

Appendix

Development of a health risk management framework in workplaces handling nanomaterials using multi-criteria decision-making methods

Naziri, S. H., Pouyakian, M., Sadegh Hassani, S., Safdari, P., & Farhang Dehghan, S. (2025). Development of a health risk management framework in workplaces handling nanomaterials using multi-criteria decision-making methods. *International Journal of Nano Dimension*, 17(2) (April 2026). <https://doi.org/10.57647/j.ijnd.2026.1701.08>

Introduction

There is insufficient information to determine the occupational exposure limits (OELs) for many manufactured nanomaterials. Figure A1 shows the challenges for quantitative risk assessment of nanomaterials.

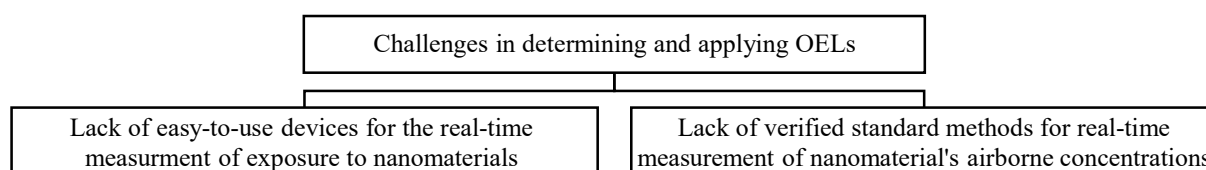


Figure A1. The challenges for quantitative risk assessment of nanomaterials [1].

Risk assessment of chemicals in the workplace begins with the accumulation of information from the potential risk characteristics. This process leads to the evaluation of hazard and exposure. Therefore, the characterization of risk assessment includes the integration of hazard and exposure data. Table A1 indicates the main components of a risk assessment process in nanomaterials workplaces.

Table A1. The main components of a risk assessment process in nanomaterials workplaces [2, 3].

Risk assessment component	Definition
Hazard identification	Identifying hazard elements with significant contribution to the risk
Toxicity analysis	Identifying the potential health effects considering the workplace
Exposure measurement	Evaluating routes of exposure in the workplace

Risk characterization	Integrating the information gathered in the previous steps
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Methods: GHS classification

This classification represents different endpoints such as acute toxicity (systemic or lethal), skin irritation, eye damage, respiratory or skin sensitization, specific target organ toxicity with a single exposure (STOT-SE) or repeated exposure (STOT-RE), reproductive toxicity, and carcinogenicity, as presented in table A2.

Table A2. GHS classification system for chemicals health hazards [4].

Hazard group	Hazard outcome	Hazard levels
Acute toxicity	Lethal	1-2, 3, 4, 5
Acute toxicity	Systemic	1, 2
Skin sensitization	Sensitization	1-1A, 1B
Skin irritation	Irritation	1, 2, 3
Eye damage	Acute	1, 2A, 2B
Respiratory sensitization	Sensitization	1
Aspiration hazard	Acute	1, 2
Germ cell mutation	Mutation	1, 2
Carcinogenicity	Carcinogen	1A-1B, 2
Reproductive toxicity	Reproductive	1, 2
Breast-fed children toxicity	Specific	-
Single target organ toxicity (single dose)	STOT-SE	1, 2, 3
Single target organ toxicity (repeated dose)	STOT-RE	1, 2

Methods: NIOSH occupational exposure banding

NIOSH method use dose-response values from toxicological studies for classification of occupational exposure limits (OEL), and the classification of toxicological parameters, as presented in table A3.

Table A3. NIOSH parameters for toxicity classification of chemicals [5].

Hazard (Route)	Hazard parameter	Measurement scale
Occupational exposure limits	OEL or OEB	$\mu\text{g}/\text{m}^3$ or ppm
Acute toxicity (Ingestion)	LD50	mg/kg-bw
Acute toxicity (Skin contact)	LD50	mg/kg-bw
Inhalation	LC50	mg/L-4hr
Carcinogenicity	TD50	mg/kg-bw
Reproductive toxicity (Ingestion - Skin contact)	LD50	mg/kg-bw
Single target organ toxicity (Ingestion - Skin contact)	STOT-RE	mg/kg-bw
Chronic inhalation toxicity	Specific	mg/m^3

A list of Toxicology databases to extract information needed in 2nd layer of hazard banding was presented in table A4.

