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An Ethical Appraisal of Hormesis: Towards a Rational Discourse on the Acceptability of Risks and Benefits

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Abstract: It is ethically mandated that potential beneficial aspects of low exposure to potentially hazardous material are incorporated in the risk-benefit balancing procedure. The potential harm done by pollutants does not justify the invocation of a categorical principle. Minimisation of risk is not required if health benefits are also at stake. Society needs to find an informed consent on the threshold of risk below compensation of goods is legitimate and morally justified. Such a threshold can be defined context-specific but any human action associated with potential health impacts makes such an acceptability judgment - implicitly or explicitly. Incorporating hormesis into risk management forces regulators to make such thresholds explicit. Once as risk is below this threshold all positive and negative impacts are subject to a relative balancing towards reaching a final judgment on acceptability and necessary risk management options. This balancing risk cannot be reduced to body counts: equity issues, context specific circumstances (voluntary or involuntary exposure, for example), avoidance of risks, the nature of vulnerable groups and many other factors need to be taken into account. Such a complex weighing exercise is best performed by an analytic-deliberative process by which the best available knowledge of impacts (including their uncertain ties) is fed into a deliberating body of individuals representing all sides of the debate. Organizing and structuring an analytic-deliberative discourse for assigning painful trade-offs goes beyond the good intention to have all relevant stakeholders involved in decision making.. Discursive processes need a structure that assures the integration of technical expertise, regulatory requirements, and public values. These different inputs should be combined in such a fashion that they contribute to the deliberation process the type of expertise and knowledge that can claim legitimacy within a rational decision making procedure.

Keywords: Hormesis, ethical principles, ethical approaches to risk, ethical schools, acceptability criteria, risk management, decision analysis, analytic-deliberative process

INTRODUCTION

Industrial production and consumption produce unintended side effects that scientists and regulators try to identify and assess. The most important component of such an assessment process is the characterization of risks associated with the activity in question. The normal risk assessment process follows a well-defined protocol of toxicological or epidemiological procedures, which ensure that regulatory or other management actions are based on proven evidence of a potential damage^[52]. Until recently, the common wisdom of risk assessors in the field of chemicals has been to distinguish two types of substances: the first groups include potentially toxic substances that may cause physical damages to human being or the environment above a certain threshold of exposure or intake. Risk management agencies are therefore advised to make sure that the concentration levels would never reach or even surpass these thresholds. With respect to

human health, additional safety factors (normally 100-1000 for most risk domains) are applied to adjust for inter-species extrapolation and inter-individual variation. The second class of chemicals is believed to cause harm at any level above zero (stochastic effects). These have been associated with genotoxic effects implying the possibility of irreversible damage to the DNA at an exposure level of a single molecule (oneshot-hypothesis). The regulator has been advised to minimize exposure of people to these stochastic risks As Low As Reasonably Acceptable (ALARA) and define a level of tolerable risk based on the extrapolation from large to small doses.

This conventional view of toxicity and risk has lately been challenged in the risk assessment and management community. First, the ALARA principle does not specify what "reasonable" means and how much effort needs to be invested in order to reduce risks to a level deemed acceptable. Second, the extrapolation from high to low doses must be done on the basis of a

theoretical assumption about the slope and shape of the dose-response function. There are always more than one possibility to draw a regression line from empirical known effects (at high dose) to theoretically modeled low dose effects. Until today there is no communitywide agreement about the shape and slope when it comes to modeling the effects of risk-inducing substances or radiation. In order to avoid these two problems some risk assessors and risk assessment agencies have proposed to use another method, i.e., the Margin of Exposure Approach (MOE) This method is based on the definition of a benchmark on a given empirically derived dose-response $curve^{[10,11,74]}$. The preferred benchmark suggested by the proposers is the point of the dose response curve where 10% of the investigated species show the targeted negative health effect, i.e. the development of a tumor, at the 5% mark representing the upper boundary of the 95% confidence interval (the so called BMDL). Alternatively the 25% point has also be selected if the 10% mark is impossible or difficult to determine (called the T25 solution).

