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ARTICLE

Proposals for risk management in environments with activities involving nanomaterials

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ABSTRACT

The handling of nanomaterials presents enormous challenges for risk management in research and production of new materials. However, data on the impacts of these new materials on human health and the environment need to be expanded. Several efforts have been made to mitigate the hardships and offer guidelines for the management of risks associated with nanomaterials. This article aims to provide a broad and comparing view of the main proposals in the literature. The methodology was systematic analysis encompassing 17 proposed risk management with nanomaterials. The results indicate that, although there is no consensus on the metrics used to characterize the risks of nanomaterials, the adoption of the Precautionary Principle, the control banding approach and stakeholder involvement stands out among the documents analyzed.

KEYWORDS: Nanotechnology; Risk; Safety; Nanomaterial; Management

Introduction

The handling of nanomaterials implies new challenges for risk management. On one hand, nanotechnologies are increasingly incorporated in the research and production of materials, and data are lost regarding the impacts of these materials on human health and environment.

In this scenario of uncertainty, considerable effort has been taken to mitigate the hardships with the aim of offering guidelines for the management of health risks associated with nanomaterials. Various approaches are found in the literature regarding the actions to be taken[1,2,3,4].

Paik et al.[3] points out that the traditional approach of Occupational Hygiene (OH) for the risk assessment of exposure through inhalation of dangerous particles is based on (i) sampling of the air breathed by a worker in a representative manner, (ii) determination of the concentration of the contaminant contained in the sample, and (iii) evaluation of the exposure limits for this contaminant.

Gaps in the knowledge of various aspects of the effects of nanomaterials, such as the metric that best represents the contamination danger, the contamination levels, and exposure limits, are barriers to the free adoption of assumptions used by OH[3].

Brouwer[5] compared some approaches, enabling the understanding of the complexity of the problem and their different goals and structures. He showed that some of the difficulties in working with nanomaterials are related to the metrics used both in the hazard characterization and their exposure. The study was primarily based on proposals that used control bands (Control Banding - CB), which is derived from the initiative of the *UK Health and Safety Executive*[6]. The CB is a plausible alternative to the traditional OH approach in an effort to overcome the abovementioned barriers. CB can be used where both hazard and exposure data are scarce. Both exposure and hazard issues may be qualitatively valued (not necessarily quantitatively), yielding tracks (or risk levels) leading to suggested control actions for each. This study offers a comprehensive and comparative view of 17 proposals found in the literature, which are analyzed on the basis of their principal characteristics. Furthermore, we sought to classify existing studies according to their scope in relation to the shares allocated to each of the strategies and principles to supervise these nanotechnologies.

Method

Seventeen papers were analyzed with a common and generic goal of managing safety and health risks caused by nanomaterials. On the basis of the examined proposals, we created a comprehensive list of strategies and actions of which they are composed. This list served as the basis for creating a chart for comparing the various documents, which indicates the presence or absence of these actions and strategies, or in some cases, a generic or implicit reference made to these. In parallel, each proposal was summarily described, pointing out their main differences compared to others.

All the reviewed studies were initially categorized into three groups according to their main focus: 1) strategic focus defining “what to do” (the strategy) and not “how to do” (the actions); 2) methodological approach, which provides, in addition to strategies, a practical set of measures to control the risks caused by nanomaterials; 3) the pragmatic approach, which sets a priority with regard to “how to do” (actions). In the last group, we have the tools supported by the “focus to CB or bands” (*CB approaches*), stipulated by Brouwer[5].

Strategies and actions were grouped according to the basic principles outlined for the oversight of nanotechnologies, and these principles were defined by the International *Center for Technology Assessment - ICTA*[7]. The following principles are mentioned and described as those required for regulation of activities with nanomaterials: 1) the precautionary principle, 2) specific nano compulsory regulation, 3) protecting the health and safety of the public and workers, 4) environmental protection, 5) transparency, 6) public participation, 7) inclusion of wider impacts, and 8) manufacturer responsibility.