Table A4. Toxicology databases to extract information needed in 2nd layer of hazard banding (NIOSH OEB).

Toxicologic endpoint	Database	Abbreviation	Reliability
Carcinogenicity	U.S. National Toxicology Program Report on Carcinogens	NTP-ROC 2016	High (1)
	U.S. EPA Integrated Risk Information System	EPA-IRIS 2014	High (1)
	International Agency for Research on Cancer	IARC monograph	High (1)
	Health Canada	HC 1996	High (1)
	State of California Office of Environmental Health Hazard Assessment	Cal OEHHA 2010	High (1)
Reproductive toxicity	U.S. National Toxicology Program	NTP 2016	High (1)
	Health Canada	HC 1996	High (1)
	California Environmental Protection Agency	CalEPA 2016	High (1)
	Agency for Toxic Substances & Disease Registry Toxicological Profiles	ATSDR 2016	High (1)
	Organization for Economic Co-operation and Development	OECD 2016	Low (2)
	World Health Organization International Programme on Chemical Safety	WHO-IPCS 2015	Low (2)
	EPA Office of Pesticides: Reregistration Eligibility Decision Documents	EPA 2016a	Low (2)
	ECHA; Registration, Evaluation, Authorizations and Restriction of Chemicals	REACH 2016	Low (2)
STOT-RE	Agency for Toxic Substances & Disease Registry Toxicological Profiles	ATSDR 2016	High (1)
	U.S. EPA Integrated Risk Information System	EPA - IRIS 2014	High (1)
	California Environmental Protection Agency	CalEPA 2016	High (1)
	U.S. National Toxicology Program Report on Carcinogens	NTP - ROC 2016	High (1)
	Health Canada	HC 1996	High (1)

	ECHA; Registration, Evaluation, Authorisation and Restriction of Chemicals	REACH 2016	Low (2)
	Organization for Economic Co-operation and Development	OECD 2016	Low (2)
	World Health Organization International Programme on Chemical Safety	WHO-IPCS 2015	Low (2)
Germ cell mutagenicity	U.S. National Toxicology Program Report on Carcinogens	NTP 2016	High (1)
	Agency for Toxic Substances & Disease Registry Toxicological Profiles	ATSDR 2016	High (1)
	U.S. National Toxicology Program Report on Carcinogens	NTP-ROC 2016	High (1)
	World Health Organization International Programme on Chemical Safety	WHO-IPCS 2015	High (1)
	Hazardous Substance Data Bank	HSDB 2016	Low (2)
	ECHA; Registration, Evaluation, Authorisation and Restriction of Chemicals	REACH 2016	Low (2)
Respiratory sensitization	Organization for Economic Co-operation and Development	OECD 2016	High (1)
	ECHA; Registration, Evaluation, Authorisation and Restriction of Chemicals	REACH 2016	High (1)
	World Health Organization International Programme on Chemical Safety	WHO-IPCS 2015	High (1)
	Agency for Toxic Substances & Disease Registry Toxicological Profiles	ATSDR 2016	Low (2)
	U.S. EPA Integrated Risk Information System	EPA-IRIS 2014	Low (2)
	Association of Occupational and Environmental Clinics	AOEC 2016	Low (2)
	NIOSH Skin Notation Profiles	NIOSH-SK 2009b	High (1)
Skin sensitization	ECHA; Registration, Evaluation, Authorisation and Restriction of Chemicals	REACH 2016	High (1)
	Organization for Economic Co-operation and Development	OECD 2016	High (1)
	World Health Organization International Programme on Chemical Safety	WHO-IPCS 2015	High (1)
	Hazardous Substance Data Bank	HSDB 2016	Low (2)
	National Library of Medicine ChemID Plus	ChemID 2016	High (1)
Acute toxicity	U.S. EPA Superfund Chemical Data Matrix [EPA 2016b]	US SCDM	High (1)
	Pesticide Properties Database	PPDB 2007	High (1)
	World Health Organization International Programme on Chemical Safety	WHO-IPCS 2015	High (1)
	Hazardous Substance Data Bank	HSDB 2016	Low (2)
	Agency for Toxic Substances & Disease Registry Toxicological Profiles	ATSDR 2016	Low (2)
	NIOSH Skin Notation Profiles	NIOSH-SK 2009b	High (1)
Skin irritation or corrosion	World Health Organization International Programme on Chemical Safety	WHO-IPCS 2015	High (1)
	ECHA; Registration, Evaluation, Authorisation and Restriction of Chemicals	REACH 2016	High (1)
	Organization for Economic Co-operation and Development	OECD 2016	High (1)
	Agency for Toxic Substances & Disease Registry Toxicological Profiles	ATSDR 2016	Low (2)
	U.S. EPA Integrated Risk Information System	EPA-IRIS 2014	Low (2)
Eye damage	Organization for Economic Co-operation and Development	OECD 2016	High (1)
	World Health Organization International Programme on Chemical Safety	WHO-IPCS 2015	High (1)
	ECHA; Registration, Evaluation, Authorisation and Restriction of Chemicals	REACH 2016	High (1)
	Agency for Toxic Substances & Disease Registry Toxicological Profiles	ATSDR 2016	Low (2)
	U.S. EPA Integrated Risk Information System	EPA-IRIS 2014	Low (2)

