to chemicals, the potential severity of the consequence and the effectiveness of controls in place in the specific exposure scenario under consideration.

RMM: Risk Management Measures are the applied controls to manage or mitigate risks.

RPE: Respiratory Protection Equipment ranging from half to full face respirators to powered air purifying respirators (PAPR) up to supplied air respirators is used to protect employees from the inhalation of hazardous substances. These substances can be in the form of airborne vapours, gases, dust, fogs, fumes, mists, smokes, or sprays.

SEG: Similar Exposure Group is a group of workers having the same generic exposure profile for the (chemical) agent(s) being studied because of the similarity and frequency of the tasks performed, the materials and process with which they work, and the similarity of the way they perform the tasks.

STEL: Short Term Exposure Limit is the acceptable average exposure over a short period of time, usually 15 minutes.

STOP: Outlines the hierarchy of controls following Substitution, Technical, Organizational and Personal measures.

TWA: Time-weighted average, is the average exposure over a specified period, usually a nominal eight hours.

3. Summary

- Work-related chemical hazards must be identified and related health risks must be assessed and controlled to an acceptable level
- The need for an exposure monitoring program is based on the results of the Occupational Safety and Health Risk Assessment (OSHRA). The exposure monitoring program may include quantitative exposure modelling and measurement as outlined in this document
- Measures must be defined and implemented to mitigate risks to an as low as reasonably practicable level. In the selection of measures the hierarchy of controls must be applied. Substitution has priority – where possible – followed by technical solutions, organizational measures and personal protection measures
- All chemical exposure must be below the relevant Occupational Exposure Standard (OES) and likely to remain so on a long-term basis. If no regulatory, binding limit value is set by competent authorities, then internal reference values must be derived from toxicological data where possible and adhered to
- Exposure monitoring is required to identify potential exposure, to demonstrate compliance and verify adequate control for substances with an OES
- For chemical substances without an OES, or when an OES is not developed control bands should be used to define the appropriate level of technical control. Exposure is then evaluated against the occupational exposure bands
- Periodic exposure monitoring must be conducted to demonstrate exposures remain below the limit value and action must be taken before non-compliance occurs
- Sampling results as well as core information for interpretation of exposure data are recorded (preferred electronically) and retained for a minimum of 30 years (or longer if legally required).

4. Responsibilities

It is recommended that the procedures described in this guidance document are always performed by sufficiently qualified and trained experts with adequate qualification and experience with the competencies indicated below, i.e. EHS professionals, Industrial Hygienists or Occupational Health Physicians.

The quality and consistency of the approach outlined in this procedure highly depends on the experience, knowledge and competence of the assessor. It is crucial that the persons that execute exposure assessments is trained in the methodology and meets the competence requirements as indicated (see Annex 13 for guidance).

Competence level	Description
'Expert Level' EHS Resource	Qualified at 'Expert Level' whose education and experience meet the qualification requirements for certification by an organization recognized by the International Occupational Hygiene Association (IOHA) National Accreditation Recognition (NAR). These experts ensure methods and approaches used to support continuous compliance with legal and professional developments in the field of Industrial/ Occupational Hygiene.
'Knowledge Level' EHS Resource	Possessing a profound understanding of chemical exposure and risk assessment as outlined in this procedure. To qualify as OH Knowledge Level resource some recommended trainings are included in Annex 13. Knowledge Level resources are preferably coached by global experts to become independent professionals. Knowledge Level experts support local, site EHS experts in the implementation of this practical guidance document.
'Awareness Level' EHS Resource	EHS professional trained in and with 'Awareness Level' understanding of the implementation of this practical guidance document. The EHS professional develops the basic characterization as described in this document but needs Knowledge Level expert support especially in the in-depth risk assessment as described. Local EHS professionals are trained in the implementation of this procedure to Awareness Level resources.

5. Process description

INTRODUCTION

The evaluation and control of potential chemical exposures in the workplace requires a systematic approach. To ensure that all chemical exposures are below the limit value, the exposure levels must be known and when unknown, assessed.

The starting point for this assessment is the Occupational Safety and Health Risk Assessment (OSHRA). The OSHRA is a semi quantitative risk assessment approach that addresses a wide range of hazards.

In some work environments exposure to chemicals is clearly not relevant, in others it may obviously be an important topic and in some it is unclear if a chemical risk assessment is required. The OSHRA must therefore define when an exposure assessment is required. In the OSHRA, health risks are defined as the likelihood of occurrence of a negative (health) effect. For chemicals, this likelihood is a combination of the exposure level and the potential severity of the effect (the hazard).

Exposure assessment is a standard instrument in the toolbox of Industrial Hygiene and together with the hazard identification, a crucial element of the generic OSHRA. When in the OSHRA the exposure and thus the risk is identified as 'Low', no detailed exposure assessment is required. Then the OSHRA is documented and regularly updated to re-evaluate the effectiveness of the controls in place. When the potential exposure and risk levels are identified as 'Medium' or 'High' (i.e. potentially close to or exceeding the limit value), an in-depth exposure assessment is needed. An example of an OSHRA approach is provided in Annex 1.

The occupational exposure assessment as described in this document is designed to demonstrate with a high degree of confidence that workers during the manufacturing process are unlikely to be exposed to concentrations higher than the relevant limit value. If an official limit value for a chemical from authorities in the US, UK, Germany, or EU, and in rare cases of the WHO, is available, the lowest value shall be used. When a legal limit value or a limit set by a recognized professional organization (e.g., voluntary limits such as ACGIH threshold limit values [TLVs] and American Industrial Hygiene Association [AIHA] Workplace Environmental Exposure Limits [WEELs]) is not available, an in-house OES must be derived.

The assessment approach follows the current state of the art in occupational or industrial hygiene. It addresses the problem of exposure variability and indicates how the use of exposure modelling, use of read-across data and use of a limited number of measurements can be sufficient to demonstrate that workers are unlikely to be exposed to concentrations exceeding the OES.

First, the need for exposure monitoring is defined to reduce the number of exposure measurements and required assessment resources. Subsequently, personal air samples are collected if required among a selection of workers within similar exposure groups (SEGs).

DETAILED PROCESS

The overall process flow of the exposure assessment strategy for hazardous chemicals might be as follows:

1. Perform a basic characterization of risk

- a. Develop an inventory of hazardous chemicals (Annex 2)
 - This register should include at least the physical-chemical properties, hazard information and applicable OES of the chemicals used
 - If no binding OES are set by competent authorities, then internal reference values should be derived from toxicological data (Annex 10)
 - When an OES is not available an Occupational Exposure Band could be derived as described (Annex 3).
- b. Develop an inventory of workplace factors that influence exposure (Annex 4)
- c. Assess the exposures against the OES or target airborne concentration (e.g. Control/ Occupational Exposure Band) by considering workplace factors with quantitative models (Annex 5) or by read-across data from similar workplaces or exposure scenarios (Annex 6)
- d. Evaluate the estimated exposure levels against the OES (Table 1) and decide on further action if required. The evaluation thereby should be based on the applicability of the used model in combination with available input data.

Table 1. Suggested best practice criteria for the evaluation of risk based on modelling results

Criteria for evaluation of model estimations	Conclusion	Control Strategy
Estimated concentration is well below the OES	Risk sufficiently controlled (Low Risk)	Control Strategy A (see Annex 11)
Estimated concentration is close to the OES	Risk is unclear (Medium Risk)	Perform in depth characterization of risk. Control Strategy B (see Annex 11)
Estimated exposure concentration is above the OES	Risk is probably too high (High Risk)	Perform in depth characterization of risk. Control Strategy C (see Annex 11)

*the estimated concentration in the breathing zone (without use of RPE) is preferably validated by comparison of the model outcomes with measurement data.

The outputs of the basic characterization are:

- A register of hazardous chemicals
- A semi-quantitative evaluation of risk.

The basic characterization will indicate when an in-depth characterization is required.

2. Perform an in-depth characterization of risk

- a. Identify Similar Exposure Groups (Annex 7) and perform exposure monitoring, i.e. task or shift based (preferably personal sampling in breathing zone)
- b. Compare concentrations with the limit value or OES and define the required control strategy (Annex 11). Where needed (e.g. in multi-purpose facilities for development purposes) appropriate surrogates can be used for exposure monitoring (instead of the active ingredients themselves)
- c. Decide on further action if required and define the needed periodic monitoring (Annex 8)
- d. Document the results (Annex 9) and use for read-across when applicable (Annex 6).