The dose that is equivalent to the chosen benchmark is then divided by the actual exposure in humans. The result of this division signals the distance from the 10% level to the actual intake. The authors of the report of the European Food Safety Authority EFSA t suggest that a result of 10,000 and more could be interpreted as a tolerable risk level. A factor of 10,000 means that the concentration of this substance is 10,000 times smaller than the concentration by which at the 5%confidence level 10 percent of the investigated species would develop a tumor. Accordingly, if the 25% benchmark were used, the tolerable level would be divided by an additional 2.5. The same report stresses that the MOE approach does not pre-determine the level of tolerability or acceptability but may help to provide a better comparative foundation for setting priorities. Any substance that has a lower MOE than another substance is potentially more dangerous and would need more attention. Whether 10,000 or any other number should be used to serve as the demarcation line between acceptable and unacceptable risks, is clearly a political decision which needs to be made by risk managers (may be in conjunction with stakeholder involvement). The MOE method itself provides a more reliable base for comparing different substances and facilitating the setting of political standards but does not pre-impose a special tolerability threshold.

However, the picture becomes even more complex if hormesis is also taken into account^[8]. Hormesis has been defined as a dose-response relationship in which there is a stimulatory response at low doses, but an inhibiting response at high doses, resulting in a U- or inverted U-shaped dose response (Calabrese and Baldwin 2001). These hormetic effects have been studies for more than two decades (see for example Stebbing 1982; 1998). Toxic agents that are detrimental to human health above certain threshold levels may induce positive effects at a dose that is significantly lower than the No Adverse Effect Level (NOAEL). Many recent publications (including those collected in this volume) provide impressive evidence for the existence of such positive stimulatory effects of low dose exposure. Calabrese and Baldwin report that 19.5% of 1089 samples showed a clear positive hormesis effect, in 80% of the cases such a hormetic effect could not be statistically proven (no significant difference to the control group), yet only 0.6% turned out to be false-positive candidates (Calabrese and Baldwin 2001, p. 350). In spite of the evidence for hormesis, the topic is still a matter of high controversy among toxicologists.

Until now, regulatory agencies have been reluctant to address this new challenge or adjust their routines for regulating such substances. All regulatory regimes throughout the world are still based on the traditional risk model: either to define a standard based on thresholds modified by appropriate safety factors or to define tolerable risk levels for stochastic risks caused by chemicals or physical agents (such as radiation). If the hormesis thesis were to be recognized by the scientific community as a new valid paradigm of doseeffect relationships, regulatory systems would need an adjustment and develop new management rules for dealing with the potentially positive effects of low dose exposure. The recent proposal of using a MOE approach could be modified by applying less stringent distance parameters (varying from 10,000 to 1,000) if hormetic effects are likely to occur at these low exposure levels.

If we turn to the public, the effect of the debate on public opinion so far is confusion. Most people simply demand healthy and safe products and like to act on the assumption "better safe than sorry" (Lee 1981). This attitude is likely to encourage regulators to err on the safe side and continue to "ignore" potential hormesis effects. At the same time, however, people as consumers have an interest in a large variety of products, low prices and job opportunities. Unless risk information explicitly addresses aspects of potential benefits and social needs, it will not correspond to the expressed and revealed preferences of the people it is supposed to serve.

Based on these considerations about major risk trade-offs in risk management, it is essential to review the ethical implications of hormesis in risk assessment and management. What kind of values should govern the regulation of substances and radiation that may cause positive and negative impacts at the same time (depending on dose and individual variability)? This paper tries to address this question. It is divided into two major sections. Section 1 and 2 will introduce the essentials of ethics and the application of ethical principles to judging the acceptability of risks to humans and the environment. Sections 3 and 4 address the application of these principles to risk management taking into account the hormesis challenge.

Basic ethical principles: Should people be allowed to do everything that they are capable of doing? This question is posed in connection with new technologies, hazardous substances, radiation, or human interventions into the natural environment. Intuitively everyone answers this question with a definitive "No": No way should people be allowed to everything that they are capable of doing. This also applies to everyday actions. Many options in daily life, from lying to minor deception, from breaking a promise up to going behind a friend's back, are obviously actions that are seen by well-intentioned observers as unacceptable. all However, it is much more difficult to assess those actions where the valuation is not so obvious. Is it justified to break a promise when keeping the promise could harm many other people?