Methods: Evaluating control measures

In the GTECM method, in addition to the Haddon matrix, other groups of decision-making criteria including risk and quality factors were also evaluated based on the consensus of the expert group's opinions and the corresponding score (See Fig. 2A).

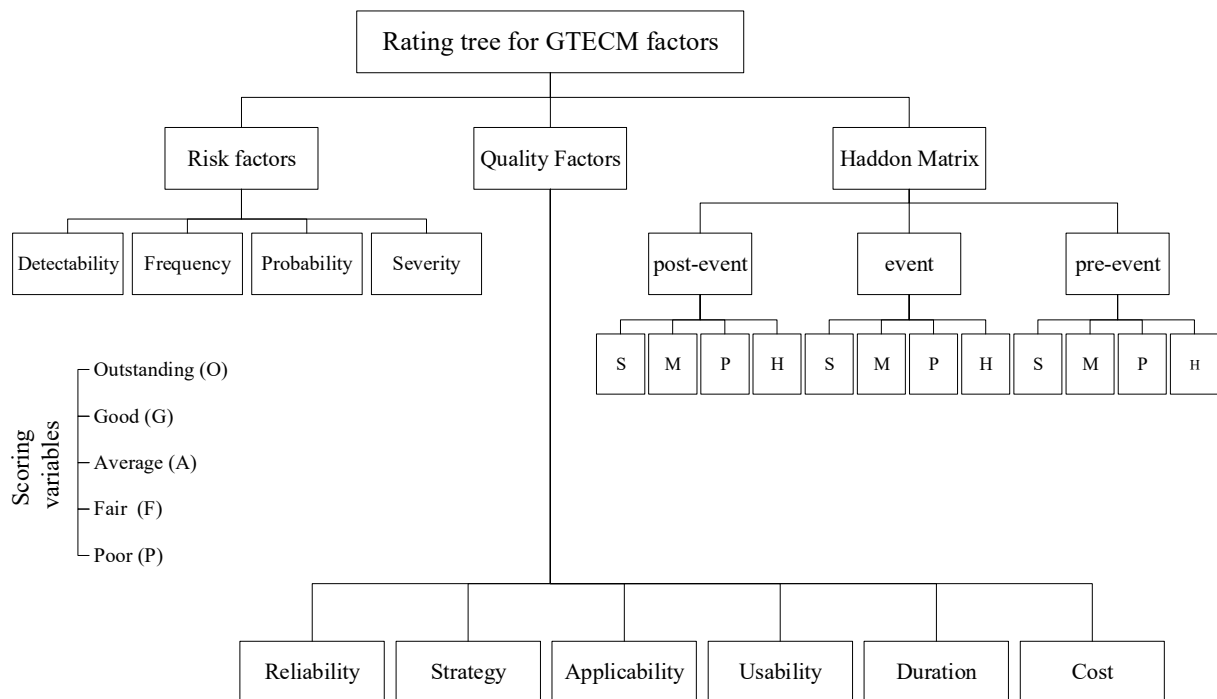


Figure A2. Evaluation parameters of control measures using GTECM [6].

According to GTECM, each cell has a local weight based on FAHP, which will be counted as ‘HM’ score for any control measure which will be used in further calculations (See Table A5).

Table A5. Weight (HM) of Haddon Matrix components according to GTECM [6].