Table 2. Suggested best practice criteria for the evaluation of the in-depth characterization of risk by air monitoring according to CEN (2016)

Criteria for evaluation of exposure measurements		Conclusion on exposure	Control Strategy
N=3	All samples < 0.1 OES	Low: Risk is sufficiently low, exposure is compliant with the OES. Concentration in workplace atmosphere is sufficiently low.	Control strategy A (see Annex 11)
N=4	All samples < 0.15 OES		
N=5	All samples < 0.2 OES		
N ≥ 6	Upper Tolerance Limit (95%, 70%) ≤ OES		
N=3	One or more samples > 0.1 but all samples < OES	Medium: risk is unclear, exposure may vary so may not be compliant with the OES.	Control strategy B (see Annex 11)
N=4	One or more samples > 0.15 but all samples < OES		
N=5	One or more samples > 0.2 but all samples < OES		
N ≥ 6	Upper Tolerance Limit (95%, 70%) > OES but distribution is not log normal.		
N=3,4,5	One sample > OES	High: Not compliant	Control Strategy C (see Annex 11)
N ≥ 6	Upper Tolerance Limit (95%, 70%) > OES	Concentration in workplace is too high and non-compliant with the OES.	

* N = number of measurements per SEG

The output of the in-depth characterization of risk is:

- Demonstration of compliance with the OES
- A plan of action for further reduction of exposure and improvement of control measures as needed
- Once any improvement measures have been implemented re-check is needed to demonstrate effectiveness of measures and compliance with OES.

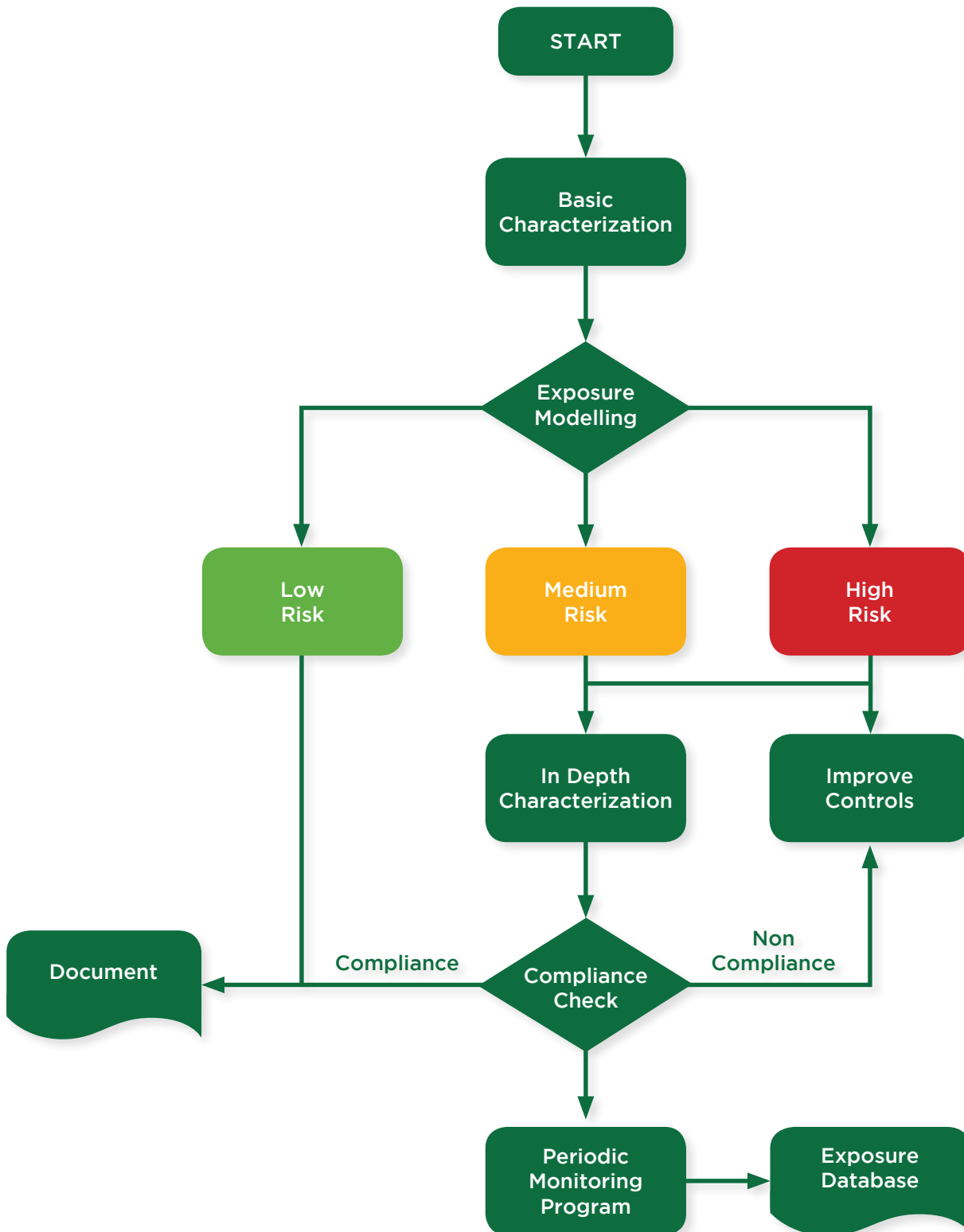
3. Perform periodic monitoring to ensure compliance and control of risks

The effectiveness of the exposure control measures must be demonstrated. A systematic evaluation of the risks as required by the OSHRA procedure stipulates the (risk based) minimum review intervals for risks that has been identified to be low. Regular reassessment and a robust management of change process are essential to identify any changes in the workplace, work-force and chemical agents used and this may trigger reassessment of exposure. Periodic monitoring is used as an additional control mechanism that identifies subtle but important changes that otherwise might not be noticed. Guidance on a risk based periodic monitoring frequency for carefully selected tasks/workplaces is included in Annex 8. This periodic monitoring program may include the use of direct reading instruments and the use of biological monitoring, the latter measures the effectiveness of the personal protective equipment used.

4. Documentation of exposure assessment results

To ensure correct interpretation of the assessment results it is crucial that not only the assessment results but also the assessment approach and exposure influencing factors are carefully documented. A structured documentation of the task or the activity assessed and exposure modifying factors like workplace and control measures in place as well as the objective of the assessment, the assessment strategy and methods used will enable the correct interpretation of the assessment outcomes. This also allows a trend analysis and mitigation of future liabilities (Annex 9).

Figure 1. Overall workflow of exposure assessment



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Annex 1. Occupational Safety & Health Risk Assessment (OSHRA)

The OSHRA has the following generic approach:

1. Define all jobs, activities carried out in the unit, e.g. workplace, plant
2. Identify the hazards
3. Assess the likelihood of harm to health (injury, adverse effects and occupational diseases)
4. Define measures to avoid harm to health and reduce risks to a level that is considered as low as reasonably practicable.

The risk for injury, adverse effects and occupational diseases could be assessed and classified using a risk matrix (Example Table 3) and further assessed as follows:

- Low risks: are to be documented in the OSHRA documentation
- Medium risks: are to be evaluated in more detail and exposures are measured where needed
- High risks: are to be evaluated in more detail to confirm compliance with applicable standards and exposures are assessed to define how risks can be reduced to an acceptable level.

Exposure monitoring results are then used to update the OSHRA and document the actual risk levels, to confirm and document compliance and to document the effectiveness of existing or needed controls.

Many health hazards have chronic effects, thus evidence of actual harm may not be obvious immediately or even for a long period after exposure. In these cases, the likelihood of harm is therefore defined as likelihood of exceeding a threshold above which there is the potential for adverse effects, e.g. OES. The OSHRA serves as a screening tool for the potential of health effects and can indicate when exposure monitoring and more detailed risk assessments are required.

Table 3. OSHRA Risk Matrix.

Probability of occurrence P	P ↓	Severity (or consequences) S			
		Lost work days <1 day Slight injury or health effect	3 days ≥ lost work days ≥1 day Minor health effect	Lost work days <3 days Major health effect	Permanent irreversible damage, total disability or death
Certain – will occur and is common	4	4	8	12	16
Probable – is likely to occur, has happened or may occur	3	3	6	9	12
Possible – could occur, have heard if it’s happening in other places	2	2	4	6	8
Remote – unlikely to occur, practically impossible	1	1	2	3	4

R > 9: High risk, measures with increased protection necessary

R > 3: Medium risk, measures with normal protection necessary

R ≤ 3: Low risk, no further measures necessary

Guidance for assessing the likelihood of (chronic) harm to health from exposures to health hazards:

Table 4. Exposure probability rating for OSHRA

Exposure probability	Definition	Description
P = 1	Very Low	The basic characterization shows that the risk of exposure to chemicals is well controlled and/or the in-depth characterization shows that exposures are well below the applicable occupational exposure standards (<10% OES).
P = 2	Low	The basic characterization shows that the risk of exposure to chemicals is sufficiently controlled and/or the in-depth characterization shows that exposures are in compliance with the applicable occupational exposure standards (10% -50% OES).
P = 3	Medium	The basic characterization and/or the in-depth characterization shows that the risk of exposure to chemicals is unclear, more information is needed to conclude compliance with the applicable occupational exposure standards (50% -100% OES).
P = 4	High	The basic characterization shows that the risk of exposure to chemicals is probably too high and/or the in-depth characterization shows that exposures are non-compliant with the applicable occupational exposure standards (>100% OES).

