Key Analytical Capabilities of a Best-in-Class Regulator

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Executive Summary

This paper describes a diverse array of analytical capabilities that would ideally be mastered in best-in-class regulatory agencies that manage risks to the public. The term regulator is used broadly, and could constitute a set of regulatory agencies acting in concert. The term risk is defined, and related to the concepts of safety, hazard, and benefit.

A key question addressed in this paper is the meaning that is implied by the qualifier "risk-based." The term has become a "badge of legitimacy" for regulatory organizations, yet has no formal meaning. The principle of proportionality (in risk assessment, and in the extent of risk controls required) would appear to be the primary motivation for describing regulatory approaches as risk-based. Efficiency in resource allocation would be a primary benefit of proportionality in allocating resources to address risks. This outcome is critical to regulatory agencies with large numbers of field personnel (e.g., inspectors).

We distinguish between rule-based and risk-based approaches to regulation. Rule-based refers to constraints on industry or the regulator which may or may not have an explicit basis in risk when the rule is made, or when compliance with the rule is verified. Risk-based refers to the development of standards, or the enforcement of standards, that is directly linked to the level of risk or risk reduction to be expected. The continuum from pure-rule-based to risk-based is discussed, including parallel and hybrid approaches where the standard may be rule-based, but the enforcement is risk-based, or vice versa. A regulatory system will inevitably be a mix of rule-based and risk-based approaches. A key determination for the modern regulatory agency is to define what the ill-defined notion *risk-based* will actually mean to the agency, the regulated industry, and stakeholders.

In describing analytical capabilities, we have applied a very broad and inclusive definition of analysis. The analyses to be mastered include the development of a risk governance model for the regulated sector, the development of risk-related policy frameworks to guide day-to-day analytical and decision-making functions, and to develop broad causal systems models of the system being regulated (and importantly, including the impact of the regulator on the system's level of risk or level of assurance of low risk). We also explore the need for analytical capabilities associated with the social sciences and cross-disciplinary assessments including the establishment of approaches to determine risk tolerability. An additional capability needed by public risk regulators is to maintain an appropriate firewall between assessments of public risk and the enterprise risk management function which would consider these same risks and controls from the perspective of organizational objectives. The implementation of enterprise risk management requires some accommodations for the fact that the organization's primary objective is the management of risks to another risk bearer (i.e., the public).

A central analytical capability for a public risk regulator is the setting of priorities to address the diverse set of sources of risk within its mandate. The challenges in designing a priority-setting scheme are described, including various trade-offs, and the benefits and challenges of expert committees' and public and stakeholder input into priority-setting. Finally, the core analytical capability of formal risk assessment is described with respect to guiding principles and the main steps and sub-tasks for consideration.

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I. Introduction

A. What is meant by "regulator"?

Regulation is a type of law and thus a key power of government, applying to the control of behaviour in domains in which government has jurisdiction and responsibility. Regulators are government bodies with a mandate assigned by legislators to control activity in a given area for the protection of the public or the public good.

This article applies generally to all regulation. However it focusses more explicitly on the analyses required in risk regulation. This is a specific type of regulation that is oriented towards protection of the public from the adverse outcomes that may result as an unintended or unavoidable side effect of a regulated societal activity. The identification, prediction and control of these risks in many cases have a scientific or technical underpinning. The science-based nature of many types of risk regulation mandates a number of core analytical functions of risk regulators that revolve around gathering and interpreting information on the causes and levels of risk to the public or public goods and determining the extent of any risk control that is needed within the regulated sector. As a scientific activity, the analysis is often expected to comply with good practice in the scientific and technical community including peer review. Often, the ultimate impact of regulation is achieved in a multi-organizational context (multiple government agencies, departments or ministries, non-profit authorities, standard-setting organizations). As such, the concept of a regulator can be extended to a set of regulators (or a meta-regulator) that might require analytical capabilities, both as individual organizations as well as a collective entity acting in a co-ordinated fashion in the public interest.

All regulation is set in a broad context consisting of societal and political values and structures, specific policy frameworks and objectives, legal jurisdictions, legislative requirements and powers, and a regulatory community consisting of the regulated industry, and other involved and interested stakeholders and the public. Most specific to this discussion of analytic capabilities required in regulation is the legislative framework that gives a regulator its mandate and determines many aspects of the regulatory approach the agency will take in filling its mandate.

B. What is meant by "analysis"?

According to Merriam-Webster, analysis is "a careful study of something to learn about its parts, what they do, and how they are related to each other."[1] In strict definitional terms, it

[1] http://www.merriam-webster.com/dictionary/analysis

refers to the separation of a whole into its constituent parts; a detailed examination of the constituents of something. In this sense it is distinguished from synthesis, which is the combination or putting together of separate elements.

For this purpose of this article, the concept of analysis is used more generally in the sense of Merriam-Webster's second definition, "an explanation of the nature and meaning of something." In this broader sense, analysis is a systematic consideration of something which includes, in various applications, both analytic and synthetic approaches.

In the context of regulation, many different types of processes are discussed as *analyses*. These are all, to varying degrees, systematic and structured, though some are formal methodologies while others are more deliberative, contextual and tailored. Both approaches should be based on consistent principles or harmonized procedures, as Majone (2010) notes, as these are critical for consistency and legitimacy, particularly where regulation is applied in trade or other international contexts, or where a regulator has multiple parallel missions.

C. What is meant by "risk"?

Risk, as used here, is a concept that integrates the probability and severity of adverse outcomes to individual entities or populations relevant to the domain of regulation. The technical definition of risk used here is relevant to regulatory agencies and regulated industries that are responsible for managing adverse outcomes as seen by the public (the outcomes can be varied but are valued or needed by the public, e.g., health, property, infrastructure, cultural artifacts, fairness in commerce, human rights, animal welfare, functional banking systems). It is distinct from the sense in which the concept has been articulated recently in relation to enterprise risk management[2], which emphasizes risk as the effect of uncertainty in the achievement of an organization's objectives, including both positive and negative outcomes. This distinction is discussed further in section 3.9 below.

The technical concept of risk typically embeds the concept of a source, a pathway and a receptor. Given that this definition of risk is primarily concerned with adverse outcomes, the source (e.g., chemical X) or some potential condition along the pathway between source and receptor (e.g., failure to properly label the container containing chemical X), are often characterized as **hazards**. The term hazard refers to the potential for (or possibility of) harm. The concept of risk, as the outcome of a risk assessment, is the result of a situation-specific conversion of the possibility of harm into a specific set of predicted outcomes with corresponding probabilities and consequences. By situation-specific, it includes properties of the source, pathways and receptors (including how many) that contribute to both the likelihood and severity of the adverse outcomes. This distinction is applied when describing approaches to managing risk as either hazard-based or risk-based. A strictly hazard-based approach might prefer to completely avoid a hazard with high potential for harm regardless of how likely the outcomes might be. A strictly risk-based approach might prefer the situation with lower risk which would integrate the potential for harm with the probability and severity of outcomes.

[2] As in for example, ISO 31000 and associated Guide 73.

With respect to risk regulation, risk is commonly considered in relation to two other concepts: **safety**, and **benefit**. The stated goal of regulation is often to achieve safety. It is the term most often used in political statements and the public relations functions in an agency. It is often used in the name of a regulatory agency and in its enabling legislation. In its most simplistic use, the concept of safety may be equated with the absence of hazard or the absence of risk. (This potential for equivalence is a desirable property making the term the preferred word in corporate communications and public relations applications for both regulatory agencies and regulated industry). In reality, risk is rarely completely eliminated, and zero-risk is not even seriously contemplated as an expected outcome in most regulatory applications. To apply the concept in practice, regulators will also use parallel language that is more technically defensible where safety is often described as a variation upon "freedom from unacceptable risk"[3] to allow for situations with non-zero risk levels to be given the label "safe" through the use of the qualifier that the level of risk is not "unacceptable."

The adjective "safe" and the noun "safety" allows for the conversion of the concept of the continuum of risk into a binary concept with two states - safe and unsafe. The conversion occurs through the explicit, but more often implicit, application of the concept of the **tolerability** of risk. This conversion is often done in qualitative or abstract terms where the level of risk is not explicitly measured or estimated, and the threshold of risk that is considered tolerable is not explicitly stated. The use of the term "safety" can be preferable for a number of reasons as it is more comforting as an expressed goal or as an assessment outcome than "acceptable risk." It is also easier to use when there are no actual estimates of risk, or no clear policy on what level of risk should be considered to merit the label "safe."

There are a variety of ways in which a situation may be deemed "safe," despite the absence of an estimate of risk, or an agreed-upon acceptable risk standard. The determination and delineation of the range of acceptable means by which a regulatory agency and the industry it oversees can assert and defend a claim of "safety" or, perhaps more appropriately "tolerable risk," is a fundamental policy choice of the regulator as it applies to its own determinations, and as it applies to the industry it oversees. The choice is also influenced by legislation, regulation, case law, industry and NGO pressure efforts, and the central agencies of government that oversee the decisions and analytical requirements of the regulator. The choices in this regard have important implications for required analytical capabilities, and the ultimate effectiveness of the regulator in serving the public interest. In many cases (unfortunately) the causality is reversed in that the analytical capabilities of the regulator, or the industry, will determine what will be construed as a reasonable justification for safety.

When viewed across different industries, there are extremes in expectations for competence in risk assessment in both regulators and the regulated industry. The reasons for the extremes has not, to our knowledge, been systematically considered, and tends to be based in the history of the industry (for example, high profile major accidents in the past) rather than an active and up-to-date determination of what competencies should be expected based on the current level of risk posed or other current considerations.

[3] International Standards Organization (ISO) Guide 51 Terminological Standard's definition of "safety."

The concept of **benefit** is applied in two very different contexts. To the extent that an action (e.g., a new regulation) will reduce risk, the justification for the action will often be based on the balance between the *benefits* of the action (i.e., the risk reduction) and the cost of that action (an estimate of the economic burden on industry, consumers, and governments). This application of the concept of benefit is employed in cost-benefit or cost-effectiveness analysis.

The other application of the concept of **benefit** relates to the beneficial aspects of the regulated sector, in terms of its products or services. The most straightforward example of risk-benefit balancing is in the area of regulating therapeutic products (i.e., drugs and medical devices). In this case, the regulation is explicit about both requiring measurable benefit (e.g., efficacy, improvement in quality of life) and a known and tolerable risk to the patient. In many cases, safety and benefit are directly juxtaposed in deciding to approve specific recommended doses of drugs, in effect, seeking more benefit while avoiding toxicity. Some drugs have relatively high and well understood risks, but are expected to be taken only by those who are facing risks that are even higher if they don't receive the drug.

Most risk-benefit tradeoffs operate at the population or societal level. Societal benefits (e.g., the utility of products that are derived from chemicals or mined commodities, the availability of abundant electrical energy) are thus posed against the risks of that activity as part of an evaluation of the rationale for conducting the activity in spite of its risks, and for the degree of risk that may be tolerated given the benefits that accrue from the activity. Accordingly, the benefits of an activity may also be assessed in order to understand the risk-benefit trade-offs implicit in the activity. A regulator (when empowered to do so) may need to determine the appropriate balance, and distribution, of the risks and benefits for both public sector activities (e.g., designing transportation or water resource management infrastructure) and private activities (e.g., manufacturing, resource extraction) in society. The balance of risks and benefits is often a trade-off rather than a balance, since the competing aspects of an activity often appear in different domains (such as economic benefits and environmental risks) and are valued and measured in different terms (such as monetary gain, health risk) and, in many cases, the risks and benefits will accrue to different groups in society.

The characterizations of hazard, risk, safety, and benefit above are what should be understood as technocratic definitions of hazard and risk. A regulator must also operate with the awareness that, in broader public discourse on matters of risk, stakeholders and the public are not bound by these definitions in choosing to form and communicate opinions and judgments about risks. For example, some members of the public may focus exclusively on the consequences (for example, a worst case scenario) and equate their contemplation of the potential consequences as "the risk" on this basis alone, and may reject any suggestion that contemplation of the relative likelihood is equally important. Others may choose to focus on the frequency of the risk (constant) while placing less emphasis on, or completely disagreeing with, an assessment that the outcome may not be technically considered to be sufficiently adverse to warrant regulation (e.g., a slightly undesirable odor or taste with no associated health effects in drinking water).