HM score	Human (H)	Machine/Equipment (M)	Physical Env. (P)	Social Env. (S)
Pre-event (Pr)	0.153	0.159	0.200	0.164
Event (Ev)	0.042	0.077	0.079	0.056
Post-event (Po)	0.019	0.012	0.020	0.017

Methods: Reliability measurement

Kappa coefficient was evaluated based on the data represented in table A6.

Table A6. Interpretation of numerical values of Cohen's Kappa coefficient [7].

Inter-rater reliability	No agreement	Partial agreement	Relative agreement	Moderate agreement	Good agreement	Perfect agreement
κ value	≤ 0.00	0.01 - 0.20	0.21 - 0.40	0.41 - 0.60	0.61 - 0.80	0.81- 1.00

Results: Hazard banding based on physiochemical properties (layer 3)

We aimed to represent the above classifications into the decision tree for hazard and exposure banding for better user experience. This could also lead to a tree-shape algorithm which could be used for developing a manual in future.

Hazard bands classification for 3 above layers are represented in figures A3-6.

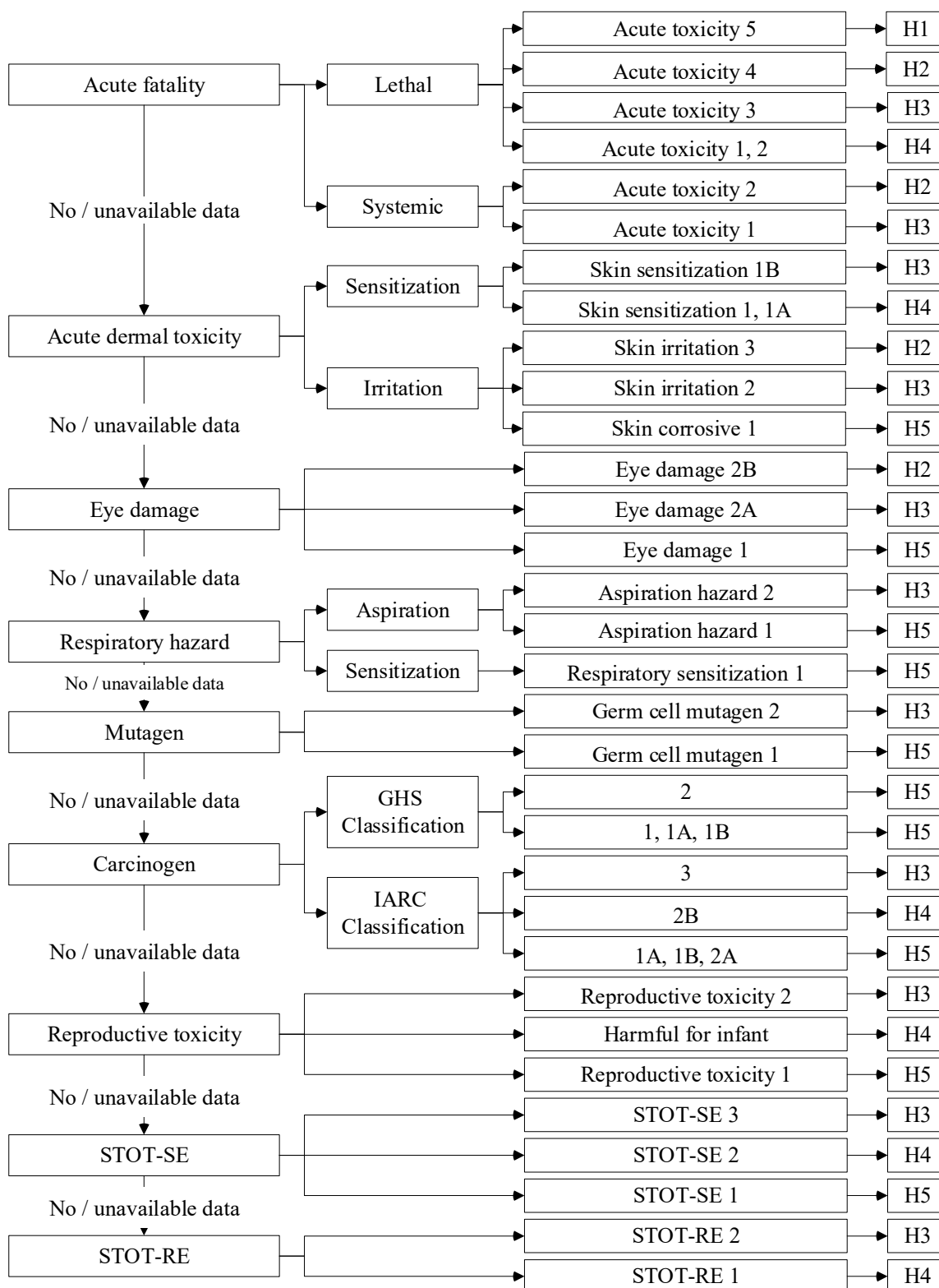


Figure A3. Decision tree for H-bands, based on GHS system classification [4].