The severity of the potential consequences is defined in terms of health impact or by the chemical hazard band according to Annex 3 and as shown below in Table 5.

Table 5. Severity or consequence categories for health effects

Severity Level	Definition	Description
S = 1	Low: Slight injury or health effect	Not affecting work performance or daily life activities. Examples: <ul style="list-style-type: none"> • First aid cases and medical treatment cases • Noticeable discomfort • Minor irritation or transient effects reversible after exposure stops • Chemical hazard band: A (Table 6).
S = 2	Medium: Minor health effect	Affecting work performance, daily life restrictions, reversible effects. Examples: <ul style="list-style-type: none"> • Restricted work day cases or lost work day cases • Short term work restrictions (< duration, to be decided) • Illnesses such as skin irritation or food poisoning • Chemical hazard band: B (Table 6).
S = 3	High: Major health effect	Affecting work performance longer term, irreversible damage to health. Examples: <ul style="list-style-type: none"> • Long term disabilities (Permanent Partial Disabilities) • Long term work restrictions (> duration to be decided) • Illnesses such as sensitisation, noise induced hearing loss • Chronic back injury, repetitive strain injury • Chemical hazard band: C (Table 6).
S = 4	Very High: Permanent total disability or death from occupational illness.	Examples: <ul style="list-style-type: none"> • Illnesses such as corrosive burns, asbestosis, silicosis, cancer, occupational asthma • Chemical hazard band: D and E (Table 6).

Finally, the exposure probability (P 1, 2, 3 or 4) and the Severity rating (1, 2, 3 or 4) are combined to conclude the potential risk level (Low, Medium, High) from exposure to chemicals.

All potential medium and high risks then require a basic and in-depth characterization of exposure and risk (start with potential high risks). The exposure and risk levels are confirmed and the OSHRA document is updated with reference to the detailed exposure and risk assessments as carried out.

It is highly recommended to use an assessment tool that facilitates read-across for activities with a similar risk profile and document the assessment results therein. This avoids duplication of administrative efforts by registering assessment results details also in the OSHRA.

Annex 2. Inventory of Hazardous Chemicals

An actual and up-to-date inventory of all chemicals, including products and their constituents handled on site is the required basis for OSHRA (Annex 1).

Such an inventory of hazardous substances should contain at least the following information for each chemical:

- substance name and, where appropriate, an identification number (e.g. CAS number, company identification number)
- hazardous properties, i.e. classification and labeling information.

The following relevant information for an exposure to a hazardous substance may be also documented:

- percentage of the substance in the mixtures
- routes of potential exposure (including skin notation, if applicable)
- physical state (solid, liquid, gaseous)
- boiling point, vapor pressure
- OES (including information on the source)
- etc.

In case such information is not available, it should be taken either from the Material Safety Data Sheet or from valid databases (e.g. GESTIS, eChem Portal, etc.).

Different formats can be used for this inventory, for an example see Example file 1 below that allows uploading of additional data, i.e. for exposure modelling (see Annex 5).

Note that the above suggested register aims to support the chemical exposure and risk assessment process. The use of excel inventories such as this may not be needed when it is faster and/or easier to directly work in a software tool specifically developed for risk assessment. This may allow for a more focused start. This approach would be to:

- a. select a number of chemicals/active ingredients per workplace or per activity (based on the dustiness and vapor pressure of the chemicals)
- b. assess exposure potential and use read across (Annex 6) when possible
- c. apply the results to a wider range of chemicals at these workplaces/activities.

After this the inventory of hazardous chemicals is completed, starting with those workplaces for which exposure potential was identified.

For more details see Annex 5, Exposure Modelling

Example file 1. Register of Chemicals



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Annex 3. Control Banding, tentative limit values

APPLICATION OF CONTROL BANDING IN AGROCHEMICAL INDUSTRY

Control banding is a valid approach for the management of hazardous dusts in agrochemical industry. The various approaches adopted in several companies are summarized as follows:

- Control banding is only used when no health-based OES are available
- Control banding does not replace exposure assessment where health-based OES exist
- As part of exposure assessment processes, there is a movement towards the use of exposure modelling tools to focus on targeted exposure monitoring (i.e. helps to determine when to move from qualitative to quantitative)
- Development of in-house validated exposure scenarios using both modelling and exposure monitoring data is viewed as the solution to guide engineering design.

Multiple banding approaches are defined and the ones quoted below can be considered as best practice examples.

- COSHH Control bands are defined by the GHS Hazard (H) phrases or additional available in house toxicological information on the substance of interest. If available, this toxicological information overrules the use of H phrases
- NIOSH recently developed so called Occupational Exposure Bands (OEB), which are airborne concentration ranges (i.e., concentration bands) for products without an OES but with a similar hazard profile. These OEB provide target air concentration ranges that can be used for traditional occupational risk management purposes and identify the adequacy of existing exposure control strategies. These exposure bands are intended to reflect the range of full-shift OES that would be expected for a chemical with a similar hazard profile. The purpose of OEB is to be used to measure the effectiveness of the controls that are in place, and whether additional controls would be advisable (Center for Disease Control, 2017).
- The International Chemical Control Toolkit (ICCT) was developed by the International Labour Organisation (ILO), and is based on COSHH Essentials. In addition, ILO developed a number of relevant instruction guidance/control sheets developed for the safe handling of a substance under the given control conditions. When this guidance is followed exposures can be expected to be within the defined control band.
 - A complete list of guidance sheets and the complete toolkit can be found online at: http://www.ilo.org/legacy/english/protection/safework/ctrl_banding/index.htm
 - The guidance sheets for the different control approaches can be found here: http://www.ilo.org/legacy/english/protection/safework/ctrl_banding/toolkit/icct/sheets.htm

Table 6. Control Bands as per NIOSH and COSHH/ILO

Hazard Band (A - E)	Toxicological properties	COSHH/ILO Band		Hazard phrase (GHS)	NIOSH Occupational Exposure Bands (OEB)	
		Liquids in ppm	Solids in mg/m ³		Liquids in ppm	Solids in mg/m ³
A	Minor effects only: Irritating to eyes and respiratory system	50 - 500	1 - 10	H303, H304, H305, H313, H315, H316, H318, H319, H320, H333, H336 and all other H phrases not listed	>100	>10
B	Harmful: Short-term (adverse) health effects. Possible risk of (reversible) effects	5 - 50	0.1 - 1	H302, H312, H332, H371	>10 - 100	>1 - 10
C	Toxic: Irreversible (toxic) health effects or other serious long lasting adverse effects, toxic, burns, sensitization	0.5 - 5	0.01 - 0.1	H301, H311, H314, H317, H318, H331, H335, H370, H373	>1 - 10	>0.1 - 1
D	Very toxic: Irreversible health effects, limited evidence of a carcinogenic effect	<0.5	<0.01	H300, H310, H330, H351, H360, H361, H362, H372,	>0.1 - 1	>0.01 - 0.1
E	May cause cancer, may impair fertility	Expert advice	Expert advice	H334, H340, H341, H350	≤0.1	≤0.01

Annex 4. Inventory of workplaces and activities

Many workplace characteristics influence if and how exposure may occur. These include:

- the size of a workplace or work area
- the ventilation type and capacity
- the production processes and process characteristics (process temperature)
- the applied engineering controls (fully, partly closed or open systems).

Also, the information on the performed task should be documented, including:

- task frequency and task duration
- the personal protective equipment used
- varying work (hygiene) practices.

Thus, observation of the individual work practices is crucial for the correct assessment of exposure potential and interpretation of exposure monitoring results.

For a systematic collection and further use of all information on different activities and workplaces the use of standardized format, e.g. tables, is recommended.

Annex 5. Exposure modelling

The estimation of exposure by calculation using mathematical models is another option to quantify exposure to single chemicals. Because modelling of exposure is time and location independent, it can be used to estimate exposure in various occupational settings by simply altering the input parameters required for calculation. This flexibility allows also the assessment of these parameters and their potential influence. However, it always needs to be considered that a calculation might not be able to completely reflect the real situation existing in every detail.

An exposure modelling approach could be helpful in cases where air monitoring is not feasible, e.g., due to the lack of adequate technical and/or analytical methods. It also allows for effective screening of risks for a large number of products with multiple determinants of exposure in a standardized, transparent and systematic process.