The associated benefits of a risk-generating activity will be valued very differently among individuals, and in different communities, with correspondingly different tolerances of

the associated risk. Often, the public will reach a determination on risk after they have included, in their analysis, various aspects of the risk situation that are typically excluded as evidence in a technical analysis of a regulated industry (e.g., trust in the regulator, the transparency of the decision, readily recalled disasters, or whether they believe the industry shares their values with respect to various potential consequences of the regulated activity). As a result, the concept of risk within technical discussions and the concept of risk in public discourse are linked but fundamentally different in their framing (e.g., the questions being asked and answered, the types of evidence that are admitted and preferred, and the scope of public values that are deserving of protection, and the range of solutions to the problem that should be contemplated).

This technical-public *risk dissonance* is an indelible aspect of risk regulation in a liberal democracy, and may be expected to increase with readily accessible public information resources of highly variable reliability where information and highly value-laden opinions are inextricably intermingled. The key question related to analytical capacity is the degree to which the regulatory agency can effectively participate in the public process, balancing competing legitimate demands for analytical and participatory processes, while serving the best interests of society. While not generally understood by technically trained analysts, the basis for public judgments about risk and the resulting discrepancy between technical and public assessments of risk is highly amenable to analysis, both in general and in specific situations. There is a considerable literature and well-developed techniques in the social sciences that can significantly improve the capacity of the regulator to understand, first, and then participate more effectively in the public discourse on matters of risk. As such, they constitute important components of analytical capability. These are discussed further in sections 3.5 and 3.6 below.

D. What is meant by the adjectives "risk-based" or "risk-informed"?

There are increasingly calls for regulatory systems, decisions, and operations to be "risk-based" though the term has no fixed meaning and tends to be extremely flexible in application, at present. There are a number of properties that are implied by the label risk-based or risk-informed, based on the rationale usually offered when promoting a transition to a more risk-based regime:

- That the level of risk is estimated (the output of a risk assessment) when describing a situation and when presenting information to decision-makers. Further, the analysis necessarily includes the ***joint*** consideration of severity and likelihood of adverse consequences. In this way, it is meant to imply that an analysis that considers only hazard (the potential for harm), only severity of consequences or only likelihood is not sufficient to earn the label, *risk-based*.
- That the level of risk and, ideally, the extent of risk reduction associated with an activity is one of the key considerations in determining the necessity, frequency and intensity of risk controls. As such, the principle of **proportionality** – that attention to risk, and costs and resources expended to control risk, be proportionate to the level of risk – is often the explicit or implicit principle being asserted in the transition to being more risk-based.
- It can be applied at many levels, and applies to both industry and the regulator: an occupational chemical exposure threshold could be established as "risk-based," the frequency with which the basis for the threshold is revisited by scientists could be "risk-

informed," the firm's provision of protective equipment to avoid exposure above the threshold could be risk-based, the frequency of inspection of facilities that handle chemical X could be determined in a risk-informed approach.

The extent to which risk is truly estimated (as opposed to merely being considered in qualitative or narrative terms) is highly variable among organizations who nonetheless claim to be risk-based. Because the term has no formal meaning, it can easily be used as an aspirational goal with little fundamental impact on the organization's analytical activities. Organizations that do not disseminate their analytical work to the public or external bodies are more likely to maintain an aspirational status due to the lack of scrutiny of the extent to which they are truly estimating risk.

In recognition of the range of factors beyond the level of risk that are typically integrated into regulatory decisions, this approach has sometimes been referred to, perhaps with the intent of greater honesty, as "risk-informed" rather than risk-based. This is based on the reality that risk levels inform, but do not solely determine, the risk management decisions or resource allocations. By contrast, the term risk-based may imply a stronger linkage between risks and decisions than can be promised and delivered.

Risk-based regulation is defined by Bounds (2010: 16) as follows:

> A risk-based approach to regulation explicitly acknowledges that the government cannot regulate to remove all risks and that regulatory action, when taken, should be proportionate, targeted and based on an assessment of the nature and magnitude of the risks and of the likelihood that regulation will be successful in achieving its aim. Regulatory responses are therefore to be informed by an assessment of the probability of harm expected to arise from, for example, a market failure, where this can be known. Where the probability of harm cannot be calculated, a risk-based approach would require a rational and transparent consideration of other relevant factors that remain uncertain.

In a fully risk-based regulatory regime, consideration of risk to the public from specific regulated activities is explicit, and the level of risk may form the basis of day-to-day decisions on individual regulatory actions that are made by a range of agency personnel on each decision. The essential questions to be addressed are how much risk reduction is required, and by what means the risk prevention is to be achieved (Wiener 2010). Risk (as well as economic, benefits, and social concern) assessments inform the entire regulatory cycle, as case-by-case decisions such as which risks to manage, to what level, with what regulatory instruments, with what inspection frequency, and extent of enforcement are based on information on the level of risk involved. Regulatory performance is evaluated and adjusted for improved effectiveness based on data collected on regulatory decisions and their outcomes, including the level of public risk (if it can be inferred or observed).

A risk-based approach to regulation "involves the development of decision-making frameworks and procedures to prioritize regulatory activities and deploy resources, principally

related to inspection and enforcement, based on an assessment of the risks that regulated firms or activities pose to the regulator's objectives." There is thus a heavier demand for analysis in risk-based regulation, in terms of risk and other assessments as well as systematic evaluations required to make regulatory decisions.

The shift to risk-based regulation has been attributed to several different rationales. Kadak and Matsuo (2007) trace its origin to the development of probabilistic risk analysis in the nuclear industry, which provided the technical ability to characterize risks in complex systems accurately, thus generating the information required for a risk-based approach. The wider adoption of the approach by governments was due to its facilitation of more cost-effective regulation, as efforts could be allocated to higher risks, and to government interest in becoming more flexible with regulated industries.

Black (2010; 189) cites a number of key reasons that many regulators have adopted a risk-based approach. These include:

- To facilitate the effective deployment of scarce resources and improve compliance within those firms that pose the highest risk;
- To improve consistency in the assessment of risks and regulated firms, and enable regulators with broad mandates to compare risks "across a widely varying regulated population within a common framework."
- To provide evidence that risks are not being over- or under-regulated;
- To comply with legislation, which in many jurisdictions increasingly requires a risk-based approach.

Risk-based regulation is arguably becoming accepted as regulatory best practice, and "a badge of legitimacy" (Black, 2010, 189). Wiener (2010) suggests that risk-based regulation achieves better results, but requires more information. While it has been suggested (Naime and Andrey, 2013) that risk-based regulation is too narrowly based on technical factors characterized by risk assessment, others (Renn, 2008; Amendola, 2001) assert that risk-based regulation has in practice evolved to include explicit attention to contextual factors and societal concerns. Renn (2008) links risk-based regulation with risk-benefit balancing and normative standard setting.

E. What is the difference between rules-based and risk-based regulation?

Two main approaches to risk regulation are discussed here: the traditional rule-based (prescriptive, or compliance-based) approach and the emerging "risk-based" approach. Most regulatory systems are currently rule-based, in which only a subset of the rules have a known and explicit relationship to levels of risk.

In both types of systems, regulatory requirements are set to control risks (Black, 2010), and in that limited sense are both based on risk. However, they differ in the types of analysis that are conducted, and at which points in the process. They also differ in terms of the degree to which the regulatory requirement has a known relationship to a level of risk. To be most accurate, risk-based approaches should be considered to be a subset of rules-based, since even risk-based determinations are ultimately implemented in the form of a rule. For present purposes,

we will use the term ***rules-based*** to refer to the subset of all rules or activities that lack a risk-basis, and ***risk-based*** to refer to those for which the rule was established, or where policy or operational decisions are made, in light of the results of an estimate of risk or risk reduction.

In a rule-based approach, most analytical functions that are related to risk (even if not formally assessed) are conducted in the design stage. In this approach, regulatory requirements, including limits or constraints on industry practice, are determined when the regulatory regime is developed, and are then applied uniformly to all regulated products and firms through pre-determined regulatory activities and schedules. At the operational level, agency personnel evaluate and enforce firms' compliance with these standards or criteria and do not modify their approach in response to changes in the level of risk except as manifested by an instance of non-compliance with a rule. The public's level of exposure to risk is implicit in the standards and enforcement actions. The public is presumed to be experiencing a tolerable level of risk (i.e., there is safety or "freedom from unacceptable risk") wherever regulatory requirements are being met. In other words, the level of public risk that is acceptable is not estimated or measured. The level of public risk can only be known to be less than or equal to the maximum level of risk that a compliant industry would generate. As such, the act of non-compliance is an end in itself (the breaking of a rule) and not interpreted as presenting a particular level of risk.

How might risk be implicitly or explicitly employed in regulatory decision-making? There are a number of ways of establishing rules and these may or may not have been developed with a linkage to the level of risk that is prevented when industry complies with the rule, or equivalently, the level of additional risk that is generated when an industry firm is not compliant. There is a continuum (rather than a black-and-white distinction) in the extent to which risk is explicitly estimated and forms the basis for decisions. The following examples of processes to establish a requirement on industry are highly variable in the extent to which there is an explicit link between the rule and the level of public risk.

a. A committee is formed to determine the particular type and quality standard of steel that should be used in a certain application expected to become common within an industry. The committee makes their recommendation which is captured in a code or standard which is adopted by reference into the regulation. Industry must use this type of steel to be compliant with the code and thereby the regulation. The level of risk associated with using this type of steel as compared to the other options is not known, and the basis for choosing this type of steel is never explicitly stated. It could have been based on historical safe use and performance in similar applications, capital cost considerations, manufacturing quality control concerns with other options, or to avoid high maintenance costs, or all of the above. The basis for the decision is not available for scrutiny (other than that it is a consensus document) and may have been a compromise position between two other options or driven by competing financial interests of the employers of committee members.

b. Installation of a piece of equipment has historically required four bolts of a certain size. A few relatively minor incidents have occurred (in the form of near-misses of major incidents) where all four bolts were compromised by corrosion and other failure modes. The regulatory requirement is adjusted to require six bolts, for any new installations,

while older installations are “grandfathered” and only require four bolts plus annual inspection for corrosion. The level of risk associated with four bolts was never estimated. The requirement for six bolts is argued to be inevitably safer, and is not burdensome for new installations. Retrofitting old equipment would require a very intrusive equipment shutdown, and on-site welding of new custom manufactured parts to accommodate the six bolt standard. The level of risk, while not estimated, is argued qualitatively to not warrant this level of intervention in existing operations, and that the requirement for vigilance for corrosion mitigates the risk for existing installations to a level that is deemed tolerable but remains unstated.

c. A chemical is found to exhibit neurotoxicity in animal studies and in accidental human exposures at high dosage levels. A committee recommends an exposure limit using conventional adjustment factors to estimate an exposure level (much lower than those used in animal studies, or seen in the human accident scenarios) that is believed to be unlikely to cause adverse effects. The exposure limit is adopted into the regulations. The level of risk associated with exposure at the limit is never estimated and the implications of exceeding it are ambiguous due to the nature of the adjustment process used by the experts and the non-quantified goal, in the charge to the committee, of being “reasonably certain that it is unlikely to cause adverse effects.”

d. Explicit radiation exposure levels for members of the public and radiation workers are established by the International Commission on Radiological Protection (ICRP) on the basis of research and expert judgment with explicit linkage to the level of public and occupational health risk (e.g., a variation on a 1 in 10^6 lifetime risk of cancer). This exposure limit (the resulting “rule”) is adopted by national regulatory agencies and compliance with it by regulated entities is enforced in day-to-day operations. This would constitute the strongest form of a risk-based rule. The consequences of exceeding the threshold are known, and the tolerable level of risk is explicitly defined.

e. An inspectorate that is concerned with radiological exposures of workers gathers data from previous inspections and determines the frequency, intensity and focus of subsequent inspections at regulated facilities based on a combination of average dose, and the number of exceedances of the occupational exposure limits.

It is clear from the examples above that there is a diverse array of ways in which regulatory requirements may be argued to be appropriate. The existing regulatory scheme in most industries is inevitably a complex patchwork of past decisions where the linkage between the requirements and the level of risk that is associated with their presence or absence was either never known, or the documentation which might provide some evidence was not prepared or is no longer available to current decision-makers. As a result, large parts of regulatory systems are not risk-based, and cannot be made to be risk-based without considerable effort. It is not clear that a wholesale conversion to being risk-based is a good investment. Rather, organizations would benefit from analyzing and then determining where a risk-based approach could serve the public interest better, and allow for the fact that rule-based regulation may be adequate for large parts of its mandate.