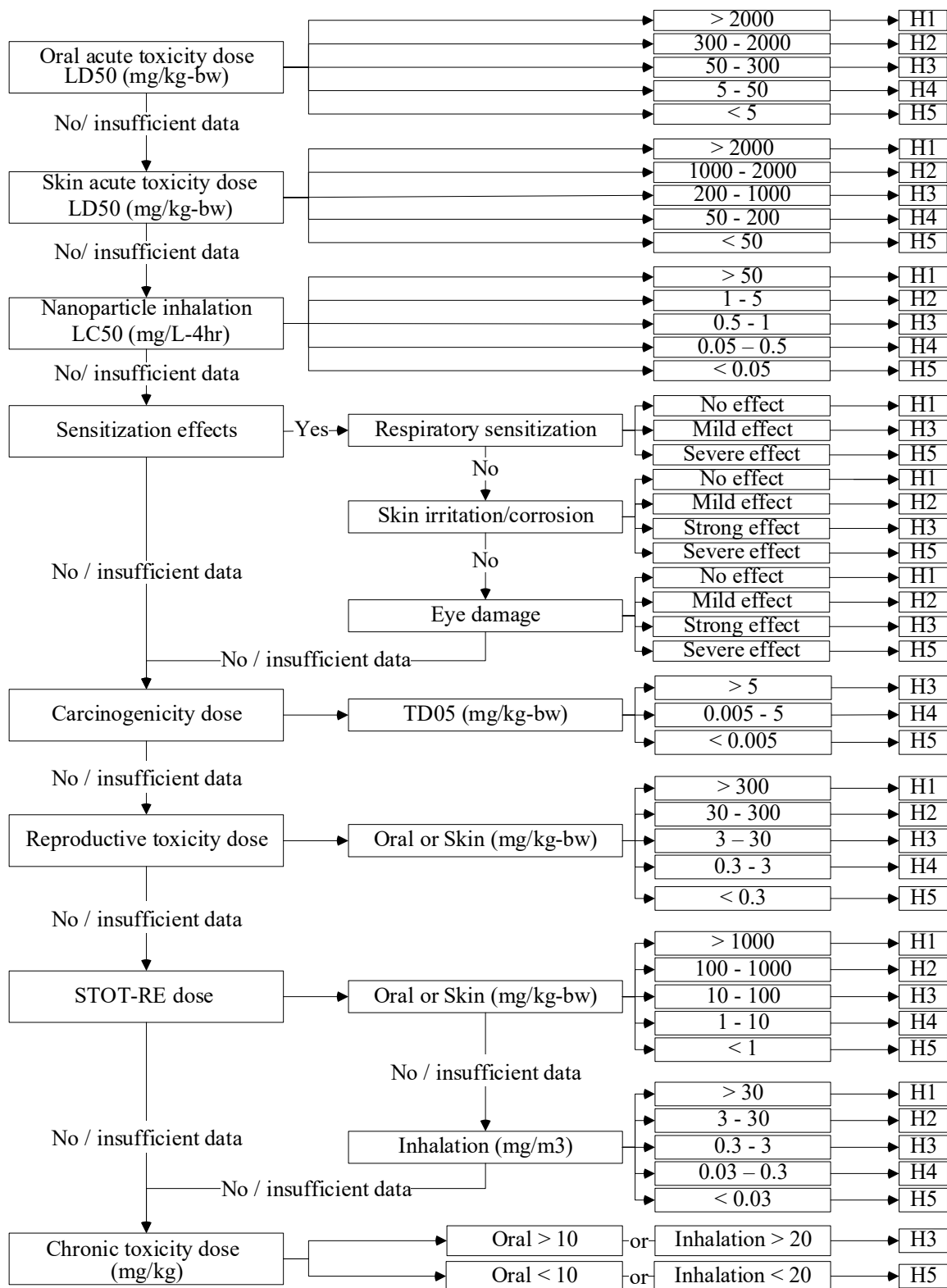


Figure A4. Decision tree for H-bands, based on NIOSH classification for dose-response values (OEB) [5].