With models like Stoffenmanager (<https://stoffenmanager.nl/>) and ECETOC TRA (<http://www.ecetoc.org/tools/targeted-risk-assessment-tra/>) activities/tasks with potential elevated risks can be identified. This screening approach allows to minimize necessary measurement and monitoring efforts because air sampling would only be done where needed. There are commercial software solution containing one or several of the modelling tools available (like www.chemrade.com) which might be helpful in effective screening of a large number of chemical exposures.

The outcome of the exposure models is a predicted exposure level during an activity (*task exposure*) and during the working day (*workday exposure*) resulting from that activity. It needs to be noted that the models are in general considered conservative and that they tend to overestimate the actual exposure level.

Like for measurement results, the mathematically estimated concentration is compared with the OES to conclude if the risk is sufficiently controlled.

There are several models available which are intended to estimate workplace exposure. As an example, the Advanced Reach Tool (ART) is an expert tool developed in a European Consortium (<https://www.advancedreachtool.com/>).

The US EPA provides a comprehensive overview of available Tools ([Exposure Assessment Tools and Models](#)).

Also, Organisation for Economic Co-operation and Development (OECD) has published a document on existing models and tools used for exposure assessment results ([http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO\(2012\)37&docLanguage=En](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2012)37&docLanguage=En)).

Annex 6. Read-across of exposure data

Available data on workplace exposure (generated via measurement or modelling) which demonstrate compliance with an OES can in certain cases also be used to evaluate exposure of chemicals with a similar exposure scenario and a similar or lower risk rating.

This grouping concept or “read-across” is a technique for prediction of information for one substance (target substance) by using information from another substance (source substance). The use of this approach can significantly reduce the exposure measurement efforts; however, the read-across assumptions must be reviewed with great care.

When applying read-across the following must be considered:

- the hazard of the source and target substance are similar, e.g. are both in the same hazard band (A-E in Annex 3)
- the exposure potential of the source and target substance are similar, e.g. the vapor pressure or dustiness
- the exposure tasks are similar, e.g. the duration and frequency of the exposure
- the workplace parameters including size and room characteristics as well as the equipment used need to be comparable
- the technical control measures in place, e.g. room ventilation (air changes per hour), the type, placement and effectiveness of the local exhaust ventilation (face and duct velocity in m/s), the type and level of enclosure or containment technique used (flow cabinet, glove box)
- the type of personal protection used (respirator, skin protection type and effectiveness).

Thus, it is in general not recommended to use the read-across from one workplace to another workplace unless it can be assured that the workplace, the exposure tasks, the equipment used and controls in place are similar for both workplaces.

Annex 7. Exposure monitoring

Sampling strategy for measuring worker inhalation exposures can include area (or static) sampling, personal sampling, or human biomonitoring.

Area sampling by using a stationary sampling device provides information on background levels in the work area, since air concentrations in the working room/area are measured. But these results do not allow for direct conclusions regarding actual workers' exposure given the variation in time and location the worker is in the monitored area. Thus, the results from static sampling should only be compared with exposure limits with great caution.

Grab sampling represents a special type of area sampling and can be used to identify a release at a specific source. Multiple (often direct reading) instruments are available for this type of measurement. Direct reading instruments are quite effective to demonstrate the effectiveness of existing (engineering) control measures. They can also identify tasks with potential exposures and therefore can have an important place in the overall design of the industrial hygiene monitoring plan.

If zero emission at source can be guaranteed based on grab sampling results personal sampling is not required.

In contrast to area sampling, personal sampling provides information on the workers' personal exposures during the activities. Usually, a sampling device is fixed on the outside of the worker's protective clothing, as close as possible to the mouth/nose to be within the breathing zone. Typically, it is attached to the worker's collar. Demonstration of compliance with an OES requires in general personal sampling.

Performing the sampling procedure should be conducted as follows:

1. Identify Similar Exposure Groups:

Similar Exposure Groups (SEG) are groups of workers with the same generic exposure profile for the agent(s) being studied because of the similarity and frequency in tasks they perform, the materials and processes they work with and the similarity of the way they perform the task.

When SEG are defined it is important to ensure that all individuals in the SEG have the similar general exposure profile for the chemicals. This is done by a careful review of the activities carried out by the individual workers in the SEG and by documentation of the activities during the sampling. It is crucial to include contextual information that may impact the sampling results, e.g. type of task, intensity of the activity, distance to source, special events that may have resulted in release of the chemicals etc.

By defining SEG, it is not necessary to sample each worker individually. For compliance testing it is recommended to take 6 or more samples per SEG.

To conclude if the monitoring results are representative for all workers in the SEG the measurement results must be reviewed and confirmed to follow a lognormal distribution and check for exceptionally high exposures within the SEG.

2. Perform measurements: task-based, shift-based for e.g. 8 hours

When preparing for sampling it is important to consider the minimum analytical Limit of Quantification (LOQ) and sampling volume to ensure concentration of 10% of the OES can be measured. This requires special caution for task based sampling given the likely short sampling duration.

Start with task based exposure measurements for the identified activities in the OSHRA and calculate the corresponding 8-hour time-weighted average (TWA) for comparison with the OES. Where exposures are discrete e.g., charging, drum filling, routine maintenance, exposure monitoring can be task based.

Continuous monitoring should be carried out for the full shift if the tasks resulting in exposure are not known. This approach should include start up, shut down and cleaning activities to measure the real 8-hour TWA exposure.

During continuous monitoring, a task analysis should be carried out and documented. Product changeover must be treated as a separate activity but cannot be excluded from the tasks that define the SEG.

Observation of the individual work practices during execution of the task, though highly time consuming, is strongly recommended to ensure correct documentation and interpretation of monitoring results.

3. Test compliance with the relevant OES using the indicated criteria and document the results

The measured concentration is compared with the OES to conclude if the risks are sufficiently controlled. For substances without an OES the upper value control bands (Annex 3) could be used as tentative OES.

However, the final compliance decision if an exposure is acceptable is an expert judgement that includes the statistical evaluation of available exposure measurement data and all other available information.

This is due to the fact an exceedance of the OES by one single measurement might occur given the temporal (hour-to-hour and day-to-day) variability in exposure levels in a SEG. However, whether these exceedances are permissible and are regarded as still being compliant with the OES might be decided after statistical evaluation of the measurement results.

Therefore, the statistical evaluation of the measurement results should be defined and it should be decided how applicable regulatory OES's should be applied (AIHA, 2015). Guidance on such statistical evaluation is given by NIOSH, AIHA or stated in EN 689 (2016). In summary, these provisions recommend that a statistical test shall demonstrate, with at least 70% confidence, that less than 5% of exposures in a SEG exceed the OES.

Thus, the 95% Upper Tolerance Limit (UTL) established with 70% certainty can be used to demonstrate compliance with an OES. However, in case there is no legal requirement for this approach, it is always a company internal decision to use those parameters.

To perform the statistical evaluation including the UTL (95%, 70%) the tool IHSTAT published by AIHA (<https://www.aiha.org/get-involved/VolunteerGroups/Pages/Exposure-Assessment-Strategies-Committee.aspx>) might be used. However, note that the original version only calculates the UTL 95,95. However, this can be changed when modifying the statistical calculations therein.

4. The results of exposure measurements are documented and summarized

Documentation should follow legal requirements. Further explanation is given in Annex 9. The results of the in-depth characterization link to the generic control strategy as defined in Annex 11.

In addition to exposure via inhalation, potential exposure via skin needs also to be considered during the risk assessment. Monitoring of surfaces at the workplace for settled dust or spilled material could be therefore useful to identify contamination and potential dermal exposure, e.g. by sampling before and after cleaning to determine effectiveness. Wipe sampling is the preferred method for such approach, where a defined surface (i.e. 10 x 10 cm) is cleaned with a wipe which is then analyzed for the substance of interest. The result is usually given in terms of quantity/100 cm² and might be evaluated against an OES, if available. Specific guidance on wipe sampling is not provided in this document.

While air monitoring provides information on inhalation exposure and wipe sampling can identify potential sources for dermal exposure, human biomonitoring (HBM) reflects the total uptake of a hazardous substance via the inhalation, dermal and/or oral route. HBM is thus particularly useful for the assessment of exposure to substances that are readily absorbed through the skin, or in the case of substances for which the total absorbed dose is responsible for an adverse effect (e.g. carcinogens). Furthermore, HBM can assist in the evaluation of the efficacy of control measures. HBM results are assessed on the basis of limit values in biological materials. Since HBM results are usually subject to medical confidentiality, human biomonitoring should always involve the occupational health physician in charge.

Annex 8. Periodic monitoring

A systematic evaluation of the risks is addressed in the OSHRA procedure, this stipulates (risk based) minimum review intervals for all occupational health and safety risks. Thus, regular reassessment and a robust management of change process are essential to identify any changes in the workplace, work-force and chemical agents used.

Periodic monitoring is therefore to be used as an addition control mechanism that identifies subtle but important changes likely to affect occupational health and that might not have been reported.