Strategies were grouped following the principles that they serve most directly, however, without representing the approach of the proposed principle. In this way, the principles in question are, in general, far more comprehensive than all assigned strategies. Some of the principles cited are not achieved by the proposed risk management procedures because they lay outside the scope of the procedure, as is the case with the principle of a nano specific mandatory regulation. Likewise, none of the proposals include strategies or actions for wide impacts (ethical, socioeconomic, commercial, etc.); these should be provided or addressed with better analytical tools. This forced us to exclude the principles of nano specific compulsory regulation and the principle of inclusion for wider impacts from the analysis. The principles about the health and safety of the public and workers, and the environmental principle were grouped by considering the similarity of the purpose: protection. Similarly, the principles governing public participation and responsibility of the producer were grouped on behalf of the partial relationships between strategies, actions, and concern to these principles.

The analysis was intended to highlight the features shown in each document without attributing a certain value (better or worse). Thirty specific actions were assigned to the set of strategies related to the principles mentioned previously. Strategies were categorized and weighted according to the action type.

Contextualization

Considering the importance of the precautionary principle, CB methodology and participation of those involved in conducting risk management processes between the proposals analyzed, a brief contextualization of these three elements was carried out.

The precautionary principle

The precautionary principle[8,9,10] suggests that (under uncertainty) prevention is better than remediation (because eventually this may not be possible). In general, this principle seems appropriate to the risk management related to nanotechnologies.

There is no single definition for the precautionary principle[9] just as there is no characterization of what is minimally necessary to meet the precautionary principle.

Stebbing[9] establishes two basic ways to address the precautionary principle. The first is strictly based on the Hippocratic premise of *primum non nocere* (first, do no harm) in which one requires inaction if the action may pose risk. The second, known as active, indicates that it should "do more and no less," applying the appropriate efforts to mitigate the risk by choosing alternatives with less risk when available and the accountability of the potential risk (*bonum facere,* also a Hippocratic premise). Stebbing[9] points out that the active form involves the incorporation of six components:

1. Preventive actions should be taken before the scientific certainty of cause and effect;
2. Objectives should be defined;
3. Alternatives must be sought and evaluated;
4. The financial responsibility and security tests should be on proponents of the new technology;
5. Duty to monitor, understand, investigate, report, and act;
6. Complete development of methods and criteria should be encouraged for deciding more democratically.

Concerning nanotechnologies, Sudarenkov[11] indicates that the precautionary principle should be adopted in its active form, incorporating the above components, respecting the freedom of research, and encouraging innovation.

As pointed by Stebbing[9], despite the support to the precautionary principle, there are also criticisms of it. In this case, the author points out three critical points: (1) "precaution" may lead to "fear of the future," as this could cause increase in risk perception, (2) how technology can be regarded as an instrument of social control, the implementation of a prevention focus may inadvertently reinforce social inequities if the context of differences between risks and benefits is not considered, (3) the precautionary principle could cause paralysis (in relation to technological improvements) if any individual choices about acceptance or rejection of the risks (unknown) were overestimated. She concludes by suggesting that the presented criticisms be answered with the early establishment of social values (in relation to nanotechnologies), as obtained by discussion and public engagement.

Control Banding (CB)

The CB approach was developed as a pragmatic tool to aid the achievement of risk management in situations involving potentially hazardous chemicals, where virtually no one has data on the toxicity of these substances[5]. In this type of approach, risk levels (bands) are determined in a matrix (Table 1), depending on exposure and danger and classifying the situation in a particular group (band) so that for each track, there are specific actions to control the risks. This is a qualitative methodology in which the risk is not measured (it is estimated instead), considering to include conditions where there is a lot of uncertainty, such as the impact of nanomaterials on human health and environment.

When excluding the more expensive quantitative surveys, the CB focus suits smaller operations such as those performed in research laboratories or in micro and small enterprises. The CB approach, created by the pharmaceutical industry, has expanded to the chemical industry, and more recently, was applied to new technologies, especially nanotechnology. Typically, these tools are limited to indicate a range or band of risk for a given operation and associated actions to mitigate risks. Thus, these tools are embedded in a larger set of actions to produce effective risk management.

The general use of this approach would be to classify the product, process, or situation in their respective range of danger (low or high), as well as their exposure range, also low or high. The risk group in which this product, process, or situation would fall into corresponds to an interpolation between the respective ranges of hazard and exposure.

The CB tool exhibits some characteristics. There is no specific limitation on the number of tracks both to risk and exposure, and the same occurs for the number of risk groups. Although there is no limitation on the number of tracks, a large sample would also determine many risk groups, which could compromise the ease of using the tool.

In the general scheme (Chart 1), risk group I represents a "low" risk and risk group II an intermediate group ("medium" risk), while risk group III would be related to the "high" risk. For each of these three groups, the tool should provide guidelines for mitigating risk control, compatible to their severity or intensity.