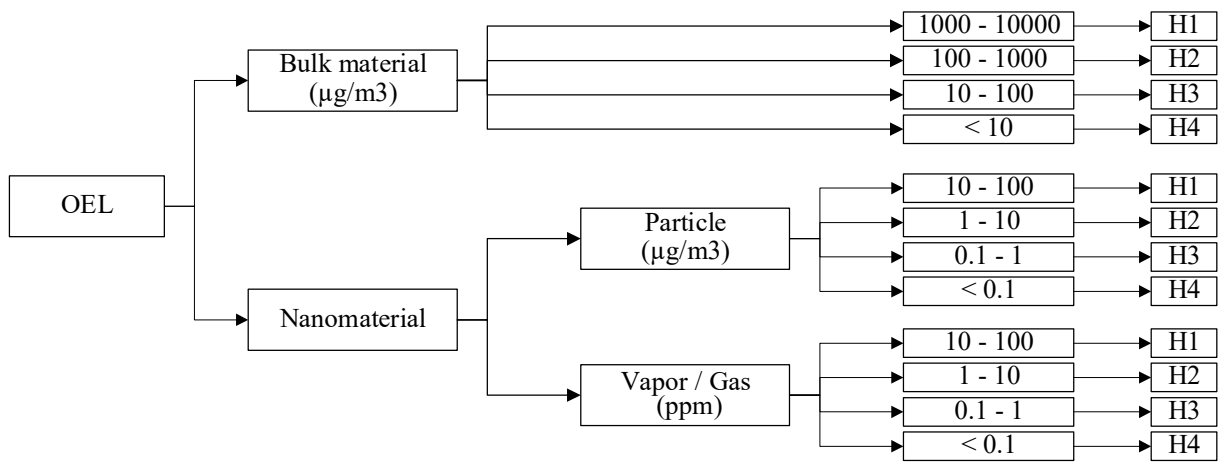


Figure A5. Decision tree for H-bands, based on NIOSH classification for OELs.

Identifying the form of matter (powder, suspended or dissolved in liquid, embedded in a solid matrix)
Specific known hazards (toxicity, carcinogenicity or hyperreactivity)
Prevention of exposure (risk management) through monitoring the performance and effectiveness of control measures
Monitoring scenarios of exposure to nanomaterials in the work environment
Development of criteria and implementation methods of engineering controls at the place of process and exposure
Providing training on hazards, how to work with equipment, how to work with nanomaterials and protective measures
Compilation of safety data sheets from manufacturers or suppliers of nanomaterials
Development of implementation methods of personal protective equipment, teaching how and when to use them
Development of implementation methods including the frequency of changing or washing personal protective equipment
Maintaining, recording and storing records of the use of personal protective equipment
Development of implementation methods for cleaning and decontamination of equipment and environment
Expert advice, for example from occupational health professionals
Carrying out research projects focused on issues related to health in nanotechnology
Benchmarking and sharing technical knowledge with other relevant organizations

Figure A7. Preventive measures in nanomaterial risk management program [9].

Results: Inter-rater reliability analysis

Rate of agreement between raters was calculated with Cohen's kappa coefficient, as a reliability index for the developed method, as presented in table A7.

Table A7. Pairwise comparison matrix for Cohen's kappa coefficient calculation.

Agreement modes		Trained person		Total	Share percentage
		Unsuccessful	Successful		
Untrained person	Unsuccessful	2	1	3	0.33
	Successful	0	6	6	0.67
Total		2	7	9	
Share percentage		0.17	0.83		

observed agreement p_o	Total agreement \div Total = p_o $(2 + 6) \div (2 + 7) = 0.89$
expected agreement p_e	(Unsuccessful share) + (Successful share) = p_e $(0.25 \times 0.375) + (0.75 \times 0.625) = 0.61$
kappa coefficient κ	$(p_o - p_e) \div (1 - p_e) = \kappa$ $(0.89 - 0.61) \div (1 - 0.61) = 0.72$

Discussion: Control banding

Control Banding is a qualitative risk assessment approach that identifies and evaluates the risk with a scoring matrix or decision tree based on the classification of the potential health effects of nanomaterials. Ideally, nanomaterials risk management should be part of a comprehensive organizational plan. The tools and frameworks allow risk assessment and implementing control measures based on a reliable approach.