Actions where there are conflicts between positive and negative consequences or where a judgement could be made one way or the other with equally good justification are especially common in the field of risk evaluation and management. There is hardly anyone who wilfully and without reason exposes people to a health risks, releases toxic pollutants or damages the environment. People who pursue their own selfish goals on the cost and risk of others are obviously acting wrongly and every legislator will sanction this behaviour with the threat of punishment or a penalty. But there is need for clarification where people bring about a benefit to society with the best intentions and for plausible reasons and, in the process, risk negative impacts on others. In ethics we talk about ,,conflicting values.

Most decisions involving risks to oneself or others are made for some reason: the actors who make such interventions want to secure good or services to consumers, for example, to ensure long-term jobs and adequate incomes, to incorporate potentially hazardous material for products and services or to use natural reservoirs (sinks) for disposing of waste materials from production and consumption. None of this is done for reasons of brotherly love, but to maintain social interests. Even improving one's own financial resource is not immoral mere for this reason. The list of human activities that pose risks onto others perpetrated for existential or economic reasons could be carried on into infinity. Human existence is bound to take opportunities and risks.

Therefore, to be able to make a sensible judgement of the balance between necessary improvements of the present status of society and the risks to human health and environmental quality posed by these activities, the range of products and services has to be systematically compared to the losses that are inflicted on human health and the environment. If important goods have to be appreciated when weighing the pros and cons of human activities, criteria are needed that can be used as yardsticks. Who can and may draw up such criteria, according to which standards should the risk inducing activities be assessed and how can the various evaluative options for action be compared with each other for each criterion?

Taking risks always involves two major components: an assessment of what we can expect from the activity and an evaluation of how desirable these expectations are. The first component addresses the risk and benefit assessment side of the risk analysis. The second component addresses the societal evaluation of these expected consequences. Whereas the estimate of consequences broadly falls in the domain of scientific research and expertise, with uncertainties and ambiguities in particular having to be taken into account (IRGC 2005; Renn 2008), the question about the foundations for evaluating various options for action and about drawing up standards guiding action is a central function of ethics. Ethics can provide an answer to the question posed at the beginning ("Should people be allowed to do everything that they are capable of doing?") in a consistent and transparent manner.

Ethical foundations of risk management:

Overview of ethical approaches to risk: Answering the question about finding the right balance between benefits and risks lies within the field of practical philosophy, ethics. Following the usual view in philosophy, ethics describes the theory of the justification of normative statements, i.e., those that guide action (Gethmann, 1991; Mittelstraß, 1992; Nida-Rümelin, 1996a; Revermann, 1998). A system of normative statements is called "morals". Ethical judgements therefore refer to the justifiability of moral instructions for action that may vary from individual to individual and from culture to culture (Ott, 1999).

Basically, humans are purpose-oriented and selfdetermined beings who act not only instinctively, but also with foresight, and are subject to the moral standards to carry out only those actions that they can classify as good and justifiable (Honnefelder, 1993). Obviously, not all people act according to the standards that they themselves see as necessary, but they are capable of doing so. In this context it is possible for people to act morally because, on the one hand, they are capable of distinguishing between moral and immoral action and, on the other, are largely free to choose between different options for action.

Whether pursuing a particular instruction for action should be considered as moral or immoral is based on whether the action concerned can be felt and justified to be "reasonable" in a particular situation. Standards that cross over situations and that demand universal applicability are referred to as *principles* here. Conflicts may arise between competing standards (in a specific situation), as well as between competing principles, the solution of which, in turn, needs justification (Szejnwald-Brown et al., 1993). Providing yardsticks for such justification or examining moral systems with respect to their justifiability is one of the key tasks of practical ethics (Gethmann, 1998).