However, it is important to note that some situations may be best addressed through traditional rule-based approaches, or a combination. Wiener (2010) outlines several additional regulatory approaches that do not conform to the principles of either rule-based (they do not enforce a general standard or criterion to manage a regulated risk) or risk-based (they do not base regulatory activity and decisions on knowledge of the level of risk). However, these approaches, when applied with risk assessment or an estimate of the degree or likelihood of harm, may be considered risk management strategies that could be applied within a risk-based approach. These approaches include:

- Hazard-based regulation (a ban or limit on a threat without respect to exposure)
- Strong version of the Precautionary Principle (prohibiting activities when there is a possibility of serious risk)
- Command-and-control ("best technology" or "as low as feasible" requirement)

Rules-based and risk-based approaches will inevitably and appropriately exist in parallel. As such, hybrid approaches of rule-based and risk-based regulation will naturally emerge in which one part (e.g., standard-setting) of the approach is risk-based and the other part of the approach (e.g., compliance and enforcement) is rule-based. As an example, consider a formal risk assessment that results in setting an exposure threshold value. In this case, the rule may be described as risk-based. The subsequent enforcement of the rule may treat all such rules uniformly, and apply or inspect for compliance with this rule equally in all facilities, at the same frequency, with equal consequences for non-compliance. This could be described as a risk-based rule, with rule-based compliance verification and enforcement. Conversely, a series of legacy rules that have been in place in various codes and standards that constrain industrial activity may lack a known risk-basis. In this case, the technical and operational arms of a regulatory agency could prioritize these rules on a *post hoc* basis and create a scoring system to judge the seriousness of non-compliance based on which rules are most closely linked to public risk. They can further use this score to increase or decrease the frequency of inspection of facilities. In this case, a set of rules-based requirements are enforced in a risk-based approach to operational decision-making.

II. Framework-Level Analytical Capabilities

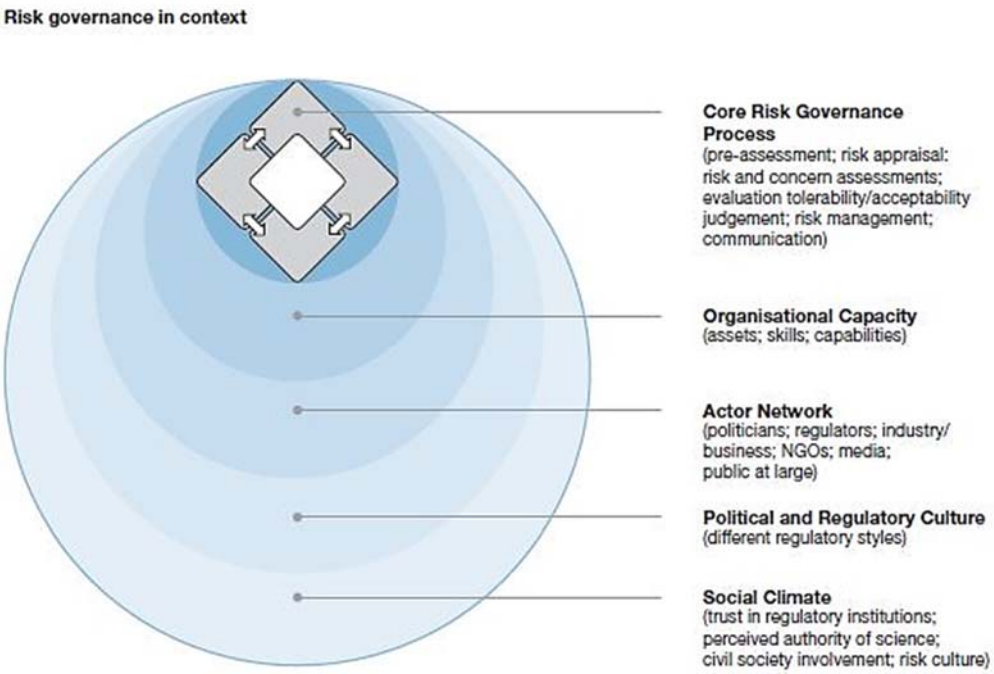
A. Analysis of societal risk governance arrangements

This level of analysis consists of a review and clarification of a regulator's societal and policy context, as well as the mandate and the provisions of the regulatory regime, which helps focus and shape the establishment of agency- and regime-specific policy frameworks.
The analyses that any given regulator will need to conduct will be shaped by its mandate and by the legislation and the specifics of the regulations that it is implementing. Many of these are shaped by the larger national constitutional, policy-making and risk governance structures and traditions in which the legislated mandate and regulatory regime are determined (Rothstein, Borraz and Huber, 2013). Other types are required of all regulation (or risk regulation), such as cost-benefit analysis, scientific analyses of risk, sometimes according to specified standards of a central agency of government.

In relation to risk-based regulation, because of the wide range of value and structural factors that are incorporated in risk management decisions, more explicit attention has been given to the broad context that shapes risk management. This perspective has been referred to as "risk governance," a term used by the International Risk Governance Council (IRGC, 2005), which defines the concept as follows (and represents it graphically in the Figure 1, below):

> Risk governance deals with the identification, assessment, management and communication of risks in a broad context. It includes the totality of actors, rules, conventions, processes and mechanisms and is concerned with how relevant risk information is collected, analysed and communicated, and how management decisions are taken. It applies the principles of good governance that include transparency, effectiveness and efficiency, accountability, strategic focus, sustainability, equity and fairness, respect for the rule of law and the need for the chosen solution to be politically and legally feasible as well as ethically and publicly acceptable (IRGC, 2005).

Figure 1: Risk Governance in Context



Source: IRGC (2005)

While this paper does not discuss the full range of aspects identified by the IRGC as part of risk governance, it is important for a risk-based regulator to be aware of the full scope of societal, political and legal factors that shape its regulatory mandate and the overall risk management activity.

B. Policy framework to support day-to-day risk-based analysis and decision-making

An explicit agency policy framework for regulatory decision-making should be set out to support case-by-case decision-making. This policy framework will consist of the broader policy objectives of the legislative and larger policy regime within which the regulatory regime is set, as well as a set of core policy elements, such as Risk Management Principles that are consistent with the given policy framework. Societal considerations will be incorporated at the operational level with concern and other types of assessments of the risk issues being managed.

The policy framework should include the development of the risk management principles that the organization recognizes as necessary to orient all regulatory decision-making to be consistent with the mandate and policy objectives of the organization. These may include principles such as beneficence, equity or fairness, transparency and public engagement, and proportionality, a key attribute that risk-based approaches are designed to achieve (see Jardine et al., 2003 for a review of the elements included in risk management frameworks, including a menu of principles for risk management).

Second, at the framework level, an analysis should be conducted of the agency's legal, political and ethical mission and orientation, providing clarity on the bearers of risks to which the agency has primary responsibility. An analysis is also done of the full range of risks associated with the system for which it has responsibility, locating those aspects for which it has responsibility among aspects for which other agencies or entities are responsible.

These analyses inform and guide agency actions at the operational level, and require an additional analysis of the specific responsibilities, powers and constraints set out in the legislation and regulations the agency implements. The agency should be aware of the analyses that it is required to conduct by law, including specific orders to which it is subject about the assessments and quality of information used in risk regulation. Such orders include, in the United States, the Principles for Risk Management, and the OMB Circular A-4, (OMB, 2003), which mandates a probabilistic analysis for assessments of regulatory agencies with costs exceeding a prescribed amount; and, in the EU, requirements for the use of benefit-cost analysis in regulatory analysis (Wiener, 2010). Many governments have established requirements for the analyses that an agency must carry out to justify the development and expectations of new regulations (such as the Canadian federal Cabinet Directive on Regulatory Management); there are also many inter-governmental and trade agreements that affect regulation in many sectors. Analysis of these essential requirements provides essential insight into the areas of its mandate that the agency will address through a rules-based approach and those in which it must, or may, use a risk-based approach.

C. Clarity in goals of risk reduction versus uncertainty reduction

Regulatory agencies serve several purposes that are inter-related. The expectations placed on regulatory agencies are to reduce the level of risk faced by the public, and to determine, with appropriate evidence, that the level of risk is as low as intended. To some extent, both of these goals can be satisfied with similar sets of activities.

1. Reduction of risk

The primary rationale justifying many regulatory activities is the reduction of risk to the public, expressed as the combination of severity and probability of adverse outcomes, while allowing for public benefit from various activities, products and services. The analytical challenge in supporting this rationale is to clearly define in qualitative and, ideally, quantitative terms exactly how (meaning a precise causal relationship) the presence and specific decisions and activities of the regulatory function intervene to reduce or otherwise constrain the level of public health risk. This is done explicitly in a risk-based regulatory approach to standard-setting and compliance verification.

Flexibility in resource allocation is a key and desirable attribute of risk-based regulation, and mobility of resources is important to enable risk-based allocation of regulatory resources as new risks emerge or regulatory priorities change. When attempting to re-allocate resources to maximize risk reduction, both sides of the re-allocation transaction (not only "to what" but "from where") require justification. The "to what" side of the transaction (addressing a current concern) may be easier to justify than the "from where" side. Both proving and publicly acknowledging that a regulatory activity is not having a significant impact are difficult. In addition, they can create conflict with a number of internal and external perspectives including those of some subset of the public, NGOs, unions representing workers involved in the activity, and other interested parties who disagree with the assessment that an activity or regulatory requirement can be foregone.

Many regulatory requirements have never been subject to this type of scrutiny, and may have no known causal relationship with public risk. Particularly in rule-based regimes, many requirements and activities are the result of the exercise of undocumented judgments in the past, or are embedded in codes and standards whose basis as a means of public risk reduction may never have been made explicit. As such, it is often difficult to justify their presence, but it may be equally difficult to justify their removal. The adoption of a risk-based compliance approach within a rule-based regime may be done through an expert elicitation of the risk and risk reduction basis inherent in each rule and the assignment of a risk score to the violation of each rule. These scores can serve as the basis for a risk-based inspection or other compliance verification function.

2. Reduction of uncertainty in the level of risks

Although related to the reduction of risk, there are many regulatory activities whose impact may be more accurately described as reducing uncertainty in the level of risk. This is an important distinction, requiring careful characterization of the purpose of the activity, and

requiring a different analytical process for justification and measurement of the performance of the activity. For many risks that are considered to be normally under control (or, of "low risk"), a regulatory activity or requirement such as monitoring or surveillance may serve as a means by which the level of public risk can be said to be known to be low. The activity allows for the potentially important distinction between "a low risk" (which may be asserted with no evidence) and "a risk that is known to be low" (presumably, to be followed by a statement of why it is known to be low).

For example, if a chemical is banned from the consumer marketplace from a prior regulatory action, the current regulatory activity may be to sample the products in the market to confirm that it is no longer being used. In this case, the risk reduction is provided by the prior regulatory action, and the industry actions to remove the chemical from consumer products. The current activity cannot be argued as a means to "reduce risk" since the risk is expected to be essentially zero. The distinction, while important, may not always be clear cut. In some cases, an activity may have both aspects of uncertainty reduction and risk reduction, such as when domestic products may be believed to be of negligible risk but it is still considered to be in the public interest to be able to provide evidence of the fact (allowing for public confidence), but imported products are of concern such that direct risk reduction (by testing and holding or recalling imported products) is a reasonably foreseeable impact of the surveillance process.

An additional example of regulatory activities that are largely focussed on reducing uncertainty is where a commercial activity is heavily self-regulated with numerous other organizations scrutinizing the activities for a variety of reasons (e.g., inspections by insurance providers, third-party certification schemes, audits by influential customers, and substantial industry self-interest in reputation and brand equity). In this case, it is difficult to argue that a regulatory authority is providing for risk reduction. Often, the term "oversight" is more appropriate, which equates to reducing uncertainty that poses a threat to public confidence. To the extent that substantive resources have been allocated away from this activity, some minimal surveillance may be desirable to prove that this reallocation was indeed a good decision.

Finally, providing information to the public on risks is a public good in itself. (Wiener, 2010: 139). This function requires surveillance, documentation and reporting practices. It supports individuals' strategies to maintain or control their own risks, provides transparency on the effectiveness of agency and broader government efforts to anticipate and manage risks to the public, and informs the work of other agencies, including other levels of government and sectoral or professional organizations that supply information and other supports to risk-reduction behaviour (such as public health organizations).

3. Allocating resources to risk reduction and uncertainty reduction

The distinction between these two public interest goals of reducing risks and gathering information to reduce uncertainty in knowledge of risk levels is important, for both (i) achieving low levels of risk and (ii) demonstrating that risks remain low. The justifications for activities and the associated allocation of resources should be clearly directed toward one or the other or, where appropriate, both of these ends. This requires the understanding that they are not simply two ways of describing the same thing.