This approach determines the level of control measures (e.g., ventilation, personal protective equipment, etc.) based on the risk band level (R-band) in a nanomaterial occupational setting, regarding the hierarchy of control measures. Various tools for implementing control banding regarding the occupational risk assessment of nanomaterials were developed [10]. For example, Paik *et al.* presented a method based on scoring different components, including surface chemistry, nanomaterial shape, particle diameter, solubility, and toxicity level, for hazard banding [5, 11].

In this study, hazard banding (H-band) was conducted in a 5-level classification in order to maintain the integrity of the ISO/TS 12901 classification pattern. Although, Buitrago *et al.* used a 3-scale H banding for classification of physicochemical nanomaterials hazard characteristics [8]. Groso *et al.* also used hazard banding in a 3-scale classification, integrating with a decision tree based on the existing classification [12]. It can be said that the 5-scale banding (e.g., R1 to R5) provides more detail and accuracy in hazard identification and risk assessment. Also, it allows more flexibility in applying different control measures to control the risk of nanomaterials in different situations [13].

By integrating GTECM with CB, we aimed to introduce a decision-support system which comes over traditional hazard identification and risk assessment, assist occupational risk managers in analyzing a broader range of risk factors, including quality factors, to inform the implementation of effective risk mitigation strategies in workplace. By analyzing hierarchy of control measures, we aimed to provide a more comprehensive approach to occupational risk management, enabling the implementation of the most effective risk control measures. We expect to be able to determine the health hazards of nanomaterial in the workplace with the minimum information available.

In general, nanomaterial risk assessment strategies often include a decision tree or scoring matrix where the users answer questions related to nanomaterial characteristics, production process, and other influencing components to determine hazard and exposure bands. As for now, real-time measurement for exposure is impractical in most occupational settings working with nanomaterials.

Existing control banding tools focused to introduce any classification system which could determine the level of hazard and exposure probability by available information [14, 15]. This information could be the safety data sheet of chemical substances, the threshold doses obtained from toxicology studies, the occupational exposure limits, if available, or the physicochemical characteristics based on the information provided by the manufacturer. According to the of Baig *et al.*, it can be said that the processes that include pulverization, spraying and aerosolization, vapor condensation, sanding, thermal decomposition, laser ablation and chemical vapor deposition have a high potential for the release of manufactured nanomaterials.

These processes include transfer of brittle materials, powders, liquids, gases, dispersing, casting, deposition, spin coating, centrifugation, drying, spraying, aerosolization, and high energy transfer [16, 17]. Nanomaterials may be released to the working environment during weighing, handling, using furnaces, machining, sanding or grinding [17]. Risk management frameworks include general approaches, basic principles, goals, and policies, which may develop various tools. However, due to the close interpretation for risk assessment and risk management, they are mistakenly used interchangeably [2, 3]. Factors such as uncertainty and availability of data and methods, public understanding and acceptance, ethical and social consequences of nanotechnology are important in choosing and reviewing frameworks. The common challenge of these risk management frameworks is to align the principles of risk management with the development of innovation [18].

Nanomaterial risk management framework	Nanomaterial risk assessment tool
<ul style="list-style-type: none"> • Research and development • Regulatory/Decision system • Life cycle approach • Tool/Database development 	<ul style="list-style-type: none"> • Reliability analysis • Risk assessment method • Transparency • Usability

Figure A8. Key components of risk management framework vs. risk assessment tool [3, 15].

As shown in the figure A8, the risk assessment method refers to the method of evaluation of potential hazards and exposure to nanomaterials, their effects on human health and the environment, which can be developed in quantitative, semi-quantitative and qualitative approaches [19]. Life cycle assessment is a technique that considers the environmental aspects, and potential impacts of a product throughout its life cycle, from raw material extraction to disposal [20], which should be a pivotal aspect when establishing frameworks and regulations in nanotechnology. The frameworks may differ in scope, purpose, approach and applicability, and no single framework can alone solve all the challenges and uncertainties related to the risk of manufactured nanomaterials in occupational settings [2].