In ethics a distinction is made between descriptive (experienced morality) and prescriptive approaches, i.e., justifiable principles of individual and collective behaviour (Frankena, 1963; Hansen, 1995). Furthermore, ethical norms can be a applied to the personal lifestyle ("good life") and to collective actions (normative guidelines) (Galert, 1998; Ott, 1999). Within normative ethics a distinction is made between deontological and teleological approaches when justifying normative judgments (Höffe, 1987). Deontological approaches are principles and standards of behaviour that apply to the behaviour itself on the basis of an external valuation criterion. It is not the consequences of an action that are the vardstick of the valuation; rather it is adhering to inherent yardsticks that can be used against the action itself. Such external vardsticks of valuation are derived from religion, nature, intuition or common sense, depending on the basic philosophical direction. Thus, protection of the biosphere can be seen as a divine order to protect creation (Rock, 1980; Schmitz, 1985), as an innate tendency for the emotional attachment of people to an environment with biodiversity (Wilson, 1984), as a directly understandable source of inspiration and joy (Ehrenfeld, 1993) or as an educational means of practising responsibility and maintaining social stability (Gowdy, 1997).

By contrast, teleological approaches refer to the consequences of action. Here, too, external standards of

valuation are needed since the ethical quality of the consequences of action also have to be evaluated against a yardstick of some kind. With the most utilitarian approaches (a subset of the teleological approaches) this yardstick is defined as an increase in individual or social benefit. In other schools of ethics, intuition (can the consequence still be desirable?) or the aspect of reciprocity (the so-called "Golden Rule" ,,do as you would be done by") play a key role.

In the approaches based on logical reasoning (especially in Kant), the yardstick is derived from the logic of the ability to generalise or universalise. Kant himself is in the tradition of deontological approaches ("Good will is not good as a result of what it does or achieves, but just as a result of the intention"). According to Kant every principle that, if followed generally, makes it impossible for a "good life" to be conducted is ethically impermissible. In this connection, it is not the desirability of the consequences that captures Kant's mind, but the logical inconsistency that results from the fact that the conditions of the actions of individuals would be undermined if everyone were to act according to the same maxims (Höffe, 1992).

A number of contemporary ethicists have taken up Kant's generalisation formula, but do not judge the maxims according to their internal contradictions; rather they judge them according to the desirability of the consequences to be feared from the generalisation (Jonas, 1979 or Zimmerli, 1993). These approaches can be defined as a middle course between deontological and teleological forms of justification.

In addition to deontological and teleological approaches there is also the simple solution of consensual ethics, which, however, comprises more than just actually experienced morality. Consensual ethics presupposes the explicit agreement of the people involved in an action. Everything is allowed provided that all affected (for whatever reason) voluntarily agree. In sexual ethics at the moment a change from deontological ethics to a consensual moral code can be seen.

The comparison of the basic justification paths for normative moral systems already clearly shows that professional ethicists cannot create any standards or designate any as clearly right, even if they play a role in people's actual lives. Much rather it is the prime task of ethics to ensure on the basis of generally recognised principles (for example, human rights) that all associated standards and behaviour regulations do not contradict each other or a higher order principle.

Above and beyond this, ethics can identify possible solutions that may occur with a conflict between

standards and principles of equal standing. Ethics may also reveal interconnections of justification that have proved themselves as examination criteria for moral action in the course of their disciplinary history. Finally, many ethicists see their task as providing methods and procedures primarily of an intellectual nature by means of which the compatibility or incompatibility of standards within the framework of one or more moral systems can be completed. Unlike the law, the wealth of standards of ethics is not bound to codified rules that can be used as a basis for such examinations. compatibility Everv normative discussion therefore starts with the general issues that are needed in order to allow individuals a "good life" and, at the same time, to give validity to the principles required to regulate the community life built on common good. But how can generally binding and intersubjectively valid criteria be made for the valuation of "the common good"?

The problem of ultimate justification: In modern pluralistic societies it is increasingly difficult for individuals and groups of society to draw up or recognise collectively binding principles that are perceived by all equally as justifiable and as selfobliging (Hartwich and Wewer, 1991; Zilleßen, 1993). The variety of lifestyle options and subjectification of meaning (individualisation) are accompanying features of modernisation. With increasing technical and organisational means of shaping the future, the range of behaviour options available to people also expands. With the increasing plurality of lifestyles, groupspecific rationalities emerge that create their own worldviews and moral standards, which demand a binding nature and validity only within a social group or subculture. The fewer cross-society guiding principles or behaviour orientations are available, the more difficult is the process of agreement on collectively binding orientations for action. However, these are vital for the maintenance of economic cooperation, for the protection of the natural foundations of life and for the maintenance of cohesion in a society. No society can exist without the binding specification of minimum canons of principles and standards.