Stakeholder involvement in the Occupational Safety and Health (OSH) process

The participation of all stakeholders, in particular workers, is essential in conducting management processes and risks arising from the study and for promoting a healthy work environment[12,13]. Indeed, the methodologies for risk management that include the participation of those involved in their administration (and/or in the construction and implementation) neither cannot be considered as a closed set of practices nor a package (model) to be imposed[14] but whose full or partial adoption should only be through dialogue and collective bargaining.

In this context, control of occupational hazards shall constitute a participatory process of ongoing collective construction. According to the European Agency for Safety and Health at Work[15], the successful management of health and safety at work requires workers to be informed, consulted, and mainly participate in discussions on all questions related to Safety and Health at Work. The ILO[13] report points in the same direction.

Participation must be understood as a political and collective process that exercises autonomy in decision making and increases

Table 1. Descriptive and comparative summary among nanomaterial management risk proposals.

Analyzed proposals / Type of approach, Assessment type, Country of origin/ year of publication, Principles, strategies, and actions	Tyshenco (A risk management framework)	Tsuji (Risk assessment of nanoparticles)	DuPont Nano Risk Framework	ERNA	Guidelines for safe handling, use and disposal of nanoparticles	A abordagem britânica (BSI) A abordagem do Quebec	A abordagem alemã (BauA) A abordagem americana (NIOSH)	Laboratory actions methodology proposal (CB included)	ANSES CB tool for nanoparticles (CB included)	CB Nanotool 2.0 (CB included)	Safely working with engineered nanomaterials (CB included)	Stoffenmanager Nano 1.0 ("Control Banding (CB)" approaches)	Precautionary matrix ("Control Banding (CB)" approaches)	Nanosafer ("Control Banding (CB)" approaches)	GoodNanoGuide ("Control Banding (CB)" approaches)	Nanosafer ("Control Banding (CB)" approaches)	GoodNanoGuide ("Control Banding (CB)" approaches)
Reference	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
Proposal type of approach																	
Strategic approach (defines strategies)	√	√	√	√													
Methodology proposal (defines strategies and actions)					√	√	√	√	√	√	√						
Pragmatic approach (defines actions only) => CB tool												√	√	√	√	√	√
Provides evidence for the type of risk assessment																	
Qualitative only	√	√	√	√	√					√	√	√			√		√
Qualitative & quantitative						√	√	√	√				√	√		√	
Proposal or author's institution country of origin and year of publication																	
Country of origin	Canada	EUA	EUA	Espanha	Irã	Reino Unido	Alemanha	Canada	EUA	Brasil	França	EUA / Holanda	União Européia	Holanda	Suiça	Dinamarca	EUA / Canada
Year of publication	2008	2006	2007	2009	2008	2007	2007	2009	2012	2012	2010	2008	2012	2012	2011	2011	2009
Principles, strategies, and actions involved																	
Transparency principle																	
Policy implementation strategies	↕		↕														
Clear and transparent writing										↑	↔						↔
Participation by all								↔	↔	↑							
Public participation principle																	
Producer responsibility principle																	
Organization focused strategies	↕		↕														
Accountability								↔		↑	↔						↑
Competence and empowerment					↔	↑		↑	↑	↑			↔				↑
Documentation						↑	↑	↑		↑	↑		↑				↑
Wide communication								↔		↑							↑
Precautionary principle																	
Danger identification strategy	↕	↕	↕	↕													
Nanomaterial characterization						↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Health and safety protection principles for the public and workers																	
Environment protection principle																	
Exposure assessment strategy	↕	↕	↕	↕													
Type of exposure (inhalation, dermal, and ingestion)					↑	↑	↑	↑	↑	↔	↔	↑			↔	↔	↔