Nanomaterials information (e.g., physicochemical characteristics, toxicity, and exposure) can be collected and stored in database, developed within the structure of a framework [3]. Tools or databases are software or websites that facilitate risk assessment and management of nanomaterials in the form of decision support systems, risk communication tools, data collection, and etc. Risk assessment tools are used to facilitate and implement the elements of risk management, communication, identification, evaluation and mitigation of risks [2, 21].

Small companies face various challenges for nanomaterials risk management. Though, these companies make up a large share of businesses, they often lack the resources, expertise, and knowledge needed to effectively assess and manage risks. Therefore, it is very interesting to develop and implement appropriate tools and frameworks that can help these companies comply with regulatory requirements, ensure the safety of their products and processes, and increase their innovation potential and competitiveness in the market [22, 23].

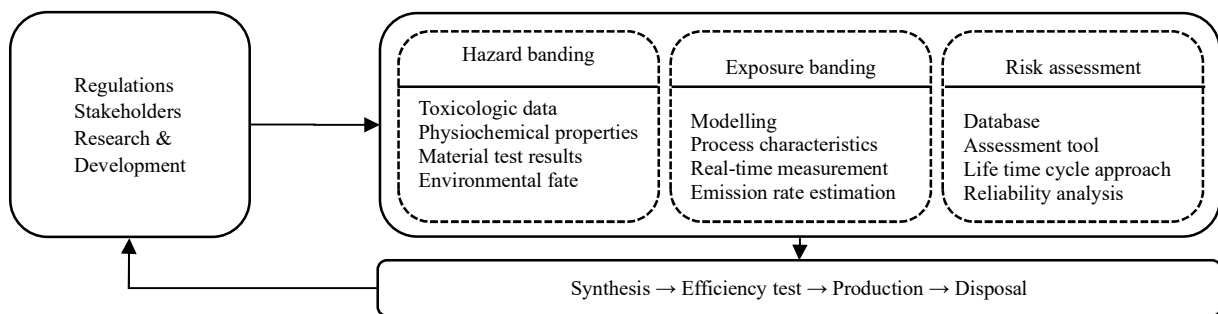


Figure A9. Comprehensive framework structure for the risk management of manufactured nanomaterials [2, 3].

Manufactured nanomaterials risk management frameworks provide methods or models to guide or support risk analysis, identifying, characterizing, and quantifying their associated hazards and exposures. Achieving a

comprehensive and integrated framework is the ultimate goal to resolve existing challenges and limitations [24]. The deal structure of a nanomaterials risk management framework has been presented in figure A9.

Discussion: Control measure evaluation

The ranking obtained for control measures based on the GTECM method helped to facilitate the decision-support process in risk management by providing information on the characteristics of control measures applicable in occupational settings with nanomaterials. Haddon matrix is often used as a tool in the allocation of resources, identification and prioritization of controls. Deljavan *et al.* claimed, this matrix can lead to the determination of appropriate and optimal control strategies, the decision-making process for choosing a control measure in brainstorming sessions, revealing the hidden points of the processes and collecting the required information [23]. In management, risk prevention is prioritized and the implementation of solutions before the occurrence of an unfortunate event (for example, skin contact with a corrosive nanomaterial) may always have significant impact, which could be interpreted from matrix analysis [25]. Studies have not focused on ranking and determining the characteristics of control measures in order to improve the decision-making process. Groso *et al.* categorized controls in 3 levels based on the hierarchy of control measures giving general recommendations regarding the risk level [12].

According to the rating approach in the GTECM method, measures with a greater impact in the design pre-event phase will get a higher score than in the post-event phase. Consistent with the results of Pouyakian *et al.* [6], the overall ranking was higher for actions with higher risk severity scores, considering the weightings.

The rating is dependent on personal experiences and comparison, which may not solve the scientific need for all different situations. It should be noted that there is almost no strategy for risk control that can have a mitigation effect on all 4 risk factors at the same time.

It is expected that the results presented from the evaluation of control measures will provide a suitable guide for managers to make decisions in the process of choosing and implementing risk reduction and control strategies in the workplace, according to the situation inside respective organization and the identified risk. In this study, compared to similar studies in the field of developing nanomaterials risk assessment and management methods, determining the score and importance of each risk and quality factor in general for each control measure was done for the first time. In this way, in the process of risk management, decision makers can implement control measures according to

their conditions by examining factors such as cost and time required, reliability and usability before making a choice. During the development stages of the proposed framework, a lot of research and attention was done in the field of collecting and applying information and methods.

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