The reassessment frequency and the selection of chemicals to be measured should be risk based. It is therefore recommended to perform periodic exposure monitoring for:

- CMR chemicals (if applicable as per legal requirements)
- chemicals with the highest exposure and risk potential, based on the activity/ product/ workplace combination as defined in the basic or in-depth risk characterization.

If the interval for periodic measurements is not defined by legislation/requirements, DIN EN 689 (2016) as shown below in Table 7 or AIHA (2015) can be used for guidance.

A risk based example frequency for carefully selected high risk tasks/ workplaces is given below (Table 7).

Table 7. Intervals for periodic measurements

Measured concentration	Periodic Interval
GM* < 0.1 OES	3 years
0.1 < GM < 0.25 OES	2 years
0.25 < GM < 0.5 OES	1-2 years (18 months)
0.5 OES < GM	1 year

GM = Geometric mean of measurements results

Annex 9. Recordkeeping of exposure monitoring data

The documentation should be kept up-to-date and should be revised when new substances are used in the workplace, when new hazard information on the hazardous substance is available (e.g., lower OES, new classification, etc.) or when the exposure profile has changed (e.g., change of production processes, other work organization, new tasks, etc.). It is recommended to define a due date for a regularly review of the documentation. For the recording of exposure assessment, the following information is recommended:

- Name of the product/substance considered
- Name and CAS number of the chemical agent considered
- Percentage of the agent in the product
- Description of the workplace factors (room size, ventilation, local exhaust ventilation)
- Exposure determinants like exposure pattern (continuous, daily intermittent, occasional)
- Level of control (full containment, local exhaust ventilation, segregation, general ventilation)
- Type of measurement (task, daily average, peak)
- Sampling strategy (random, worst case, representative)
- Sampling position (personal, stationary back ground, stationary source oriented)
- Sampling medium (badge, pump, real time sensor)
- Sampling duration (minutes)
- Measuring procedure used
- Sampling date
- Department and Workplace
- Activity sampled
- Measured exposure concentration
- Job type or Similar Exposure Group of the sampled individual
- Respiratory protection (including the Applied Protection Factor)
- Other personal protective equipment used
- Identification and traceability of analytical results.

Annex 10. Occupational Exposure Standards

INTRODUCTION

An occupational exposure limit (OEL) is an upper limit on the acceptable concentration of a hazardous substance in workplace air for a particular material or class of materials. OEL are defined as airborne concentrations (expressed as time-weighted average for a conventional 8-hour work day and a 40-hour work week) of substances to which it is believed that nearly all workers may be repeatedly exposed for a working life time without adverse effect (ECETOC, 2006).

OEL are an important tool in risk assessment and in the control of activities involving handling of substances.

OEL are typically set by competent national authorities (or even supranationals like the European Union) and enforced by legislation to protect occupational safety and health. However, there are many substances for which there are no occupational exposure limits set by competent authorities. In these cases, OES voluntarily set by manufacturers (internal reference values) need to be used to define reference values as a reliable basis for risk assessment and safe handling.

This annex highlights procedures for the derivation of OES dependent on properties and extent of available data of active ingredients and raw materials used in the agrochemical industry.

CHALLENGES FOR AGROCHEMICAL INDUSTRY

For any substance featuring a binding OEL, the risk is evaluated based on these values. These binding values are set by national or supranational organizations, such as:

- U.S. Department of Labor, Occupational Safety & Health Administration (OSHA)
- European Commission (Binding and Indicative Limit Values)
- Hazardous Substances Commission, Germany
- UK Health and Safety Executive.

Where different values have been adopted by the above organizations, the lowest value should be accepted for application. However, the general rule of precedence of national law should be accepted (i.e. occupational exposure limits defined at national level being mandatory).

If such values have not been established, then limits as released by other regulatory and authoritative organizations (e.g., Derived No Effect Levels (DNEL) as published by the European Chemicals Agency (ECHA) as part of the REACH process) need to be considered.

For a huge number of active ingredients and raw materials used in agrochemical industry neither binding exposure limit values nor limits prescribed by other regulations are available, as illustrated by the following example.

Example: European Union:

- Registration of Active Ingredients under Regulation (EC) No. 1107/2009 does not imply a risk assessment of the manufacturing process
- Registered Active Ingredients are exempted from Regulation (EC) No. 1907/2006 (REACH) and thus not subject to a Risk Assessment as part of REACH
- Raw Materials are referred to as “Intermediates” under REACH with reduced data requirements (no exposure assessment)

- Consequently, substance-specific occupational exposure limits for active ingredients and most raw materials are not available in the European Union. The situation is similar in other regions.

Moreover, a significant share of active ingredients and raw materials is rated as hazardous dust. However, since General Dust Threshold Limit Values are only applicable for inert or non-hazardous dusts, it is also not possible to make reference to these values.

- Therefore, internal reference values based on adequate toxicological information for substances with sufficient data need to be derived. These internal reference values should be considered as globally applicable standards for all sites and plants (including production, formulation and filling) where no binding occupational exposure limits are available.

CHALLENGES FOR AGROCHEMICAL INDUSTRY

Procedures for setting internal reference values are generally based on No Observed Adverse Effect Levels (NOAEL) from repeated dose animal studies with application of appropriate assessment factors to account for uncertainty and variability in the data set. Internal reference values are not regulatory binding endpoints but help to ensure internal company-specific safety standards.

There are various well-established procedures for setting internal reference values. Generally, the application of these procedures requires expert judgement and an in-depth understanding of the concerned substances. Where appropriate, it is recommended to seek and take into account relevant data and experiences of other companies producing and/or handling the substance under consideration.

Generally, the process that is used for setting reference values is in most cases confidential and case-by-case, so company specific approaches have been established. It is not possible to define an overall standard process that could be applied to all active Ingredients and raw materials in agrochemical industry.

However, main principles and some basic rules for setting internal reference values are summarized as follows:

- Inhalation exposure is perceived to be the most significant route of exposure, however dermal exposure is significant in many situations. Chronic inhalation reference values and dermal reference values are derived for workers (short-term reference values are derived if indicated).
- All available data are assessed and most relevant and/or most sensitive endpoints are selected as starting points.
- Life-time exposure scenarios have preference over short/medium-term studies (i.e. subacute or sub-chronic studies), i.e. duration of exposure is generally considered to be chronic (greater than 3 months per year). However, the route of exposure has precedence over study duration. Topical effects are considered and discussed, if necessary.
- Chronic feeding studies are a major source of information for calculation of chronic reference values, if no inhalation or dermal studies are available.
- To account for the different routes of administration, information on the biokinetics (in rats) is used to derive an estimate of bioavailability following oral administration, whereas for inhalation exposure the bioavailability is estimated to be 100% if no other data are available.
- ECHA Guidance document R.8 is used for orientation when deriving DNELs (ECHA; 2012)
- Where long term studies are not available, additional assessment factors need to be applied to adjust for longer exposure times.

- Assessment factors should be used as indicated in ECHA guidance document R.8, and are modified on a case-by-case basis, if relevant data are available. Generally, the choice of assessment factors is subject to expert judgment. There is also room for other approaches which are not bound by the ECHA assessment factors.
- Internal reference values need to be documented in written justification (including list of the applied assessment factors and a full toxicology overview).
- It should be stated if there is need for either biological monitoring or health surveillance programs to be followed when handling the substance under consideration.
- It is recommended to establish a specific analytical method for the determination of the substance under consideration in air. The analytical Limit of Quantification (LOQ) and the sampling volume of the method should ensure concentrations of 10% of the internal reference value to be measured.

An example of a company-specific calculation of a OES for an active ingredient was provided by BASF SE.



OES Setting BASF
Example.pdf

The above described process requires a full toxicological data set which is often not available, particularly for raw materials and intermediates. In this case the calculation of OES is not possible and the application of a Control Banding Approach is recommended (see Annex 3).

CONCLUSIONS

Internal reference values derived from toxicological data should be the basis for risk assessment when no binding occupational exposure limit values are available.

General Dust Threshold Limit Values are only applicable for inert or non-hazardous dusts and should not be applied to active ingredients or raw materials.

Control banding approaches should only be considered when available toxicological data do not allow setting of internal reference values.

There is no unified standard procedure for setting internal reference value for Active Ingredients or raw materials. However, there is a common understanding of the basic principles incl. toxicological data, methodology and assessment factors that should be applied.

Internal reference values should be applied globally in all cases where no binding occupational exposure limits are available.