Continue

Continuation

Biological indicator monitoring (medical surveillance)						↑		↑	↑	↑		↔	↑				↑
Occupational and environmental monitoring						↑	↑	↑	↑	↔			↔	↑		↑	↔
Involved staff assessment and possible exposures						↑	↑	↑	↔	↑		↑			↑		↑
Toxicity evaluation strategy	↕	↕	↕	↕													
Toxicity studies			↑	↑													
Exposure safety limit assessment			↑	↑													
Risk characterization strategy	↕	↕	↕	↕													
Risk calculation								↑							↔	↑	
Model extrapolation								↑			↔	↔				↔	
Risk hierarchy						↑		↑	↔	↔	↑	↑	↑	↑	↑	↑	↑
Risk management strategy (planning and implementation)	↕		↕	↕													
Technical measures of risk prevention and control					↑	↑	↔	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Organizational measures of risk prevention and control					↑	↑	↔	↑	↑	↑	↔		↑	↑	↑		↑
Labelling/stocking					↑	↑		↔	↑	↑							↑
Cleanup/spilling					↑			↔	↔	↔			↔				↑
Transport					↑			↔		↑			↔				↑
Destination/ waste elimination					↑	↑				↑			↔				↑
Individual protection equipment					↑	↑	↔	↑	↑	↑			↑	↑			↑
Nanoparticle fire or explosion risk						↑		↑	↑	↑							
Monitoring or surveillance strategy	↕		↕														
Monitoring						↑		↑	↑	↑	↑			↔		↑	↑
Investigation (accidents and incidents)						↑		↑		↑	↔						
Auditing/review						↑	↑	↑	↑	↑	↑						↑
Administration critical analysis								↑	↔	↑							↔
Improvement strategy			↕														
Prevention and/ or correction						↑		↑	↔	↑	↑						↑
Continuous improvement						↑		↑	↔	↑	↑			↔			↑

√ = Category belonging indication
↕ = Referred strategy
↑ = Direct reference action
↔ = Implied or generic reference action

Observation: In the strategic proposals, only reference is indicated to this strategy because by definition, there is no indication of actions, except for the assessment of toxicity, where this occurs.

Source: Andrade e Amaral (2013)

the empowerment of workers through dialogue and cooperation. Therefore, it is important that there is a conducive environment for the participation of all involved, as well as the analysis of those who may be involved in the process, such as economic, educational, informational, and affective aspects about the situation for which participation is desired[14]. If the defense of workers' participation is not unanimous, we must understand its relevance, even with the possibility of generating conflicts. If it is necessary to resolve conflicts and obstacles for participation and transparency and not exclude those who suffer the risk, one cannot deny participation in any form. This diversity of opinions points to the existence of several viewpoints such as those indicated by Bordenave[16] which are briefly shown in Charts 2 and 3.

It is worth to note that there is no better or worse model classification. The same occurs in relation to participation itself, i.e., the "building together" is not necessarily better or worse than the "collaboration." It will require the most appropriate format to be adopted. Thus, the presented classification criteria solely lend themselves to a better understanding of this phenomenon and, therefore, do not constitute a value scale.

Chart 1. Generic scheme of a Control Banding array.

Danger exposure	Danger range 1 (low)	Danger range 2 (high)
Exposure range A (low)	Risk group I (low)	Risk group II (average)
Exposure range B (high)	Risk group II (average)	Risk group III (high)

Source: Authors of this document.

Chart 2. Some ratings regarding decision making participation – section 1.

Participation types			Description
Microparticipation			Voluntary association of two or more people in a common activity in which they do not intend to solely take personal and immediate benefits.
Macrovasculopatia			Human intervention in social building or modification processes, in other words, in the "history of society." In this particular case, "society" would have the group of workers involved in the risk control participation process as a measure of comparison.
Participation modes			**Description**
Actual			Group existence prompts the individual to participate, i.e., it is about the participation that all human beings are compelled from the moment they decide to live or be in a group.
Spontaneous			In this case, the individual only participates in certain groups, at free will, such as the groups of neighbours and friends. These groups are not organized nor have a formal and stable purpose.
Imposed			Individuals are obliged to participate, either by moral code or legislation.
Voluntary			Group is created by the participants themselves who define their organization mode, objectives, and functional methods.
Provoked			Participation is brought about by an external agent.
Granted			Organizations and/or public agents bestow decision making powers to the subordinates and/or citizens.
Participation levels	**Control**		**Description**
	L	**M**	
Information/reaction	↑	↓	Group members are only informed about something already decided. Example: the workers are informed that the plant will close within a certain time.
Optional consultation			Criticisms and suggestions are requested from the members of the group. Example: suggestion box in a company.
Compulsory consultation			The subordinates are consulted (mandatory), but the decision belongs to the administration. Example: salary negotiations between employers and employees.
Preparation/recommendation			Preparation process whereby the refusal of the suggested recommendation acceptance must comwe along with a justification by the decision maker. Example: suggestions made at the company with feedback from the administration.
Co-management			Shared administration by co-decision and collegiate. Example: factory Committee, or specifically the Occupational Health and Safety Service.
Delegating			Autonomy in certain fields or jurisdictions. The autonomy may be terminated. Example: the decision maker delegates autonomy to someone.
Self-management			No external authority may, eventually, terminate the decision making power. Example: self-managed companies by groups of workers, cooperatives.