While direct risk reduction is usually the primary goal, some level of uncertainty reduction through information gathering is likely to be an ongoing obligation of regulators. On the other hand, pressure to reduce uncertainty in a level of risk that is legitimately believed to be tolerably low may divert resources from the reduction of known higher risks thereby acting against the broader public's interest in the allocation of resources. The pressure to reduce uncertainty may come from past or present concerns expressed by the public or non-governmental agencies.

In addition to providing the basis for reducing uncertainty, or increasing confidence, the regulator itself is able to control its own risk (enterprise risk management) through activities that demonstrate that risk is low. The desire to control reputational risk in the regulator (and the political entities responsible for its performance) creates the potential for a conflict of interest between the regulator's interest, political interests and the public interest.

D. System-wide causal analysis and mapping

A regulator (or a set of regulators) controlling risks to the public interest must, at various intervals, systematically assess the entire system that contributes to the level of risk to which the public is exposed. This exercise can be part of a scanning or surveillance function (depending on the specific risk management context), in which the agency will identify emerging risks that are within its mandate as well as those that arise elsewhere but that could affect its risk management responsibilities. The exercise can contribute to the prioritization of the risks for which the agency is responsible and the allocation of resources across those risks.
Consider the example of a pipeline having the potential for causing both public and environmental harms. The overall system includes many elements, a few of which are listed below:

- the design and manufacture of the pipeline components
- the design of the pipeline system
- the reliability of any infrastructure that it relies upon (electricity, etc.)
- the siting of facilities and the routing of the pipeline
- the current and future land use around the pipeline
- the standard operating procedures for the pipeline
- the emergency response management capabilities of the operator and the local emergency response capacity along the pipeline route
- the required training and certification of designers and operators
- codes and standards that govern each of these components
- the competence and integrity of the standards development organizations whose products are being actively or passively relied upon by the regulatory system
- the level of compliance with standards and regulations
- the financial condition of the pipeline operating business
- the cost of various risk mitigating investments and the incentives and disincentives in applying them
- the current and future climate and other natural hazards

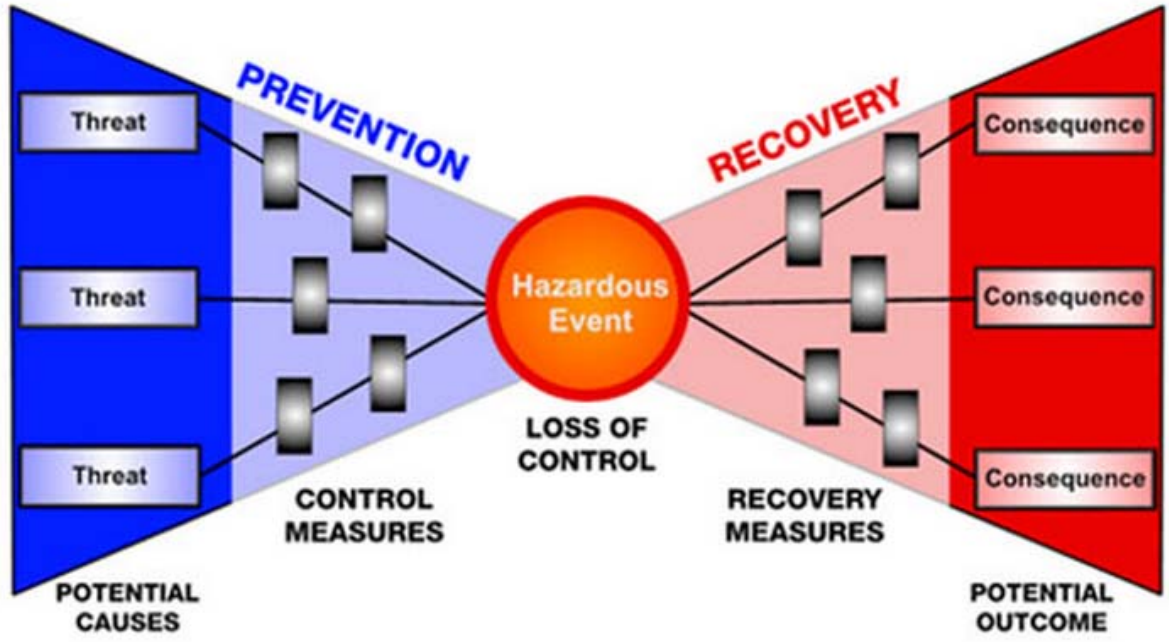
- the likelihood and severity of accidents (ruptures due to corrosion, landslides, unauthorized digging)
- the role and impact of regulatory inspection
- capacity to conduct and learn from accident investigations
- impact of other overseeing external organizations such as insurers, other levels of government, third-party certification
- the properties of the materials transmitted by the pipeline and their potential adverse effects on people, property and the environment.

One of a regulator's key analytical roles is to arrive at a professionally and scientifically defensible position as to whether or not the pipeline, in light of the totality of vulnerabilities in the safety system, is operating or will operate safely (i.e., within a tolerable level of risk). When considering the number of points of potential failure in a system as complex as the 50-year operating life of a pipeline system, and the diverse and highly variable consequences of these failures, this requires a considerable capacity for systematic and integrated information collection, interpretation, prediction, and documentation of a complex inter-related system. An analogous argument based in system complexity can be made about the risks posed by many regulated products and services such as processed food, pharmaceuticals and medical devices, chemical manufacturing, consumer products, modes of transportation, or financial services. Any claim that such a product or service is "safe" implicitly or explicitly relies on a judgment regarding the overall integrity of a very complex causal network (more complex than the simplified elements of the pipeline system described above).

Once the pipeline regulator has arrived at the determination that a pipeline system is "capable" of being operated safely, the regulator has the continuing task of allocating regulatory resources to ongoing risk reduction (i.e., detecting and correcting non-compliant system components) and oversight of risk control (i.e., sufficient observation of the elements of the system to justify, with adequate confidence, a conclusion of continuing safe operation of the system). Given the variety in the system components there are numerous locations and opportunities within the system to intervene or to observe. The regulator must choose a few, among a large number of available options, of the potential means to reduce risk by detecting non-compliance. In addition, the regulator must choose a few, among a large number of options, of the means and locations of observing the system elements to provide sufficient information to allow the inference of a tolerable level of risk. These choices are critical, are very complex if considered fully, and are frequently under-estimated analytical challenges.

Two of the challenges associated with developing and maintaining a complete causal characterization are information management and visualization of the entirety of the risk generating and protective systems. There are aspects of the problem that are sufficiently generic that regulators can adopt best practices from industrial sectors that are very different from their own. An example of such a tool that helps with both causal system characterization as well as visualization is the development of bowtie diagrams (Figure 2).

Figure 2: A Generic Bowtie Diagram Illustrating a Causal System



Note: This diagram (from left-to-right) documents various hazards or threats and the variety of control measures (pre-event and post-event) that can limit the level of risk. Excerpted from Bowtie XP software documentation (CGE, 2015).

Many regulatory organizations are under-served by information technology with respect to their core mandate due to the competing demands for information technology projects which will span the organization's needs (e.g., finance, human resources). A dedicated scientific/technical computing capacity focussed on enabling and informing the external public risk mandate is required, to avoid hampering the organizational capacity to do its most important function. To paraphrase frustrations we have had heard from regulatory officials: "With my new IT systems, I can very easily book travel to conduct an inspection, and have it approved at four levels of management. However, I can't get access to the results of the last inspection, or basic data on what the facility produces. I can travel there with administrative efficiently, but I can't get any information to inform what I should do when I get there."

E. Risk communication

Risk communication, though it is appears to be a work product, also has a clear role as an analytical task of a regulator. Risk communication can be necessary to prepare risk information for decision-makers (Thompson and Bloom, 2000; Bier, 2001, Fischhoff, 2012), to support participatory decision approaches, to help determine tolerable risk levels, or to provide accurate and authoritative information in the event of an emergency.

Risk communication is an exchange of information about risks that takes place between interested parties, generally including experts, stakeholders and the general public (Renn, 1992). It is meant primarily to enhance the audience's understanding of a technical or complex matter, so that they may make a more informed decision on a matter involving a risk. It combines an understanding of the perceptions, concerns and values that underlie an audience's perspective on a risk with a presentation of technical information that considers the audience's information needs. Risk communication may be informational, providing information to support audience decision-making; or persuasive, intending to influence the decision made by those in the target audience (Fischhoff et al., 2011). Risk communication is not public relations or advertising, and regulators should carefully evaluate their goals for communicating with the public or stakeholders. Persuasive risk communication is appropriate in public health settings in which the goals is to encourage healthier or safer behaviour (such as smoking cessation, or promotion of healthy diet or exercise habits); it should not be attempted in highly politicized or contentious context, where it is likely to be unsuccessful or even counterproductive.

Risk communication involves activity at both the system level, on which policies and guidelines are developed, and the operational level on which a particular risk issue is managed. At the system level a regulator needs to be aware of the types of risk situations and contexts on which it expects to communicate, and of the audience or audiences that may be targeted, their relationship with the risk source and their information needs and comprehension levels. A regulator may also need to develop expectations for regulated parties' conduct of risk communication with their own clients or customers, as a condition of permit or licence approval and compliance.

Several key analyses are important to inform and support risk communication.

- Understanding the audience to which the communication is targeted. This includes their need for the information, level of interest and levels of comprehension of the type of information to be presented.
- Understanding perceptions of the risk involved and of broader values and attitudes that shape those perceptions. Most societal attitudes to risks are shaped by broader value and attitude frameworks that are highly stable and persistent, and not easily altered through new information. Risk communication therefore needs to take account of the effect the information can, and should be, expected to have on the audience's understanding of the risk situation, providing information where that is needed by the audience and taking care to respect broader values where those are relevant.

Risk communication can be an important means of managing a **risk issue**. A risk issue is a risk matter that has the potential to become a serious social concern, often disproportionate to assessed risk levels (Leiss, 2001; Breakwell and Barnett et al., 2001). It may incorporate into information about a risk an acknowledgement of contextual factors such as elevated social concern, ethical considerations or other controversies that can shift a risk into a public risk issue. In these situations risk communication may be interactive, attending and responding to concerns and priorities expressed by those participating in the risk issue.

A large amount of guidance has been written for risk communication, in addition to a large literature on concepts, perceptual and cognitive processes that underlie communication processes, ethical considerations, and the influence of politics and values on risk communications. Some guidance describes general principles (for example, NRC, 1989; Morgan et al., 2002; Leiss, 2004; Aven and Renn, 2010; Kasperson, 2012; Frewer, 2004). Other literature addresses risk communication in a wide range of applications, including some that stand as disciplines on their own (such as medical decision-making); only a few can be mentioned here. Guidance on risk communication includes; for example, in regulatory settings (NRC, 1989; Fischhoff et al., 2011; ILGRA, RRAC, 2009; EPA Superfund; Bouder and Lofstedt, 2010); with respect to particular regulatory domains (OECD, 2002, on chemicals; Larson et al, on vaccines; Ferguson et al., 2002, on workplace communication; Frewer, 2004, and EFSA, 2012, on food safety; EDCD, 2013 on communicable diseases; and Falhlquist et al., 2015, on nuclear energy). In addition there are guidelines for risk communication in certain contexts, such as situations of uncertainty (Fischhoff and Davis 2014; Peterson et al., 2013); communication of science and probabilities (Bruine de Bruin and Bostrom, 2013; Fischhoff, 2013; Visschers et al., 2009); and risk communication in politicized environments (Scheufele, 2014; Lupia, 2103).

F. Risk perception

The term "risk perception" was coined to describe perspectives held by non-experts, or members of the public, whose attitudes about many types of risks are consistently seen to differ from risks as assessed by technical experts. A field of research developed from the 1970s that took as a starting point the assumption that non-experts based perceptions of risk on emotional responses to risk sources and misunderstanding of statistical probabilities, in contrast to experts whose judgments incorporated a more technically accurate understanding of the risk. More recent research, however, has shown that while some risk perception factors remain relevant (to experts as well as non-experts), people make multi-dimensional risk judgments based on previous knowledge and attitudes, including social and personal values as they relate to the risk situation. Initial risk perceptions become more considered risk judgments as individuals bring their attitudes, values and priorities to bear on the risk and the context in which it appears. These will be specific to the individual and the risk source: technical specialists may pay particular attention to quantitative probabilities of a risk event, for example, while others may be more concerned with values associated with the activity that produces the risk.

A number of key factors have been found to be influential in the formation of risk judgments. Certain types of risk sources are known to be considered higher risks, such as those that are involuntary, unobservable, that affect children or future generations, or that result in catastrophic events or outcomes of particular concern (such as cancer). People will often consider a technological risk to be greater than a risk from nature, typically rating chemicals and industrial technologies and products to be higher risk than many natural events, or substances, even when these pose a greater threat to safety or health (Tversky and Kahneman, 1974; Slovic 1992).