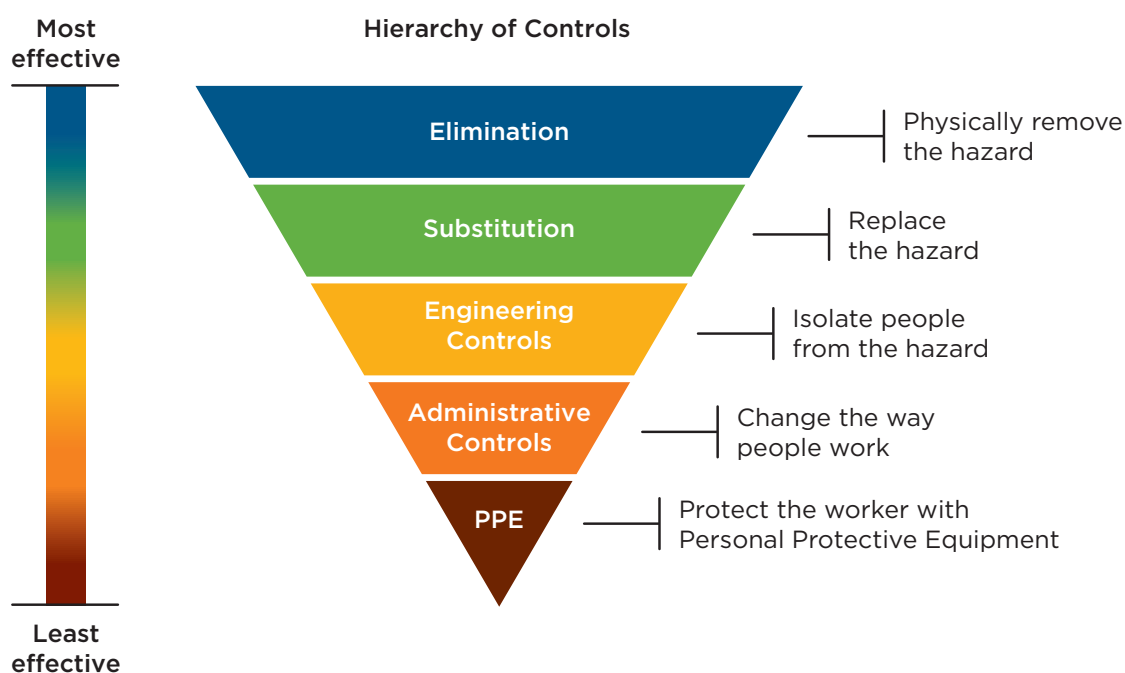
Annex 11. Control Strategy

INTRODUCTION

With a good understanding of the hazards and potential exposures of substances control strategies can be developed to protect not only the workers, but also the environment and the facility. It is preferable to consider the controls early in the design phase of a project since implementation of engineering controls after the facility has been built can potentially lead to retrofitting the facility and higher costs.

HIERARCHY OF CONTROLS

When considering the controls, the hierarchy of controls should be considered as seen in the figure below. The higher the control is on the triangle, the more effective is the mitigation of exposure. Thus, eliminating the hazards is more effective than prescribe Personal Protective Equipment (PPE). PPE is also the last resort in the hierarchy of controls and should not replace engineering controls or be used long term.



Source: NIOSH

ELIMINATION/SUBSTITUTION

Eliminating or substituting are the first line of defense when controlling exposure to hazardous dust. This approach is often not feasible, since hazardous dust being controlled is often the product that the company is producing for commerce, but there could be intermediates or co-formulants that cannot be changed that are potentially creating an issue as well. Therefore, it is important to review the process, preferably in the design phase, if there are potentially different methods to produce the product. There may be another method available, that will result in the same final product, but with less hazardous intermediates.

ENGINEERING

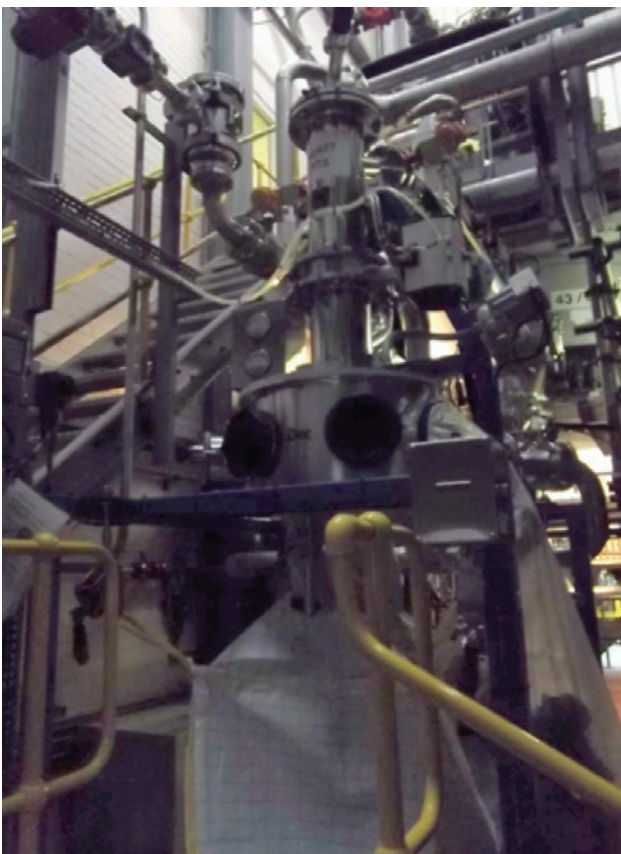
Using effective engineering controls such as closed systems, automatic transfer systems, or ventilation can eliminate exposures. Engineering controls should be investigated, designed, and installed during the design phase of the facility or process. Typically engineering controls are used to control worker exposures. Nevertheless, it is important to consider other potential hazards that need to be controlled, especially when dealing with a hazardous dust that could potentially be combustible.

When designing engineering controls, operating specifications must be developed and documented. This will provide the operating facility with the guidance so they can ensure proper operation of the engineered system. Additionally, preventative maintenance schedules should also be developed.

Operators of engineering systems must adhere to operating specifications and the preventative maintenance schedules. It is imperative that daily, weekly, or monthly (schedules must be developed) checks of the systems are to be completed and documented to ensure that the system is operating as designed. Improperly operated systems can lead to potential worker exposure either through inhalation or dermal contact or to other hazardous situations like a combustible dust explosion. Documentation of the maintenance and the specific changes made to the system help identify operational trends.

Example of an engineering controls may include the following:

1. Local exhaust ventilation to control airborne dust during the bagging operation. Capture velocities might vary between 0.25 - 1 m/s and higher depending on the air currents in the bagging area and the rate of release of dust.
2. Bagging of the final product with a minimal amount of moisture. With the product slightly wet the potential for dust to become airborne is reduced.
3. Using a Powder Transfer System that employs a glove box that allows the worker to attach bags to the system for unloading or loading, see pictures below:



In some cases, a large ventilations system may be needed. Well-designed ventilation systems are needed to control not only worker exposures but also control dusts to prevent dust explosions., In seed production activities, for example, dust is created at all stages of the process (cleaning and sizing of seed, treatment, and packaging).

The selected engineering controls must ensure exposures are reduced to levels below the OES. The required controls should be defined risk based, e.g. based on the exposure and risk assessment as outlined in this knowledge document.

In Table 8 the potential risk-based control strategies are visualized including examples of engineering controls. However, the application should be based on company-specific risk assessment results.

The given risk ratio ($\text{Risk Ratio} = \text{Exposure}/\text{OES}$) quantitatively represents the result of the risk assessment and indicates the applicable control strategy.

Table 8. Example of selection matrix for ventilation and containment solutions from COSHH Essentials

Hazard Band	Toxicology	COSHH/ ILO Band	Hazard Band	ILO	Containment Matrix							
					1. General ventilation		2. Partial Containment			3. Full containment		
		Solids in mg/m ³		Control strategy	Dilution Ventilation	Local Extraction	Local Extraction with captor hood	Local Extraction with captor booth	Fume cupboard partial containment	Fume cupboard/ Glovebox	Closed (dis) charging systems	Closed (liner) systems
E	May cause, may impair fertility	Expert advice	H334, H340, H341, H350	5								
D	Very toxic, irreversible health effects, limited evidence of a carcinogenic effect	<0.01	H300, H310, H330, H351, H360, H361, H362, H372,	4								
C	Toxic: Irreversible (toxic) health effects or other serious long lasting adverse effects, toxic, burns, sensitization	0.01 - 0.1	H301, H311, H314, H317, H318, H331, H335, H370, H373	3								
B	Harmful: short-term (adverse) health effects. Possible risk of (reversible) effects	0.1 - 1	H302, H312, H332, H371	2								
A	Minor effects only	1 - 10	H303, H304, H305, H313, H315, H316, H318, H319, H320, H333, H336 and all other H phrases	1								
	Minor effects only	>10	No H phrases	1								

Risk Ratio = Exposure/OES **LOW** ← → **HIGH**

Note: the indicated controls are examples only and should be made company specific based on risk assessment results. Controls must be defined risk based.