Caption: control rises in the direction of the arrow. L = leader; M = member

Source: Based on Bordenave[16].

Chart 3. Some ratings regarding decision making participation – section 2.

Participation levels of importance	Description
Level 1 (participation of greater importance)	Doctrine and policy formulation of the institution
Level 2	Determination of objectives and strategy establishment'
Level 3	Description
Level 4	Doctrine and policy formulation of the institution
Level 5	Determination of objectives and strategy establishment
Level 6 (participation of lower importance)	Preparation of plans, schedules, and projects
Participation styles	Allocation of resources and administration of operations
Superficial	Action taking
In depth	External agent, if there is one, identifies himself as "an equal" to the group members. In this case, there is the risk of leadership and power relations being overlooked within the group.

Source: Based on Bordenave[16].

The diversity explained in Charts 2, 3, and 4 refers to the need to be defined more objectively, what type, manner, degree, style, and level of participation would be most appropriate for conducting **OSH** processes in the workplace.

Citing Gandin, Santos[17] also establishes some levels in which participation can be exercised, as shown in Chart 4.

In addition to the intrinsic characteristics of the participation processes, Bordenave[16] and Borba[18] point out some participation principles that do not exhibit a dogmatic character; however, they serve to support and eventually guide the adoption of this type of process.

According to these authors, the following are the participation principles:

- Participation is a human need, therefore, it is a person's right.
- Participation is justified in itself, and not by its results.
- Participation is a process of developing critical consciousness and empowerment.
- Participation leads to ownership of the development group.
- Participation is something that one learns and perfects (although it is a human need, it needs to be learned).
- Participation can be provoked and organized, and this does not necessarily mean manipulation.
- Participation is facilitated through the organization and setup of communication channels.
- In order to participate, individual differences must be respected.
- Participation can resolve conflicts, but it can also generate them.
- One should not "sacralize" participation: it is neither a panacea nor is indispensable at all times.

These authors show some of the defining factors of participation that can be either facilitators or barriers to participation, depending on their presence or absence and the way in which they are related, including personal qualities and differences between group members; the social philosophy (or set of values) of the institution or group; social structure; historical conditions; the limits derived from the complexity and size of an organization, a group, or a situation; the strength of social institutions; the informal social organization; the convergence of objectives; access to information; feedback; dialogue (communication); lack of knowledge, time, and financial resources (not necessarily in this order) and also not in a mutually exclusive way.

Chart 4. Practice levels of participation for decision making.

Practice levels of participation	Description
Collaboration	At this level, authority has already defined, decided, and searches among group members the legitimacy for the decision taken, although it might be by means of the group silence or inertia.
Decision	At this level, participation happens as a "choice between alternatives." Broader and fundamental aspects of the process are not analysis targets. An example of such process is before a legal obligation ("what to do") that cannot be discussed, one decides "how to".
Joint construction	At this point, the whole process is effectively discussed and agreed by the group that needs to overcome in order to achieve it, their internal differences.'

Source: Based on Santos[17].

In addition to the already mentioned constraints, Bordenave[16] refers to "participation spaces" such as family, community, and work space; the latter including the participation advocated by this study.

One can therefore state that participation, in the conduct of risk management (or more broadly, the **OSH**) in the workplace, ideally should be macro participation (in relation to the type) caused, or preferably granted (in relation to the way), in co-management or delegation (in relation to the degree), level 1 to **OSH** issues (regarding the level of importance), deep (in relation to the style), and built together (in relation to the levels of exercise).

On the basis of the listed principles and constraints, participation should be exercised and promoted in the workplace, with the aim of establishing a safer and healthier workplace. An open policy for the effective participation in **OSH** issues is one that offers correct information, carefully listens, and actively consults the involved ones.