People construct comprehensive judgments or "framings" of activities in to which "risk perception" factors are integrated, to arrive at an overall "risk-dominated" or "benefit-dominated" perspective on an activity or other risk agent (Alhakami and Slovic, 1994). When

people focus on the benefits of an activity they tend to downplay the risks; in contrast, when people do not have the personal experience with the benefits of an activity and perceive themselves to be susceptible to imposed risks, they are likely to frame that activity as a risk (Leiss, 1989; Leiss and Chociolko, 1996).

It has been found numerous times that people's risk judgments are influenced by their broader social and political attitudes and values, and that these are stable and do not shift with new information. For example, people's beliefs about and values for nature influence the risks they will perceive in technology. Those who hold "ecological" values are more likely to consider technology to be a risk (Axelrod, et al., 1999). This principle applies to experts' risk judgments as well as non-experts'.

Recently researchers have focussed on the role of trust in risk judgments, and have found that disapproval of major technologies that are considered to be high risks is associated with a lack of trust in those who manage the technology, including industry and government and regulators (Siegrist et al. 2000).

Risk judgments are contextual, value-based perspectives on a risk, which in many cases amount to political judgments of the important aspects of technology, the benefits of the activity and their distribution, and the adequacy of the management of the activity and its risks. Members of the public are "less concerned with making choices about which risks they are willing to tolerate than they are with grasping which political interests lie behind the promotion of particular choices" (Priest et al., 2013).

G. Risk tolerability

Risk tolerability is a concept that is particularly important for regulators. A tolerable risk is generally defined as one that is worth taking in return for the benefits provided by the activity (or product), but that requires efforts to reduce the risk to a reasonable level (Ely et al., 2009; Renn, 2008; HSE, 2001). This is distinct from an acceptable risk, or one that is low enough that no further risk reduction is necessary. A regulator will usually be concerned with social tolerability, a judgment that includes a consideration of the societal risks and benefits, and their balance and distribution, as well as legal and policy requirements, ethical considerations and economic constraints. This judgment will include consideration of public concerns and management preferences, but is broader than these preferences.

A key strategic policy determination that should be made is the level of risk that should be achieved through regulatory action, considered both in terms of the level of risk to the public that is to be achieved – often determined as a system standard as well as for specific instances- and the degree of risk reduction that is required, in terms of justification of risk by benefits and, cost-effectiveness standards. As Black (2010) notes, the risk regulatory framework for risk-based decision-making should also include consideration of the levels of risk to the public that will serve as triggers for regulation and guidelines for the extent of risk management that is required. Perhaps most importantly in a risk-based framework, the agency needs to establish risk tolerance levels and make these explicit, particularly the level of risk that is low enough that it does not plan to expend resources for further reduction (Black, 2010).

A fundamental requirement is to establish guideline criteria for risk levels associated with key regulatory responses and actions, primarily a low level at which regulatory action may be minimal, and a high level at which regulatory action is required – including a prohibition of regulated activity that results in this level of risk. Further discrimination and determination of appropriate action for risks that fall between these lower and upper thresholds requires the establishment of decision-making principles and criteria, (Hansson, 2003; HSE, 2001; Vanem, 2012; Marszal, 2001) as well as decision-making support tools and processes.

Developing a tolerable risk policy requires several more system-level analyses, including criteria for assessing risks and benefits, economic analyses such as cost-benefit and cost-effectiveness analyses, and analyses of ethical and societal concern. The application of this analysis at the operational level incorporates the results of assessments of risk, benefits, cost and effectiveness, and ethics and social concern.

A well-known framework for determining risk tolerability evaluation applies the principle of ALARP (as low as reasonably practicable; HSE, 2001), and consists of a cost-benefit analysis of risks that fall in a "tolerable" zone between established acceptable (no risk reduction required) and intolerable (prohibited or permitted only in cases of high need, with strong risk control). In the application of this principle the determination of what is a "reasonably practicable" degree of risk reduction is the core challenge in assessing the tolerability of a risk, and in many cases rests on analyses of costs and benefits that increase the analytical burden on regulators. In the UK, the legal concept of the degree of sacrifice that is expected to reduce a risk sufficiently is based on a demonstration that efforts of further risk reduction would be "grossly disproportionate" to the benefits achieved by that risk reduction (HSE, http://www.hse.-gov.uk/risk/theory/alarpglance.htm). Cost-benefit analysis is required of regulators to establish tolerable risk levels, and the HSE provides guidance on conducting such analyses in this context (HSE, 2003).

A comparable principle that applies to occupational settings in the US is the "significant risk doctrine," which states that an employer is not required to provide an environment that is risk-free, but must eliminate "significant" risks as long as the cost of doing so does not "destroy the entire industry" (Majone, 2010). Majone (2010) notes that the application of this principle did not require cost-benefit analysis, though more quantitative analysis was required in the determination of a "significant" risk; however, CBA was essentially required in order for regulators to meet broader government requirements that regulators show that the potential benefits of a proposed regulation would outweigh its costs.

Several recent guidance documents offer guidance on making these determinations, including the IRGC (Renn, 2008), and the FAO (2006) as an example of a domain-specific guideline, related to food safety regulation. There are several guidelines on establishing quantitative tolerable risk levels for application in large industrial or infrastructure settings (Marszal, 2001; Trbojevic, 2004; Duijm, 2009) which do not consider social concerns as would be appropriate for decisions on individual risk issues.

H. Precaution

A regulatory agency may give special consideration to the development of guidelines for the determination of the conditions under which a precautionary approach should be taken. These considerations are important to risk regulators as many jurisdictions, including particularly the EU, have legal requirements that regulators apply a precautionary approach when there are indications of serious harm to human health or the environment (Ahtensuu and Sandin, 2012; Cusson, 2009).

Precaution is distinct from a more generic "cautionary" risk management approach, but beyond that it has been defined, interpreted and applied in many different ways. There are many reviews of the various versions of the principles and their application (see, for example, De Fur and Kaszuba, 2002; Sterling, 2007; Dineen, 2013). A precautionary approach may be considered to address high risk issues that appear to require urgent or significant management, but for which there is considerable uncertainty. The approach is thought to be most applicable when the usual standard for the adequacy of information for an evidence-based decision is not met, but due to the potential risk, a management decision cannot be delayed until that information is available. There is extensive debate on the interpretation, application and implications of the precautionary principle; the main considerations for regulators are noted here.

First, there are several definitions and many more interpretations of the precautionary principle. In essence, precaution involves the need to make a decision where there is the potential for serious or irreversible harm, but where the usual standard of scientific knowledge or evidence is lacking. Precaution has two very broad approaches: the "strong" approach holds that regulation (or risk management) is required when there is a possible risk, even when evidence is weak and costs of management may be high. The "weak" approach is that a lack of full scientific evidence does not preclude action in cases where damage could be serious and irreversible. Other variables in interpretation include accommodation to the different capacities of agencies (or jurisdictions) to apply risk management measures, and incorporation of cost-effectiveness or proportionality into the application of precaution.

This lack of consistent interpretation is compounded by what some claim is an intractable lack of clarity in certain key concepts, including uncertainty, and the scenarios of harm that should be considered to invoke the principle, to the extent that the principle is not really operational (Dovers and Handmer, 1995; Cussen, 2009; Sunstein, 2003).

Second, some argue that precaution, particularly in its strong form, stifles innovation by essentially prohibiting actions that are associated with any possibility of harm, and that this potential has been used by environmental groups and other NGOs to block development (Rogers, 2001). A related argument is that precaution is incompatible with science, by requiring decisions and actions without sound scientific evidence (Cusson, 2009). Others (Sterling, 2007; Hansen et al., 2008; Todt et al., 2014) argue that precaution is consistent with science and can support innovation.

Third, the application of precaution in any given regulatory instance is challenging. The decision to apply a precautionary approach may require careful policy guidance at the agency

level, as there are challenges and implications in its use. The use of strong precaution may lead to expectations of zero risk, with regulators expected to act to control any risk at any level (Wiedemann et al., 2010). The application of any version of precaution must address questions of the degree of uncertainty that is present, the potential for reducing that uncertainty, how much information is required to determine that damage could be serious or irreversible, and how much time should be allowed for gathering evidence before precautionary measures are implemented. In many cases precautionary measures may entail the application of a higher level of risk control – and thus greater costs - than more complete information, when it is available, may show to be necessary. However, when screening assessments or other available information suggest that the level of risk could be high and more complete information is not immediately forthcoming, it is deemed "better to be safe than sorry." There are many examples of major events or developments that have been portrayed as avoidable if action had been taken in time, described in two editions of "Late Lessons from Early Warnings" (Harremoës et al., 2001; EEA, 2013; see also Wilson, 2011, on the use of precaution in transfusion medicine in light of the HIV blood scandals of the 1980s).

To guide regulators on the application of precaution, researchers (e.g., Goklnay, 2002) and some governments have developed guidelines for the use of precaution by regulatory agencies. An example is the Government of Canada's *A Framework for the Application of Precaution in Science-Based Decision-Making about Risk (*Canada, 2003). Guidance on the application of precaution is often included in more general risk management guides (IRGC, 2015; Renn, 2008; Ahteensuu and Sandin, 2012).

Because a decision is made and risk control measures implemented on the basis of incomplete information, a precautionary measure is usually implemented for a short period, after which the situation is reviewed in light of more complete information.

I. Maintaining separation of public and enterprise risk management

Government regulation is a distinct function carried out for the social good, designed by parliaments or other representative legislative bodies, and its implementation is delegated to functional agencies that are accountable to legislators and ultimately to citizens for fulfilling that mandate. A network of legal powers and constraints and policy requirements, in addition to political and public accountability, reinforce this public interest orientation (Seiler, 2002). This means quite explicitly that regulators "are enforcing regulatory standards in order to achieve broad public policy objectives stated in their legislative mandates, and their decisions are expected to benefit the public at large. The sectors or companies in them may benefit as well, of course, but that is not the principal objective of the regulations" (Pal and Maxwell, 2004: 2). Public risk management is the management of a risk to the population or a significant portion of it, implying specific relationships:

- A public risk manager is accountable to manage risks borne by the public (or to a public good) resulting from activities in the sphere of concern. The specific hazards to be managed by the organization may be set out in legislation or other legal form.
- An additional layer of relationships is involved when the PR manager protects public from risks generated by an activity permitted and sanctioned by the government ->

regulation. The regulator manages the activity is such a way as to control the level of the risks that it poses to the public.

Many commentators have studied the shifting approach of risk regulation to enterprise risk management (ERM)-type management, recently articulated formally in ISO 31000, Risk Management – Principles and Guidelines. This is a broad approach to organizational risk management that is presented as generic to all types of organizations and as adaptable to a range of specific functions and activities; and still employs the business paradigm of enterprise risk management.

A number of researchers (Hood and Rothstein, 2000; Rothstein et al., 2006a; Rothstein et al., 2006b; Hutter, 2005; Bounds, 2010), argue that the application of business risk management to public sector risk regulation can have adverse results for the quality of regulation. Bounds (2010) summarizes the different orientations and strategic objectives of private and public organizations as they predispose each organization to a different risk management approach. Business risk management is concerned with "the profit centre of the organization; improvement to shareholder value; and to provide decision tools linked to corporate strategy" (Bounds, 2010: 27; see also Hood and Rothstein, 2002). Bounds states that "there is no easy equivalent found in government for these features of business risk management."

There are fundamental differences between the objectives and approaches of government and private sector risk management (Hood and Rothstein, 2000; Bounds, 2010):

- In the private sector, risk management focuses on maintaining and enhancing profitability in a single agency, whereas in the public sector it is on the delivery of public value, "the implementation of objectives and services to the citizen." This is ultimately based an assessment of what the public wants.
- Private sector risk identification and management paradigms are linked to risks to business objectives; in public sector risk management, in contrast, planning and key decision processes are oriented towards protecting external risk bearers.
- In the private sector risk assessment focuses on the possible adverse effects of a risk on the organization itself, to business value as perceived by shareholders and financial markets; in the public sector "risk is more about systemic risks of failure to deliver services to citizens."

Decision tools are different in public risk management, requiring a multi-organizational approach, and are subject to scrutiny and requirements of transparency and accountability, not often found or not nearly to the same extent in private risk management.
The adoption of a Canadian implementation guide for ISO 31000 (CAN CSA Q31001-11 4.6) acknowledges the distinct role, mandate and accountabilities of the public risk regulator, in a separate clause that was added to the guidelines document:

> These organizations can require a multi-organizational framework and process for managing these types of risks. They must recognize the distinct risk management contexts and the interrelationships in which they operate.