Once an engineering control has been put in place, that system needs to be validated for effectiveness of control of the specific hazard. This may require exposure monitoring for the specific agent that is being controlled to ensure that exposures are below the applicable OES. Additional testing may also be initiated to ensure that there are not combustible dust issues within the system itself.

ADMINISTRATIVE

Another option of exposure reduction towards worker is using administrative controls. By rotating workers from one job or task to another without exposure, the amount of time the worker is exposed is effectively reduced. To be able to implement such administrative changes, management must have a good understanding of the jobs, exposures, and work schedules of the workers.

PPE

For additional guidance on PPE, refer to Annex 12.

Table 9. Best Practice of Generic Control Strategies

Risk Level	Strategy	Potential Controls
Low Risk: Exposures are controlled well below the OES and likely to remain so in accordance with standards.	A	<ul style="list-style-type: none"> Procedures and training, general hazard communication to ensure exposures remain well below the OES Discontinue sampling Re-evaluate the process and update the exposure assessment every 5 years or through change management.
Medium Risk: Exposures are currently under control, below the OES but exposures may vary so periodic monitoring is required to demonstrate robust compliance.	B	<ul style="list-style-type: none"> Review and increase (chemical specific) training and communication as needed Confirm the effectiveness of controls and improve as appropriate Ensure PPE reduces exposure to below the OES/ tentative limit value set by the control band until further engineering controls are implemented Check log normality of the exposure data and identify exceptional exposure within the SEG (refer to DIN EN689 for guidance) Assess the exposure until periodic assessments indicate the compliance criteria are met Consider specific medical surveillance and biological monitoring Discontinue sampling when exposures or biological monitoring results indicate control of exposures Review periodic monitoring results and re-evaluate the need for exposure assessments every 3 years or through change management.
High Risk: Exposures are not controlled to meet standards, exceed the OES.	C	<ul style="list-style-type: none"> Notify site management immediately Use PPE as interim control measure Consider stopping process until effective controls are in place Improve the effectiveness of controls as soon as possible with emphasis on engineering controls Repeat measurements as soon as possible after improving controls.

CONTROL STRATEGIES REVIEW AND ADEQUACY

The following list might assist in the review of existing control measures and judging their adequacy:

- Look at what actually happens in the workplace during the task as compared to what is specified by written procedures. Question any differences that occur
- Note aspects of the task which may increase exposure potential, e.g. overtime working or shift patterns increasing exposure time, spillage and leaks, manual decanting of materials, heated products, dusty materials, high ambient temperature in work area, lack of air movement in work area, spraying of liquids, manual movement of materials/equipment, repetitive tasks
- Speak to staff to seek their knowledge of the task, associated hazards and use worst case sampling to measure for controlling exposure
- Review non-routine and intermittent activities, e.g. maintenance operations, loading and unloading, changes in production cycles
- Review ventilation system's efficacy, the number air changes per hour, the face velocity, as well as the execution of preventive maintenance as scheduled
- Take account of unplanned but foreseeable events such as interruptions in work activity, potential for accidental exposure
- Consider workers not directly involved in a particular task but present in the vicinity and potentially exposed to the hazard, e.g. workers adjacent to someone using noisy equipment or arc welding, vents, drains, waste disposal
- Check the engineering controls provided. Do they meet recommended criteria to protect against the hazard in question? Have they been adequately maintained? Are they used? If not used, why not? What training has been given?
- Check the procedural controls in place, e.g. supervision, written procedures (such as standing instructions and emergency arrangements for controlling normal and abnormal situations), quality of information/instruction/training, housekeeping, quality of records
- Check the personal protective equipment provided. Is it required? Does it provide adequate protection? Is it used? Is it user friendly? Does it create a hazard in itself, e.g. poor visibility, thermal stress, reduced hand dexterity? Is it maintained? Are records kept of issue and maintenance? What training has been given?
- Check the implementation of the behavioral safety observation program: what tasks, activities contribute most to the effective control of personal exposures, are these behaviors addressed in the observation program and developed to habit strength?
- Perform the fit-test of workers with respect to the respiratory protection equipment used
- Biological monitoring can be used to monitor the efficiency of the personal protective equipment use
- Discuss the biomonitoring results with the plant management and individual workers.

Annex 12. Personal Protective Equipment

Personal Protective Equipment (PPE) must always be regarded as a last resort when no other controls are reasonably practicable or when additional protection is appropriate to augment other controls. Since PPE cannot replace good planning and judgment, the limitations of PPE must be recognized. The PPE selections must be based on a risk assessment that identifies the hazards and the controls that are in place.

RISK ASSESSMENT AND PERSONAL PROTECTIVE EQUIPMENT SELECTION

A risk assessment that describes the minimum PPE required for all tasks involving dusts should be conducted and documented. The risk assessment must be conducted and documented when new tasks are introduced or when changes are made to existing tasks. The operating or maintenance procedures for routine work must include when to put on PPE and the conditions for when it can be removed. For unique or non-routine tasks that are not covered by a procedure, the risk assessment, PPE requirements and other controls must be specified in the work permit or communicated to the worker by other means. It must be verified that all parties who might become involved in the job have agreed to the specified controls before starting the job.

Although this document is specific to working with dusts, when selecting PPE for a task the permeation of any other materials/chemicals that the worker may come into contact with such as solvents, etc. should also be taken into account. It may be appropriate to conduct permeation testing on the mixture. The mechanical impact on the PPE during work, e.g. abrasion and puncture, must also be considered.

PPE should be specified, available, and used when breaking into any system in dust service. These PPE requirements shall be based on normal system operating conditions and associated hazards, even if the system was thoroughly decontaminated and if local exhaust ventilation is in use.

An example of a template for documenting a PPE selection based on a risk assessment for a task:



PPE Risk
Assessment Docume

RESPIRATORY PROTECTION

The selection of suitable respiratory protection will depend upon the task, type of contaminants and the potential level of exposure, and whether the respiratory protection is required for primary or secondary protection. The time for which respiratory protection needs to be worn should also be taken into consideration as should comfort, fit, and compatibility with other PPE, to ensure that there are no issues that could result in incorrect use, or misuse.

The following are examples of the type of respiratory protection available that may be used by member companies when handling particulates to cover a range of contingencies.

- Disposable orinasal masks (which must be well-fitted) (filtering facepiece respirators)
- Half mask air purifying respirators (with appropriate cartridge filters)
- Full face mask air purifying respirators (with appropriate cartridge filters)
- Powered air purifying full face mask or hood respirator (with appropriate cartridge filters)
- Positive pressure air supplied full face masks or hoods.

The above respirators are listed by increasing level of protection or efficiency. The specific level of protection that is required to provide the necessary protection should be determined based on the results of a risk assessment for the particular task. For example, in the United States and the European Union the assigned protection factor (APF) for a given type of respiratory protection is referenced in conjunction with the known hazards and potential contaminant concentrations to determine the appropriate level of respiratory protection required. An APF is the decrease of the concentration of harmful substances in the inhaled air as a function of the filtering qualities of the respirator and potential leaks through the respirator face seal (Table 10). Refer to country specific equivalent information for further guidance.

Table 10. Respiratory protection types and their assigned protection factors

Respirator Type	United States OSHA APF	COSHH APF
Disposable orinasal masks	10	4, 10 or 20*
Half mask air purifying respirators	10	4, 10 or 20*
Full face mask air purifying respirators	50	4, 10 or 40*
Powered air purifying full face mask	1000	10, 20 or 40*
Powered air purifying hood respirator	25/1000**	10, 20 or 40*
Positive pressure air supplied full face masks	1000 (continuous flow, pressure demand or other positive pressure mode)	40 or 2000 (positive pressure demand mode)
Positive pressure air supplied hoods	25/1000 **	40

*COSHH APF dependent on type of filter used.

** The respirator manufacturer must perform testing that the respirator demonstrates performance at a level of 1000 or greater to receive an APF of 1000. In the absence of such testing, all other powered air purifying respirators and supplied air respirators with helmets/hoods are to be treated as loose-fitting face-piece respirators, and receive an APF of 25.

Wearing a disposable orinasal mask or half mask respirator may interfere with the user's eye protection. When eye protection is a concern, the use of a full face, hood or helmet type respirator may be needed to ensure adequate eye protection. In addition, it should be considered that beards and facial hair might affect the integrity of the seal of RPE.

Cartridge change out schedule

Numerous grades of filters are approved by various government agencies. The test specifications and conditions vary. The respirator manufacturer is the best source of information on filter selection. Manufacturers provide information on the performance of their cartridges either with software programs that predict service life or with data listings. Contact the manufacturer of the cartridge to obtain the information. It is recommended that a schedule for replacing air-purifying elements (i.e., canisters and/or cartridges and filters) be established when using air-purifying respirators for protection against gases or vapors. If a specific cartridge has an end-of-service-life indicator, the indicator may be used instead of a cartridge change schedule. For filters, a schedule should be determined based on the manufacturers' recommendations. Cartridge and filter change out schedules and guidance should be communicated to workers and included in training materials. At a minimum, workers should be trained to replace a filter if any increase in breathing resistance is noted.