Broad participation is a key element to effectively conduct risk control in activities involving nanomaterials. The literature shows other references to methodologies that include the participation of those involved in conducting the **OSH** process as an essential part of their development. Kogi[19] sets three of these tools: (1) *Work Improvement in Small Enterprises*, (2) *Work Improvement in Neighborhood Development*, a method for small farmers, and (3) *Participation - Oriented Safety Improvements by Trade Union Initiative*, a program for unions. To this list, one can add the proposal of Malchaire[20] *Screening, Observation, Analysis and Expertise* and the document *Guidelines on Occupational Safety and Health Management Systems* - ILO - OHS 2001[12]. In addition to these are the techniques of participatory ergonomics, as described by Nagamachi[21].

Although the theme of participation is wide and complex, as previously stated, the proposals analyzed merely indicate when they indeed need to participate in the evaluation process and control occupational hazards. Table 1 (a summary of this analysis) only illustrates the presence (direct or indirect) or absence of indication of interest without considering their possible constraints.

Results and discussion

Table 1 shows a comparison between the analyzed documents following the explicit methodology. Each briefly described tool exhibits a letter in brackets, which is a reference to the mentioned figure.

Strategic approaches

Among the strategic approaches, we can cite the study of Tyshenco and Krewski[22] [A] (*A risk management framework for the regulation of nanomaterials*), which exhibits the general structure where a set of strategies are proposed to regulate the handling of nanomaterials. Primarily, the proposal is an integrated and standardized approach to facilitate the breaking of any trade barrier in the future. By incorporating the setup and structure of regulation as an objective (and not a specific control activity), the proposal is generic even in the specifications of strategies.

Risk assessment of nanoparticles proposed by Tsuji et al.[23] [B] (*Research Strategies for Safety Evaluation of Nanomaterials*, Part IV: Risk *Assessment of Nanoparticles*) is part of a larger set of research strategies for reliable assessment of nanomaterials. It describes in detail the forms of exposure and its possible adverse effects on human health. The structure of risk assessment is more concise.

The Nano Risk Framework [C] proposal is developed in partnership with DuPont Environmental Defense[24] (USA), and is intended to provide a generic framework for managing the risks associated with nanotechnology, especially those related to possible damage caused by products containing nanoparticles are more suitable for large corporations. It contains a macro-management system, including an indication of toxicology (its differential relative to the other) tests, and includes consideration of the concept of the product life cycle.

The Evaluación de las Riesgos Nanoparticles Artificiales - ERNA [D], proposed by Anton[25], is basically supported in conventional methods of risk assessment with the incorporation of uncertainty analysis as a way to mitigate the gaps in knowledge about the effects of nanoparticles on the health of those who handle them.

Methodological approaches

Six proposals were classified as having a methodological approach; in addition to strategies, they include actions defined by using the methodology of CB. The following are the methodological proposals:

Amoabediny et al.[26] [E] referenced the work *Guidelines for Safe Handling, Use and Disposal of Nanoparticles* containing general strategies and, therefore, was classified as a methodological proposal, although it does not mention the number of other relevant points. We also have to consider that this is an older proposal, which can surely explain some shortcomings such as lack of engagement of others involved in the construction of the proposal and the surface characterization of nanomaterials.

The British approach [F] (*British Standards*[27]) shows a set of specific strategies and actions to control and manage the risks associated with nanomaterials. Unlike other options, whose evaluation is only qualitative, this standard indicates devices and methodologies enabling quantitative analysis of nanoparticles, and also points out some limits of exposure to these materials.

The Guidance for Handling and Use of Nanomaterials at the Workplace, Federal Institute for Occupational Safety and Health German (*Bundesanstalt für Arbeitsschutz und Arbeitsmedizin / BAµA*)[28] [G] is relatively generic and devotes special attention to possible contamination by nanomaterials through inhalation. Although some quantitative methods of evaluation are indicated, it provides further guidance as to the limits or methodologies to be applied.

The examples of methodological approaches include the CB methodology of the Quebec approach [H] *Best practices guide to synthetic nanoparticle risk management*, by Osteguy et al.[1], which proposes a comprehensive approach covering both general strategies for managing risks associated with nanomaterials, such as the CB-type approach based and referenced in the study of Paik et al.[3]. This proposal, also referred to as The *Quebec approach*, seems quite complete, which can be seen in Table 1.

The approach of the *National Institute for Occupational Safety and Health (NIOSH)*[29] [I] called *General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories* is comprehensive. It assumes a larger control system and risk management in the organization, which will add nano specific guidelines. Thus, a series of actions and approaches are implied herein for being part of the general system. In addition to the general guidelines, the proposal indicates the use of the CB approach as a major part of efforts to control risks caused by nanomaterials.