> The distinct risk management contexts and interrelationships should be clearly identified as key governance components for the organization in order to ensure that the potential conflicts between its mandated public risk objectives and its internal objectives are recognized and addressed. The organization can be required to implement or might choose different risk management processes for its mandated public risk objectives and its internal objectives. In such circumstances, the organizations should also ensure that these processes are appropriately aligned. (CAN CSA Q31001-11 4.6)

Adoption by regulatory agencies of risk-based regulation can overlap with an ERM style of risk management as agencies position themselves through a risk-based approach to avoid blame and prevent reputational risks to the organization. In order to ensure that a public regulator's focus remains squarely on the protection of the public (or other public goods) as it adopts risk-based regulation, it is important that the agency devote explicit attention to clarifying the bearers of risk to which it owes its primary focus. The range of potential risk bearers include:

Societal Risk (Risk borne by the Public)
The public is exposed to risk from diverse sources with diverse sets of outcomes. These are the risks to the public or the public good (environment, economy, values) that government is expected to manage, where deemed appropriate by legislators, on behalf of society.

Institutional Risk (Borne by the Organization)
A regulatory agency is also exposed to risk from diverse sources with a diverse set of outcomes. Many of these risks are generic in nature, some would be shared only by organizations of similar size, and some would be shared only by an organization with similar types of operations or assets. A key point is that some of these risks are common to all organizations and have no relationship to whether or not the organization has a societal risk protection mandate. Risks related to financial controls, workplace safety, information security, human resources, vehicles and assets, intellectual property are examples of common institutional risks that are common to many types of organizations.

Societal-to-Institutional Risk (borne by the Organization due to Public Risk)
This category of risk is an important subset of the risks borne by the institution. Societal-to-institutional risk implies the impact of any process of translation of societal outcomes into institutional outcomes. This could range from simply "bad press" to a critical loss of trust in the organization and the removal or reassignment of its mandate, as might be recommended at a public inquiry following an unacceptable societal risk event. It may also be termed "Regulatory Performance Risk."

Institutional-to-Societal Risk (borne by the Public)
This category of risk is a subset of the overall risk borne by the public. It is derived from the many roles that the regulatory organization may play in protecting the public and the fact that the organization's capacity to effectively

play these roles is related to the level of risk that the public bears. These risks result from an agency's failure or inability to manage risks to the public, or misallocating resources so that a risk to the public is not adequately managed. These failures can be acute (failing to detect an improper design in a technological system and issuing a permit allowing it to proceed) or chronic (inspectors who are not capable of judging the safety of what they are inspecting due to inadequate training or inadequate powers to compel required information).

This sub-domain of risk assessment is likely to be the most challenging for a regulatory agency to address explicitly. In essence, this risk is based in the notion that the agency "can't have it both ways." It can't justify its existence by asserting that it is protecting the public when it acts effectively (most of the time), if it not also actively admitting and assessing the extent to which it exposes the public to risk when it doesn't.

III. Operational priority-setting

It is difficult to argue that any analytical capacity of a risk regulatory agency is more important than the ability to set priorities to address public risks. Every other aspect of regulatory activity is governed by the overall and then finer-resolution priority assignments of the organization. It is also the area in which the agency might be most carefully scrutinized with respect to resource expenditures both internally and through program evaluation and in a "value-for-money" audit, especially for organizations with large numbers of field personnel such as inspectors.

Risk prioritization is a process where scientific, managerial and communication issues overlap. In some regulatory domains, the term risk analysis is used to collectively refer to the activities of risk assessment, risk management and risk communication. In this context, risk-based priority-setting has been referred to as the fourth pillar of risk analysis (Davies, 1996). As practiced, priority-setting may be appropriately described as the intersection point of the other risk analysis functions given the aspects of technical assessment, decision-making, communication and consultation.

Development and application of robust risk prioritization schemes require multiples tradeoffs. An example of such a trade-off is the need to balance technical and scientific robustness with the need for reasonable simplifications to reduce the resource burden associated with the prioritization process, and to accommodate uncertainty and missing information. In addition, the convergence of scientific issues (lack of data, theoretical uncertainty, variability in practices and effects) and managerial issues (feasibility of interventions, cost, fairness, expected levels of compliance, etc.) increases the complexity considerably. Given the complexity, there is a need for an intensive early design phase where a number of critical decisions are made.

A. Overview of comparative risk assessment

Comparative risk assessment (CRA) is also termed risk ranking and risk-based priority-setting. It can be done in a relatively limited context by comparing two or more alternate approaches to achieving the same goal (e.g., comparing two risk reduction strategies in a single

situation). Here, we consider comparative risk assessment in the broad context of government (and multi-stakeholder) priority-setting. This has also been called programmatic CRA, a process for setting regulatory and budgetary priorities involving comparison among a large number of risks. CRA has been referred to as the “fourth pillar” of risk analysis -- the other pillars being risk assessment, risk management and risk communication.

There is a fairly extensive literature on comparative risk assessment with a dominant focus on the combination of toxicological and radiological hazards and environmental media (air, water, soil, etc.). This literature is also heavily integrated with US agency and regulatory considerations, with particular focus on setting priorities for the US Environmental Protection Agency. A number of general recommendations have been made that have relevance to any risk ranking exercise. A selection of these general recommendations is provided below.

There are numerous choices available regarding the output of a risk ranking process. A fundamental distinction lies in ranking risks versus ranking risk reductions. It is often discussed that the goal of a ranking process is to distribute resources where they can optimally reduce risk. To rank risk reductions, information on risk levels both before and after a proposed reduction are required (and usually, in tandem with estimates of the cost and other considerations of the risk reduction). Given the perceived magnitude of this task, a less ambitious goal is usually chosen – to rank risks assuming current management and regulatory attention. However, several authors have noted the danger in this proposal for the surrogate activity of merely ranking risks:

> Setting priorities is more than simply ranking risks. As many have remarked … to set priorities means to guide where resources should flow; while the "biggest" problems may be mental priorities, they may bear no resemblance to functional priorities. Large risks may have no feasible, economical or politically acceptable means of control or prevention, while small risks may be eliminated through actions that carry a small or even a negative economic price. Therefore, even if none of the psychosocial and contextual dimensions of risk are to be included in the analyst's attempt at risk comparison, decision-makers and stakeholders need information on the costs and feasibilities of specific interventions to judge where resources should flow. These estimates may be as uncertain as the risk estimates are, and may add further complexity to the social process, but the alternative is either to rank the risks alone and have no guide for policy, or (perhaps worse) for decision makers to assume that the risk ranking equals the resource allocation. (Finkel, 1996)

Graham makes a series of similar points:

> From both technical and practical points of view, there are strong reasons for ranking risk-reduction options as well as ranking baseline risks. Concentrating resources on the largest risk may be unwise if little can be done to reduce it. If a 90% reduction can be made against the third-largest risk (C) and only a 10% reduction can be made against the largest risk (A), the overall risk reduction may be greater if extra resources are applied to risk C. (Graham, 1996, p. 98)

> Similarly, looking at the problem "risk by risk" conceals the promise of solutions that can reduce more than one risk. Even if risk A is the worst risk, it may be that an innovative policy option can reduce or even eliminate both the second- and third-worst risks (B and C). The resulting reduction may be more than can be achieved by even the best policy against risk A. (Graham, 1996, p. 98)

> Ranking decision options can also minimize disconcerting ambiguities about how risk should be aggregated for purposes of ranking baseline risks. For example, should the ubiquitous "criteria" air pollutants and "hazardous" air pollutants be ranked separately or ranked under the general heading "air pollution"? This is a salient yet intractable question for risk rankers but poses no ambiguity when decision options are ranked. If an option reduces both types of pollution, the resulting risk reductions are summed (absent interactions). An option that only reduces air pollution is given no credit for reducing criteria air pollution. (Graham, 1996, p. 98)

Another concern is raised where significant stakeholder input is received in the ranking process. An exhaustive effort to rank risks may generate the expectation that this ranking of risks will match the prioritization of risk reduction activities. For the reasons noted above, there is every reason for these lists not to be the same, but this may lead to accusations that stakeholder input was essentially ignored. The outcome may be the opposite of the desired consultation outcome, by breeding distrust in the meaningfulness of participation in consultations.

The foregoing discussion has presumed that the process will result in a strict ordering of either risks, or better, risk reductions. However, this need not be the preferred output of all such activities. Some commentators have argued that the format of the final output of a CRA can be a very important determinant in the initial willingness and support for the process (Wernick, 1996). For environmental health risks, Wernick advocated the concept of a Community Risk Profile (CRP) for environmental health decision-making. It is defined as:

> a resource, continuously updated with new data that makes conveniently available to a range of users the spectrum of information that characterizes the environmental and health status of a community.

The CRP as a general concept is intended as both the information resource and the process that maintains it. The authors stress that a key difference between a CRP and a CRA, is that a CRP is not intended to rank risks. The purpose is to provide an information system that serves as a continuous decision support tool for decisions on environment and health. By stopping short of ranking risks, the CRP is designed to be a non-adversarial process (i.e., to be a process that does not itself seek to identify "winners" and "losers") and one which is continuous, as opposed to a "rare spectacle to crown the champion of risks" (Wernick, 1996). This approach may be preferred in cases where there is considerable suspicion as to the goals of the process, and where consultative processes have historically been fraught with tension and mistrust. It also avoids the problem raised above, where a consensus on ranking of risks can handcuff the agency in attempts to later rank risk reductions based on cost-effectiveness and other measures.

The absence of a formal ranking scheme (for instance, in developing a resource for risk management analogous to a CRP) may be too limited where the promised end product is a priority-setting process, but the fundamental concept may be useful even within a formal ranking scheme. The pursuit of an "information resource, continuously updated" may be the core activity of the ranking process, with individual "spin-off" processes developed for specific priority-setting contexts, each based on this information resource. The key consideration here is whether the information is intended to be used in multiple ranking processes over time, perhaps with shifting foci as decision-making priorities and other contexts change.

B. Priority-setting by quantitative methods versus expert-based processes

A key question within the design of priority-setting systems is the extent to which they are driven by a quantitative analysis (e.g., maximizing incremental cost-effectiveness) or some other form of formal logic (scoring schemes) in reaching conclusions as to the final priority of agency activities. The alternative is to present the available information on a periodic basis to committees of internal and external experts and allow a largely deliberative process to determine the agency priorities. Formal decision-analytic approaches may deal better with certain aspects of the priority-setting challenge while having certain vulnerabilities, such as inability to cope with incomplete or uncertain information. Similarly, a group of experts may have considerable knowledge that is not readily available to the formal systems, but have their own vulnerabilities in reaching conclusions in a reliable, defensible and repeatable way. Hybrid approaches would naturally apply, where experts serve to input parameters into the quantitative scheme, help to shape its logic, review its output and validate the results.

Many current approaches to comparative risk assessment (Florig et al., 2001, Morgan et al., 2001, Willis et al., 2004, Linkov et al., 2006) and colleagues are of this hybrid nature and may be appropriate for the more challenging applications of priority-setting such as those situations that involve both uncertainty and value-based tradeoffs, as they were designed with such challenges in mind. A key component of these approaches by Florig and colleagues is the parallel use of both quantitative and expert-consensus based approaches to ranking risks. Quantitative (including both scoring-based and rule-based) schemes are assumed to provide a more objective treatment of the evidence, and provide a degree of transparency in the conclusions of the process by having a direct and consistent link between evidence and conclusions. Expert-consensus based approaches allow for more complete consideration of aspects of the evidence base that involve difficult and unquantifiable evaluations involving conflicting value judgments and substantial uncertainty. The expert-consensus method can be augmented by the preparation of a structured summary document containing the evidence for all alternative priorities, including some narrative discussion and the quantitative inputs that are used in the quantitative approach, while remaining silent on the final rankings. These parallel approaches can then be merged to consider the differences in the rankings from each processes and to determine a final ranking based on consideration of the two parallel methods of ranking, by adjusting one ranking result in light of what was learned in the parallel approach.