Fit testing

When tight fitting respirators are used, fit testing of respirators to ensure that the respirator forms an adequate seal with the respirator user's face to provide the intended protection is recommended. Fit testing of respirators should be performed following country specific protocols where applicable. Where country specific protocols do not exist, individual company guidance should be followed. In the absence of company procedures an industry standard such as ANSI/AIHA Z88.10 - 2010 Respirator Fit Testing Methods may be referenced. At a minimum, respirator fit testing should be required when the respirator is required to maintain exposures below OES.

Wear time of respiratory protection

Respirator usage may place additional burden on the wearer's body depending on the type of respirator worn, the conditions in which the respirator is worn and the wearer's medical status. For this reason, medical approval to wear the type of respirators worn and the job and workplace conditions should be obtained. Medical surveillance should be conducted following country specific protocols where applicable. Where country specific protocols do not exist, individual company guidance should be followed.

The British HSE guidance document, HSG53 Respiratory Protective Equipment at Work, recommends "that continuous wear time for tight-fitting (unpowered) RPE be maintained at less than an hour, after which the wearer should take a break. Otherwise, the RPE can become uncomfortable to wear, leading to loosening or removal of the mask in the work area. In these situations, where RPE is required to be worn continuously for long periods, powered respirators or airline BA, for example a loose-fitting facepiece such as a hood or helmet, are better options."

Additionally, powered respirators or supplied air respirators may be more comfortable for moderate and high work rates that may increase breathing and sweating. Powered respirators or supplied air respirators are also recommended for hot, humid environments due to potential for heat stress as well as increased discomfort and sweating.

If using breathing air, the air supply must meet minimum quality standards as defined by country specific protocols. Where country specific protocols do not exist, individual company guidance should be followed.

CHEMICAL PROTECTIVE CLOTHING

Chemical protective clothing (CPC) may be required to protect from exposures to chemicals. The parts of the body that need to be protected must be taken into consideration when selecting the type of CPC (e.g., gloves, apron, and suit) to be used. For example, the use of gloves only may be appropriate when collecting a sample from an enclosed ventilated sample box or in-line sampler, whereas full body protection may be appropriate when collecting a sample without engineering controls available.

Compatibility of the materials of construction with the types of hazards present in the work area should be taken into consideration. For example, if working with a combustible dust, flame resistant clothing may be used to protect workers in the event of a flash fire. Chemicals and other hazards that may be in the work environment in addition to dusts should also be considered when determining material of construction for PPE such as gloves, aprons, suits, etc. The abrasion and puncture resistance of the PPE should also be considered.

DECONTAMINATION OF PERSONAL PROTECTIVE EQUIPMENT

Contaminated PPE should not be worn or carried outside of designated areas. In situations where PPE has been in contact with dust a respirator must be worn until all other PPE (e.g., eye protection and clothing) has been thoroughly decontaminated or removed and placed into a sealed container for proper disposal. Each item of PPE must be thoroughly decontaminated before reuse. Based on the extent of the hazard, consider providing work uniforms and providing laundry services so workers do not transport dusts outside of the work area.

PERSONAL PROTECTIVE EQUIPMENT INSPECTION AND STORAGE

All PPE must be thoroughly inspected before use. PPE must be stored in an area that is clean and, preferably, at room temperature. Respirators, suits and hoods must be stored and maintained following the manufacturer's recommended practices.

TRAINING

Workers should be trained before their initial use of PPE and/or a respirator and annually thereafter (including those workers who voluntarily use respirators). This training should include information about:

- Why and when the respirator and other PPE should be used
- How improper fit, use, or maintenance can compromise the respirators and chemical protective clothing protection
- What the respirator and chemical protective clothing limitations and capabilities are
- How to use the respirator and chemical protective clothing effectively in emergency situations, including situations in which a malfunction occurs
- How to inspect, put on, remove, and use the respirator and check its seals
- How to inspect, put on, remove and use chemical protective clothing. Emphasis should be placed on proper removal so as not to inadvertently contaminate one's self
- When to change out the respirator cartridges
- How to clean, sanitize, maintain, and store the respirator and chemical protective clothing
- How to dispose of the respirator and chemical protective clothing
- How to make simple adjustments to the respirator or replace its cartridges or other user-replaceable components
- Caution! The respirator must never be altered beyond making simple adjustments in accordance with the manufacturer's instructions
- How to recognize medical signs and symptoms that may limit or prevent the effective use of respirators.

Annex 13. Occupational Hygiene Qualifications

The International Occupational Hygiene Association (IOHA) represents the global community of occupational hygienists. IOHA is an association of occupational hygiene organisations from across the world, all of which are dedicated to the discipline and application of the inherent principles of occupational hygiene. IOHA is supporting training initiatives, referred to as OH learning developed by the Occupational Hygiene Training Association (OHTA). OHTA was formed to promote better standards of occupational hygiene practice throughout the world. IOHA and OHTA are working together to provide formal recognition of the qualifications delivered by the OHTA training programmes.

In the context of this procedure, several organizations offer training programs to obtain OH/IH certificates or to gain an awareness level knowledge base. For example, the OHTA offers a training program to earn an International Certificate in Occupational Hygiene (ICertOH) and also offers a foundation level training course that may meet the needs of a local EHS resource. For more information as well as training providers to <http://ohlearning.com/default.aspx>.

The following are Industrial Hygiene ‘overview’ courses that are meant as an overview of industrial hygiene subject matter and are not meant to provide the same level of training that the pursuit of a college-level degree would provide. Each of these would qualify an EHS expert as Knowledge level/Awareness level resource.

Examples of basic training modules:

- 1. The OHTA module W501 Measurement of Hazardous Substances** (including Risk Assessment) in conjunction with one of the training modules below would qualify an EHS resource as Occupational Hygiene ‘Knowledge level’ resource. The courses presented in this annex are examples of available training and it is not intended to imply that these exact training modules must be followed in each region or country. Similar trainings may be available through other providers (or same content can be covered in other Masters of Science programs).
- 2. OHTA W201 Basic Principles in Occupational Hygiene**
The course aims to provide an introductory course outlining the broad principles in occupational hygiene as the basis for anticipation, recognition, evaluation and control of hazards that can be encountered in the workplace. On completing this course successfully, the student will have a basic understanding of the value of occupational hygiene and the role of the occupational hygienist, the range of hazards (physical and chemical) in the workplace, Hazard recognition techniques; Sources and potential routes of exposure Hazard evaluation, exposure assessment and measurement processes; Methods of controlling exposure; The management of occupational hygiene programmes.
The course content includes: Human physiology, Chemical hazards recognition, Physical hazards recognition, Hazard evaluation, Control of hazard.
- 3. US National Safety Council - Fundamentals of Industrial Hygiene**
NSC Fundamentals of Industrial Hygiene course will develop your understanding of industrial hygiene terminology, principles and practices. The four-day course covers 15 topics and examines four key processes in an effective industrial hygiene effort: anticipation, recognition, evaluation and control. You’ll be brought up to speed on anatomy and physiology, as well as chemical, physical, ergonomic and biological hazards in the workplace. Taught in an interactive format supported by case studies, group discussions and hands-on equipment demonstrations; this is an essential course, especially for those with limited industrial hygiene training or experience. <http://www.nsc.org/learn/Safety-Training/Pages/Courses/fundamentals-industrial-hygiene.aspx>

4. OSHA Training Institute - Advanced Safety & Health Certificate – General Industry Track - OSHA 521: OSHA Guide to Industrial Hygiene

This course for private sector personnel covers industrial hygiene practices and related OSHA regulations and procedures. Topics include permissible exposure limits, OSHA health standards, respiratory protection, engineering controls, hazard communication, OSHA sampling procedures and strategy, workplace health program elements, and other industrial hygiene topics. Course highlights include workshops in health hazard recognition, OSHA health standards, and a safety and health program workshop. (4 days).

https://www.osha.gov/dte/edcenters/certificate_listing.html#asu1

5. American Industrial Hygiene Association - EIH I: Elemental Industrial Hygiene

This self-study course is designed for EHS professionals who wish to enhance their knowledge of the occupational health sciences (known traditionally as industrial hygiene). The study program is divided into 12 parts: 11 lessons and an online final exam.

<https://www.aiha.org/education/eLearning/Pages/EIH1.aspx>

For the implementation of this best practice it is advisable for the EHS resource to qualify as 'Knowledge Level' resource by use of the mentioned or equivalent training resources.

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Date of publication: April 2019

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