In addition, integrating this group of approaches is also the study presented by Andrade and Amaral[30] [J] *Methodological proposal for occupational health and safety actions in research laboratories with nanotechnologies activities*. This methodology shows a simplified flowchart for the characterization of nanomaterials, and offers a number of suggestions on various specified and stratified control operations such as site cleanup, labeling, and disposal. The greatest advantage of this proposal is that it includes **ILO**[12] guidelines for management systems and, therefore, calls for active participation of all stakeholders and not just the technical staff, as well as the mandatory involvement of the administration in conducting the risk management of nanomaterials.

Besides the methodological approaches characterized above, one can cite the *French Agence National de focus Sécurité Sanitaire, L'alimentation, de L'environnement et du Travail*[31], *Control Banding Tool for Nanoparticles* [K]. Although Brouwer[5] considers this approach only as a CB tool, it is broader because it contains elements of the management system (planning, implementation and operation, checking and corrective action, and management review). Because of this, the approach was characterized as a methodological type.

Pragmatic approaches - Control Band (CB)

When using quantitative surveys, which are usually more expensive, the CB approach is suitable for smaller operations such as those performed in research laboratories or in micro and small enterprises. Typically, these tools are limited to indicate a range (band) of risks for a given operation and associated actions to mitigate risks. As expected, these tools must be inserted into a larger set of actions so that one can produce effective risk management.

Brouwer[5] points six tools based on the CB methodology: 1) *Precautionary matrix*[4]; 2) CB *NanoTool* 2.0[3]; 3) *Guidance on working safely with nanomaterials and nanoproducts*[32]; 4) *Stoffenmanager Nano* 1.0[33]; 5) ANSES *CB tool for nanoparticles*[31]; 6) *Nanosafer*[34]. It is understood that the Goodnanoguide[35] proposal should be added in this category.

One of the first applications of the CB methodology to nanotechnology (*CB NanoTool*)[3] [L] was proposed by Paik et al.[3], who classifies a given operation with nanomaterials into four risk levels. This classification is based on the interpolation between a severity score obtained by some physicochemical characteristics of the nanoparticles and their toxicity (or from the material in a macro scale, considering the lack of specific information from such nanomaterials) versus a probability score that considers the amount of material used, frequency and duration of operations, number of people involved, and the dustiness of the material. While the score composition may be based on quantitative information, it is possible to use the tool without any measurement.

The reference *Working Safely with Engineered Nanomaterials and Nanoproducts - A Guide for Employers and Employees*[32] [M] shows a qualitative basis methodology that allows quantitative assessments of the work environment, including an indication of exposure limits. The activities are framed in three levels of control on the basis of the interpolation between "exposure categories" and "hazard categories." The category of exposure is determined by evaluating the possibility of the emission of nanoparticles, while the hazard category is defined by means of characteristic of nanomaterials, such as biopersistence and shape.

The *Nano Stoffenmanager* tool 1.0[33] [N] is an application available on the Internet, which according to its authors does not require specific knowledge of **OSH** for its use. Stoffenmanager Nano 1.0[33] is an adaptation for nanoparticles of a generic system of the same name, for which the user can be referred in some situations. However, in situations where there is no information about the nanoparticles, the system classifies the substance risk through macro data, thereby classifying the nanoparticles in dangerous areas. The exposure is determined by 14 multipliers, which if combined, allow the determination of the exposure range. These multipliers relate to the amount of material, dustiness, handling forms, types of processes, existence of collective protection equipment and personal protective equipment, etc. The interpolation between danger and exposure areas allows us to frame the situation into three groups of risk prioritization.

The precautionary matrix[4] [O] is a tool used to generate a score that determines two classes of risk. The main parameters for setting the score are the relevance of the material (based on the size and characteristics of the particle), specific conditions of use, and potential effects of exposure. The use of these parameters indicates the need for skilled personnel to implement the matrix. A point worth mentioning is the use of the half-life concept with respect to the stability of nanomaterials. The *Nanosafer*[34] [P] approach is focused on air-dispersed nanoparticles, as based on the dustiness of nanomaterials. It points to the need for measurements in the workplace, including quantitative data. In contrast, the *Goodnanoguide*[35] [Q] approach is a simplified approach tool, allowing its use in three progressive levels: basic, intermediate, and advanced.