C. The role of public participation in priority-setting

The role of the public and stakeholders in organizational priority-setting for public risks has been discussed and hotly debated in the literature for decades. The pros and cons of including and substantially relying on public input into priority-setting continues as a central theme in addressing regulatory priority-setting particularly as it relates to intensive debates about the priorities of the US Environmental Protection Agency (Finkel and Golding, 1995; Davies, 1996). While there are strong arguments to be made about including and consulting the public from one side of the debate, there is equal and opposite concern for substantial distortions of the priority-setting to address risks that may be assessed by technical specialists as being associated with much lower risk than other priorities. The obligation to consult and listen to the public is countered by the ethical obligation to treat the most serious risks first. By analogy, a doctor must listen to the patient's complaints and priorities for action, but must also consider the best interests of the patient when faced with serious risks, and these priorities may not align with the patient's priorities. Regulatory agencies are in a similar position in having unique expertise and information which points to priorities which may not be shared by the public, but that the agency may legitimately believe to be in the public interest, and might serve what they see as a higher end (substantial public health risk reduction, versus public satisfaction with the agency's responsiveness to concerns).

Renn (2008: 43) reflects the increasing expectation that the conduct of risk management will include participation of members of the public and stakeholders; he states that the emphasis of the IRGC on risk governance underlines "the importance that IRGC places on the inclusion of stakeholders and public groups within the risk handling process, and consequently, on the establishment of adequate public-private partnerships and participatory processes." It is common for government policy to encourage or require that regulatory decision-making be transparent and participatory (Amendola, 2001). An excerpt from the UK guidance for managing risk to the public points to the intent to include substantial public input as well as the need to accommodate and explain eventual conflicting interpretations.

> Government will actively involve significant stakeholders, including members of the public, throughout the risk identification, assessment and management process. This will support timely and targeted action. Two-way communication will be used in all stages of policy development, risk assessment and risk management. Where there are differences in interpretation it will aim to clarify these through open discussion, and it will seek to balance conflicting views in a way that best serves the wider public interest. It will explain how views obtained through consultation have been reflected in its decisions. (UK HM Treasury, 2005).

In risk-based approaches, particularly in political environments in which transparency and participation are expectations of government activities, stakeholder consultation and public participation are an important component of a regulatory agency's competencies. In some regulatory settings, stakeholders, including representatives of the regulated industry or associations of affected communities, may participate in working groups monitoring regulatory performance or be consulted as regulatory decisions are considered or revisions are designed.

Involvement of the wider public is by necessity less direct and participatory, and may be conducted through invitations to review and comment on proposed measures, or information sessions on a decision affecting a specific community.

Agencies that attempt to reflect public preferences and address public concerns in establishing risk levels, in such processes as risk tolerability evaluations, will need to consult with stakeholders or members of the public either periodically or as certain decisions are considered. Concerns or priorities expressed in early participation processes may be incorporated into an entire risk management decision-making process, ensuring that critical issues are addressed in the decision (Amendola, 2001). This is particularly important in decisions on risk issues characterized as ambiguous, in which the meaning of the issues is contested, and that may require ethical or moral judgments in addition to scientific assessment.

Two aspects of participatory methods are the process by which consultation is carried out (for which there is ample guidance) and guidance on the way in which public concerns, or feedback from participatory or consultative processes, are integrated into decisions on risk regulation. Here the interest is in the latter consideration, as it pertains more directly to regulatory analyses. It is important to plan the issues on which the public will be invited to contribute comments, both to ensure that contributors that their comments are relevant and useful, and also so that the information that is most useful for the ultimate decision is elicited. A social concern assessment, one type of assessment that may be conducted for a risk issue that may involve high levels of public concern, may use participatory processes as one means of gathering information.

A more challenging analysis is that of incorporating public preferences in a decision. With respect to risk tolerability, one evaluation that includes public concerns and risk management preferences, it is important to be aware that the agency is responsible for risk tolerability, which is a system-wide consideration of risks, costs, and benefits, in relation to other regulatory risks and obligations as well as to public preferences. Public preferences are among a range of considerations incorporated into a decision, and should be balanced appropriately with other information and factors. The UK Health and Safety Executive has prepared guidance on taking account of public concerns in making risk decisions (Adams and Thompson, 2002).

D. Selected tradeoffs in the design of priority-setting schemes

Alongside the role of algorithms, experts and public input into the priority-setting scheme, a set of broad considerations need to be part of the design of a priority-setting scheme. There is considerable conflict in trying to meet all of these objectives (with budget and time constraints being the greatest conflict). A major question is the extent to which the scheme will be a permanent part of the organization's decision-making infrastructure. It will be difficult to defend the effort to "get it right" unless the long-term focus is maintained.

Table 1: Design of Priority-Setting Scheme

Design Element	Extremes	
Ranking Element	Cost-effectiveness of risk reduction	Broad Risk Categories
Primary Objective	Major Re-organization	Information System for General Support
Flexibility	Fixed, highly repeatable	Subject to change over time
Time Available	Months	Years to a Decade
Iterative Nature	One-Time	Ongoing, Continuous
Depth of Analysis	Risk categories	Detailed assessment of relative cost-effectiveness at different levels of resource intensity
Attribute Types	Strictly measurable and tangible	Holistic, broad
Number of Dimensions	Few	Many, Hierarchical
Level of Reporting	High-level overview	Detailed reporting out of assumptions, inputs, auditable

E. Risk scanning or surveillance

An important aspect of priority-setting is the ability to detect new issues in a timely fashion. Most regulators will need to have a process for monitoring the environment and detecting and interpreting signals that indicate a change in a risk for which they are responsible. For some regulators this will include a regular surveillance function that consists of, for example, monitoring reports of infectious disease incidences, or the emergence of an unfamiliar disease, and a process for determining the point at which an intervention is required. Other regulators, such as those with relatively stable risk portfolios, will instead need a process to monitor the performance of approved products and evaluate reports of unexpected risks, or identify changes in the regulatory context such as changing risk evaluations, evolving concerns or changing expectations for risk control (IRGC, 2015).

IV. Key Capabilities in Risk Assessment

The common steps in risk assessment are described by different names across public risk domains. However, all must consider similar concepts. The individual steps and associated capabilities are discussed in detail below.

A. Candidate Principles to Guide the Conduct of Risk Assessment

The practice of risk assessment is guided by a common set of principles which regulatory agencies often have in common. Regulatory agencies may wish to adopt specific versions of the principles described below with sufficient detail to set concrete expectations for the quality of analysis to be achieved (including tiers of quality to respect the first principle of proportionality).

The specific context in which the risk assessment is conducted will govern which principles are likely to dominate the choices made in conducting a given risk assessment. For example, statutory timelines or emerging hazards may dictate the importance of timeliness, the resources available for public, expert or stakeholder consultation may impact the quality and breadth of evidence available, and the nature of the scientific questions may impact the importance of considerations of variability and the degree of characterization of uncertainty.

Table 2: Candidate Risk Assessment Principles

Proportionality in Level of Effort	The scope, depth and rigour of risk assessments are expected to be proportional to the apparent level of impact of the risk. The level of impact can be assessed based on a variety of factors such as the severity of the harm, the vulnerability of the populations involved, estimates of costs associated with the available decision options, and other social or political considerations that help to determine potential impacts at stake in the decision being supported. The level of impact of the risk, or of the decision options under consideration, may not be known at the onset of the assessment. Through effective use of tiered assessments, the amount of effort applied to risk assessments can be adjusted.
Timeliness	The timeline for a risk assessment should be established in consultation with the associated decision-making to ensure that the risk assessment context is clear and realistic expectations are maintained.
Evidence-based	Risk assessments are based on the rigorous evaluation of available and timely information. The risk assessment process should use established methods in collecting and scrutinizing evidence. Particularly important in risk assessment are the methods for combining evidence to reach conclusions. To enhance quality, peer consultation and peer review are important mechanisms that can be critical to the achievement of a complete and balanced assessment.
Transparency	Information on the objectives, evidence, the process and the conclusions of a risk assessment should be made available to stakeholders and the interested public, subject to valid information security constraints.
Explores Variability	A key component of risk assessment lies in the methods for systematically considering the frequency and impact of the many possible combinations of multiple sources of variability in biological, engineered and human systems.
Characterizes Uncertainty	To ensure a balanced and complete characterization of risks, both the sources and the impact of uncertainty should be described to the decision-maker. The type, source, degree and significance of uncertainty are stated with particular attention to their potential impact on the conclusions of the assessment, and on the evaluation of any specific decision-making options under consideration.

B. Problem Formulation

Recent guidance (NRC, 2009) and best practices in various fields of risk assessment have increasingly recognized the importance of the formative stage of a risk assessment. This stage has become known as problem formulation in some fields, but may be given a variety of other names. This stage requires appropriate communication between the risk management function and the risk assessment function. It is also important that the risk assessment be structured to estimate the potential risk reduction associated with any decision options of interest to the risk manager.

Problem formulation involves characterizing the hazard or risk issue in the broader context of social, economic, political, or other factors that are relevant to the issue and the decision. This context should be described, with attention given to the elements that are determined to be within and outside of the scope of the risk assessment. For a variety of reasons, risk assessments will often address a more limited scope than the overall scope of the problem that might be discussed in the problem formulation stage. This may be due to the availability of information or knowledge of particular pathways of exposure, limitations related to the jurisdictional authority of the regulator, or a variety of other reasons. The limitations to the scope and their rationale should be clearly described in the risk assessment products. This helps to ensure that any limitations in the scope of the analysis are not misunderstood, particularly to avoid the implication that elements that are not within the scope are considered to be of negligible importance.

As part of an iterative process of decision-support, risk assessors should communicate with the risk management function and other analytical units (e.g., economic, technologic, legal, trade) at appropriate points in the process in order to ensure that the risk assessment will contribute to an integrated decision-support product.

1. Selection of Risk Measures

The risk measures used in the assessment are critical to the relevance of the process to decision-making. They may also reflect embedded value-laden judgments that should be carefully considered during the problem formulation stage.

Choices among these measures are not merely semantic or technical differences: the measures used imply consideration of different societal values, and will affect the apparent merits of risk management options being considered by the decision-maker. These could include measures of individual and population health, impacts on the quality of life, measures of the quality of ecosystem services, measures of equity in the burden of disease among groups, among many other options. Some risk attributes may not have standard quantitative metrics, and will need to be characterized qualitatively in order to complement the quantitative characterization of risk.

As an example of alternate risk measures, the risk associated with a recreational activity may be expressed in terms of the number of injuries expected per year, the number of injuries expected per participant, or the number of injuries expected per hour of participation, or a variety

of alternate risk measures. Each of these measures could show a different trend and inform the decision-maker of very different and equally important concepts. There may be an increasing number of injuries that, when considered alone, might imply a higher level of risk. At the same time, the increase may be related to an increase in the popularity of the activity, with a simultaneous decrease in the rate of injury per hour of participation. The latter measure might imply that the recreational activity, in the context of individual exposure, is becoming safer. Additional measures may indicate that the risk is decreasing in the overall population, but increasing for a specific sub-population (e.g., the elderly, drivers of mini-vans, a specific species of bird, structures built without reinforced concrete).

Multiple measures of risk providing a more complete picture of the risk situation are preferred to a single measure of risk. The appropriate measures of risk should be selected with consideration to scientific factors, integration with economic analysis and other key elements of the decision-support context, and in consultation with the risk management function.

C. Hazard or Failure Identification

Regulators of various sectors and industrial activities will inevitably employ very different terminology. However, risk assessments have in common the requirement to identify and characterize the ways in which adverse events can arise. In different fields, this process is sometimes called hazard identification, identification of failure modes, and a variety of other terms. In each case, the conclusions at this step are limited to describing the possibility of adverse outcomes including, in some cases, a characterization of the evidence for a causal relationship between a specific source of harm (i.e., a hazard) and the adverse outcomes of interest.

1. Causal Analysis

A common underlying task in hazard identification is the designation of a causal relationship between a hazard and the adverse outcome. In some cases, the causal analysis component of hazard identification can be a relatively simple task (e.g., failure of cooling pump leads to overheating). In other cases, the attribution of causality is the most complex and controversial aspect of the entire risk assessment (e.g., in determining whether an air pollutant causes asthma, or merely exacerbates asthma).

Where the underlying causal relationship is in question, careful attention should be paid to the process for inclusion, exclusion and weighing of evidence with respect to its quality, strength and coherence among other qualities. The transparency in this aspect can be critical to the credibility of the judgment. Formal and more systematic methods, combined with appropriate application of information technology, will also allow for more efficient updating of information within an iterative risk assessment process.

2. Identifying Hazards in Complex Systems

In other risk domains, the critical challenge in the hazard identification stage lies in the complexity of the system and in exhaustively identifying and recording all of the ways that a risk

may be generated. In these cases, established techniques should be applied wherever possible to systematically analyze the system. An example of a hazard identification technique, applicable to medical products and many other engineered system domains, is Failure Modes and Effect Analysis, in which a system is systematically described, and each of its components is analyzed with respect to the potential for failure and the impact of that failure. This work is often facilitated by software tools that help to ensure a systematic approach with complete documentation.