A score was calculated for each of the proposals. Table 2 shows the proposals sorted from the largest to the smallest score. The score was defined by assigning two points for each occurrence with symbol ↑ in Figure 1 and one point for each occurrence with symbol ↔. There was no assigned score for each non-mentioned action. Thus, the proposal making a direct reference to all 30 shares would receive a score equivalent to 60 (2 points for each of the 30 references). The four classified proposals (references A, B, C, and D in the text) were not included in this score because they are strategic, and hence are not included in direct references to actions.

It is worth mentioning that a proposal receiving a higher score than another does not determine different qualities *a*

Proposals	Reference	Direct Reference (↑)			Implied or Generic Reference (↔)			(Empty)	Total of	%
	In the text	Number of occurrences	Score (max.60)	% over 60	Number of occurrences	Score (max.60)	% over 60	No occurrences	escore (max.60)	Over Total
Laboratory actions methodology proposal	J	22	44	73.3	4	4	6.7	4	48	80.0
The Quebec approach	H	20	40	66.7	6	6	10.0	4	46	76.7
GoodNanoGuide	Q	19	38	63.3	4	4	6.7	7	42	70.0
British approach (BSI)	F	19	38	63.3	0	0	0.0	11	38	63.3
American approach (NIOSH)	I	12	24	40.0	7	7	11.7	11	31	51.7
ANSES CB Tool for Nanoparticles	K	8	16	26.7	6	6	10.0	16	22	36.7
Safely working with engineered nanomaterials	M	7	14	23.3	5	5	8.3	18	19	31.7
Guidelines for safe handling, use, and disposal of nanoparticles	E	8	16	26.7	1	1	1.7	21	17	28.3
The German approach (BaμA)	G	6	12	20.0	3	3	5.0	21	15	25.0
Stoffenmanager Nano 1.0	N	6	12	20.0	2	2	3.3	22	14	23.3
Nanosafer	P	6	12	20.0	2	2	3.3	22	14	23.3
CB Nanotool 2.0	L	5	10	16.7	2	2	3.3	23	12	20.0
Precautionary matrix	O	5	10	16.7	2	2	3.3	23	12	20.0

Table 2. Indicative score of the action references in each proposal.

priori. This is because the value of an action depends more on the focus and scope for which the proposal was developed.

As already mentioned, proposals A, B, C, and D were excluded from this scoring method because they exclude references to strategic actions.

Conclusions

The set of 17 reviewed proposals does not converge to a consensus approach, although the theoretical basis of all of them is the same, as explained in the ANSES[31] report. In general, all refer to the hazard identification, exposure assessment, the definition of risks, elimination, substitution, or control through technical or organizational measures.

Besides the type of nanoparticles, solubility, dustiness, and liability are more important than the amount of material involved, indicating that other metrics should be considered about nanomaterials; however, at this time, there is no consensus about what should be used to characterize the risks caused by nanomaterials.

In this scenario, the CB approach is highlighted among the reviewed documents. The explanation may lie in the fact that it is not known what exactly should be measured (and how to do it). It is reasonable to expect that a methodology that yields measurements such as the CB approach is better.

Similarly, with a plethora of uncertainty, the precautionary principle stands as a commonplace in many analyzed proposals. It seems reasonable that this is due to the consideration of earlier cases, in which potentially dangerous situations were not treated such as generating serious issues to the health of those involved, as well as huge economic losses. As examples of these situations, it is possible to cite, among others, cases involving asbestos, radioactivity, and the substitution of lead in methyl tertiary butyl ether (*methyl tert-butyl ether*) fuel, as mentioned in the report "Late Lessons from Early Warnings: the precautionary principle 1896-2000" (free translation)[36] provided by the European Environmental Agency.

Despite health issues that have immense importance, the lack of agreement on how nanomaterials should be treated influences other sectors such as law, ethics, and international trade. The inclusion of multiple stakeholders (industry, government, insurance, commerce, academia, standard organizations, media, consumers, and the public in general) is pointed as essential by many.

The risks arising from nanotechnologies are being discussed for many years; however, as identified by the references cited by van Noorden[37], there is a lack of security in laboratories involved in nanotechnology activities. Therefore, the issue addressed here requires priority. There is an urgent need to provide clear guidelines in this regard, not only for workers' health but also for legal and economical security, which are essential keys for scientific and technological progress.

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