D. Exposure Assessment

Given the breadth of responsibility of regulators, risk assessments will require consideration of a wide range of exposures that may result in negative consequences. For example, exposures to physical, chemical, biological and radiological agents present in the human environment (air, soil, water, the built environment) may need to be assessed with respect to their potential impact on the well-being of humans, animals, plants and ecosystem health. In each case, exposure assessment consists of converting the possibility of harm associated with a hazard into situation-specific estimates of the frequency and extent of the interaction between the hazard and specific receptors of interest. These estimates are the products of exposure assessment.

1. Identification of Sources, Pathways and Receptors

In an ideal analysis, all potential hazards or failures, all pathways of exposure, and all receptors facing the possibility of adverse outcomes would be considered. In practical terms, the scope of a risk assessment will involve a series of decisions to, in some cases, significantly reduce the scope of the analysis. This reduced scope may come from the institutional or jurisdictional context (e.g., the mandate of the organization does not include foodborne exposure), through deliberation in the problem formulation stage where risk managers, risk assessors and stakeholders have arrived at a decision on an appropriate scope, or it can based primarily on scientific and technical arguments that determine the most important combinations of sources, pathways and receptors.

Regardless of how the scope of the system is determined, a clear statement as to why the scope was chosen, including any limitations that may be associated with that determination, should be provided. If the scope is largely determined by factors related to the decision-context, they should be described in the problem formulation stage. Where the scope has been largely determined by scientific or technical arguments, these arguments should be provided in the exposure assessment stage.

2. Estimation of the Probability and Extent of Exposure

The probability that the effects of concern will occur can be assessed and reported in different ways, including qualitative and quantitative methods and approaches that combine the two methods. The choice of method may be determined by the type of assessment and the way in

which the assessment results will be used, or it may be a function of the amount of data available.

Qualitative methods: Qualitative methods and measures are often used in conjunction with or as a precursor to the application of quantitative methods. Purely verbal expressions of probability (e.g., unlikely, remote, often, rare) are not considered to be appropriate, except where these labels are pre-determined, in consultation with the risk management function, to have a specific quantitative interpretation (e.g., rare has been pre-determined to mean "the event has a mean return period of more than 1000 years, unlikely is understood to mean a "mean return period between 200 and 1000 years"). The most substantial challenge is to attempt to use these terms consistently within and outside the regulatory organization, given that these words are not owned by the regulatory agency. The application of simple ordinal labels may be preferred (such as I, II, III or A, B, C) and these should be linked explicitly to quantitative ranges. The use of ordinal labels avoids the value-laden nature of words like "negligible," "low," "high" or "catastrophic" and the well-known ambiguity and unreliability of verbal descriptions of probability. This helps to avoid inconsistent communication of risk and to avoid the potential for, or perception of, any manipulation of the verbal characterization of risks. It will also facilitate more consistent communication of risk in multiple languages, and to international audiences.

Quantitative methods: The probability of key events (for event-driven risks) or of various degrees of exposure (e.g., for chronic exposures that vary in their level), can be assessed quantitatively using deterministic or, preferably, probabilistic methods. The choice of methods can depend on the amount of data available, the complexity of the system, and the levels of uncertainty and variability that need to be accounted for. Probabilistic assessments provide more information on the range of the risks within a population and can address uncertainty more effectively. They require greater amounts of data and resources to conduct and are critical to assessment of risks that a) arise from highly non-linear phenomena, b) arise from the combination of a set of events and pathways of exposure, c) where there is high degrees of variability in the level of risk, and d) where there is a need for decision-makers to trade-off between one level of risk with another (e.g., in assessing risks from disinfection by-products that arise from treating drinking water as compared to the risks associated with the microorganisms being treated).

In order to adequately capture the importance of variability and to properly estimate the risk, it is important to be able to appropriately characterize the extremes of risk. The most important extremes of risk may result from the simultaneous variation in several quantities toward extreme values that yield high risk scenarios. Estimating the probability of these events requires careful use of mathematical or computational methods, to ensure that these risks (in particular, the probability components) are neither systematically underestimated nor systematically overestimated.

Numerical estimates of risk which result from propagation of either averages or "normal" values (often tending to underestimate risk) or from propagation of a series of "worst-case" values (tending to overestimate risk) should be computed and characterized with considerable care or, preferably, should be avoided through use of appropriate established techniques to propagate variation (i.e., to compute the probability of extreme risk scenarios) in order to

generate risk estimates in a more reliable, reproducible and defensible manner. Analytical methods to propagate variation can be applied for simple risk models, while computational methods to propagate variation (e.g., Monte Carlo simulation) may be required for models containing non-linear relationships or any models with a non-trivial degree of complexity. Regulators are encouraged to periodically review the nature of the risk assessments that are required and to choose a set of methods and tools to allow for appropriate characterization of the probability and extent of exposure resulting from multiple sources of variation.

E. Exposure-Consequence Assessment

In specific contexts, this may be called dose-response assessment, concentration-response assessment, damage function assessment, or a number of other terms. Despite the apparent differences in terminology, the process derives estimates for the probability, rate and/or extent of damage to the receptor *given a level of exposure (inhalation of 5 ppm of a chemical) or a specific type of exposure event (e.g., consumption of 1 gram of peanut by someone with severe allergy).* This relationship between exposures and the associated consequences is then merged with the estimates of the frequency and the extent of exposure to generate estimates of risk in the risk characterization step.

In this step, the consequences of exposure to the hazard and their severity are described as appropriate for the hazard type and the type of evidence available to measure the risk. For example, different consequences of risks associated with food might be described by the probability of cases of infection, by the frequency of adverse effects seen in animal experiments, or by estimating the relationship based on exposures to the same substances and the effects, observed in an occupational setting. The consequences of events at a hazardous facility could be described in terms of the number of people injured, the severity of the injuries received, or the geographic area that was affected by the incident.

In many cases the consequences may need to be estimated in several stages, where the damage is best described as having several cascading steps (e.g., explosion at a plant leading to overpressure as a function of distance from the plant, frequency and extent of building damage as a function of overpressure, frequency and extent of human injury as a function of building damage, economic costs of human injury and costs to repair buildings and other damages). A similar set of cascading effects can be described as further consequences of an initial acute health event such as an infection, an asthma attack, an accidental poisoning, each with a unique spectrum of further consequences of varying probability, ranging from minor, reversible effects to more serious, irreversible impacts such as fatalities, species extinction, permanent disability or complete destruction of public or private property.

Different levels of susceptibility may lead to variations in the probability or the severity of consequences among individuals or groups for a variety of reasons. Where distinct populations are identified, ideally in the problem formulation phase, that can be expected to incur consequences of greater or lesser severity than the general population, these should be computed and described separately, as well as being appropriately weighted in population-level risk estimates. Populations is used in the widest sense here, and could include animals, plants, buildings, roads, or any other collection of publicly-valued entities.

In a relative sense, this step may be more generic than other parts of the risk assessment, and applicable to many different risk assessment contexts (e.g., where the consequences of an event to the receptors of interest do not depend on how, when or where the event occurs). In some cases, it can be derived independently of a specific risk assessment context and applied in several risk assessments over time. Due to its more generic nature, it may be separately developed and peer-reviewed independently of any specific risk assessment product.

F. Risk Characterization

Risk characterization integrates the information generated in the risk assessment into a summary conclusion of the risk, in a manner that is relevant and useful for decision makers. The information provided by the risk assessment will be used in combination with other parallel assessments (i.e. technological, economical, social, and political) to inform the risk management option selection process.

Risk characterization is the critical final step in the estimation process, including both computational and narrative components. The estimation task in risk characterization is to appropriately combine estimates of the frequency and extent of exposure (resulting from the exposure assessment stage) with the relationship between exposure and consequences to yield estimates of the magnitude of consequences with corresponding estimates of their probability. Depending on the measures chosen, various specific measures that combine probability and consequence may be computed to simplify the characterization of risk. Examples include the average population risk, a specific percentile of the distribution of individual risks to demonstrate the expected variation in risk faced by members of the public, or a number of separate scenarios to demonstrate the extent of uncertainty. As discussed above, multiple measures of risk which demonstrate different conceptual aspects of the estimated risk should be presented. A subset of these estimates needs to be compatible with other analytic components of decision-making, such as cost-benefit assessment, mitigation technology assessment, ethical and legal analyses and others. These parallel analytical tasks may be identified during the problem formulation phase, or may emerge during iterations of the risk assessment and decision-support process.

The principal results of the risk assessment are the estimates of the level of risk and characterization of the extent of uncertainty. The results often include a baseline scenario (e.g., often the *status quo*, without additional risk management action) and a set of alternative scenarios corresponding to alternate assumptions. Some of the alternate scenarios will represent alternate interpretations of scientific evidence, to demonstrate and make transparent the level of uncertainty.

Other outputs of a risk assessment process (intermediate calculations, the results of validation exercises, the results of peer review) may be provided for context, and to provide assurance of the content and quality of the process producing those results. These outputs provide further background evidence in the decision-making process and foster the appropriate levels of confidence in the decision-making process among stakeholders.

The following are some key components of the risk characterization.

- Summary measures of risk. Key risk measures are presented for the magnitude and probabilities of the risks for the populations of receptors that were identified in the scoping process.
- Individual risk estimates. Where appropriate, the estimation of risks for individuals in identified populations of receptors is presented. The nature and significance of uncertainty and variability in the risks to individuals should be explained.
- Population risk estimates. Population estimates or distributions should identify the populations, or sensitive members of subpopulations, to which they apply. Uncertainty or confidence levels should be specified.
- Complementary measures of risk. Measures of risks other than, or in addition to, the key risks of interest in the assessment should be evaluated and reported, along with the terms used for measurement and the significance of those risks to the larger risk decision context.
- Distribution of burden of risk. The distribution of the burden of risk is a key factor in the consideration of equity in relation to the risk assessment and the management options selected for evaluation. The effects of a risk can vary within a population according to factors such as geographic location, age or life stage, or income level, among others.

1. Characterization of Uncertainty

Where there is uncertainty in the data or analysis, the source, type and significance of uncertainty should be specified. Approaches to the characterization of uncertainty range in sophistication and time requirements; more detailed characterization methods should be applied for parameters in which significant uncertainty can affect critical risk calculations, particularly where the uncertainty leads to uncertainty in which decision option may be preferred.
There are a variety of methods of assessing and expressing uncertainty such as the provision of bounding values, interval analysis, sensitivity analysis, and importance analysis. The rationale for employing these techniques, and the processes, data sets or inferences to which they were applied should be described. Scenario analysis can be used to characterize uncertainties in models, to make transparent the impacts of specific assumptions.

2. Assessing the Risk Reduction Impact of Risk Management Options

To estimate the benefits of specific decision-making options, a range of risk management options is selected for evaluation and comparison, against each other and against the baseline scenario. In essence, this step simply repeats the risk characterization step of risk assessment for a selection of decision options, and focusses attention upon the differences in the level of risk among the various options and as compared to a baseline scenario (for example, *the status quo*). Depending on the decision context, a selection of risk management options may be known in advance and can be evaluated throughout the risk assessment process. In many cases, options may be identified as a result of the primary risk assessment and then subsequently assessed in further iterations of the risk assessment and decision-support process.
The evaluation and comparison should include the effectiveness of the risk management option to reduce risk (through reductions in probability or severity, or both), the possible creation of

new risks through the measures to control the baseline risk, and any other known side effects of each option.

- Measures of risk reduction from baseline. The effectiveness of each risk management option in reducing the severity of the risk, or the probability that it will occur, should be estimated.
- Characterization of risk-risk trade-offs. Risk trade-offs created by the risk management options should be identified and characterized. These may include a trade-off between the risks of an activity and those of foregoing the risk activity, or weighing the significance of ancillary risks or adverse effects generated by the risk management option intended to reduce a target risk.

The specification of the risk management options, including the timing, the scope (e.g., applies only to large businesses for the first five years, etc.) and other details needs to be co-ordinated with other analytical units in order to ensure that an integrated decision-support product is available to decision-makers.

The risk assessment report should characterize the change in levels of risk estimates associated with each option, while avoiding the use of value-laden terminology (e.g., "a *significant* reduction," "reduces the risk to *safe* levels") to the greatest extent possible. The determination that a specific option (e.g., a regulatory action, application of a numerical threshold of exposure) is preferred is a product of risk management and should not be characterized or implied by the risk assessment.

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Key Analytical Capabilities of a Best-in-Class Regulator

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