But how can agreement be reached on such collectively binding principles and standards? What criteria can be used to judge standards? The answers to this question depend on whether the primary principles, in other words the starting point of all moral systems, or secondary principles or standards, i.e., follow-on standards that can be derived from the primary principles, are subjected to an ethical examination. Primary principles can be categorical or compensatory (capable of being compensated). Categorical principles are those that must not be infringed under any circumstances, even if other principles would be infringed as a result. The human right to the integrity of life could be named here as an example. Compensatory principles are those where temporary or partial infringement is acceptable, provided that as a result the infringement of a principle of equal or higher ranking is avoided or can be avoided. In this way certain freedom rights can be restricted in times of emergency. In the literature on ethical rules, one can find more complex and sophisticated classifications of normative rules. For our purpose to provide a simple and pragmatic framework, the distinction in four categories (principles and standards; categorical and compensatory) may suffice.

But how can primary principles be justified as equally valid for all people? Although many philosophers have made proposals here, there is a broad consensus today that neither philosophy nor any other human facility is capable of stating binding metacriteria without any doubt and for all people, according to which such primary principles should be derived or examined (Mittelstraß, 1984). A final justification of normative judgements cannot be achieved by logical means either, since all attempts of this kind automatically end either in a logical circle, in an unending regression (vicious cycle) or in a termination of the procedure and none of these alternatives is a satisfactory solution for final justification (Albert, 1991).

The problem of not being able to derive finally valid principles definitively, however, seems to be less serious than would appear at first glance. Because, regardless of whether the basic axioms of moral rules are taken from intuition, observations of nature, religion, tradition reasoning or common sense, they have broadly similar contents. Thus, there is broad consensus that each human individual has a right to life, that human freedom is a high-value good and that social justice should be aimed at. But there are obviously many different opinions about what these principles mean in detail and how they should be implemented. In spite of this plurality, however, discerning and wellintentioned observers can usually quickly agree, whether one of the basic principles has clearly been infringed. It is more difficult to decide whether they have clearly been fulfilled or whether the behaviour to be judged should clearly be assigned to one or several principles. Since there is no finally binding body in a secular society that can specify primary principles or standards ex cathedra, in this case consensus among

equally defendable standards or principles can be used (or pragmatically under certain conditions also majority decisions). Ethical considerations are still useful in this case as they allow the test of generalisation and the enhancement of awareness raising capabilities. In particular, they help to reveal the implications of such primary principles and standards.

Provided that primary principles are not concerned (such as human rights), the ethical discussion largely consists of examining the compatibility of each of the available standards and options for action with the proposed primary principles. In this connection, the main concerns are a lack of contradictions (consistency), logical consistency (deductive validity), coherence (agreement with other principles that have been recognised as correct) and other, broadly logical criteria (Gethmann, 1998). As the result of such an examination it is entirely possible to reach completely different conclusions that all correspond to the laws of logic and thus justify new plurality.

In order to reach binding statements or valuations here the evaluator can either conduct a discussion in his "mind" and let the arguments for various standards compete with each other (rather like a platonic dialogue) or conduct a real discussion with the people affected by the action. In both cases the main concern is to use the consensually agreed primary principles to derive secondary principles of general action and standards of specific action that should be preferred over alternatives that can be equally justified. A plurality of solutions should be expected especially because most of the concrete options for action comprise only a gradual fulfilment and infringement of primary principles and therefore also include conflicting values. For value conflicts at the same level of abstraction there are, by definition, no clear rules for solution. There are therefore frequently conflicts between conserving life through economic development and destroying life through hazardous materials. Since the principle of conserving life can be used for both options a conflict is unavoidable in this case. To solve the conflicts ethical considerations, such as the avoidance of extremes, staggering priorities over time or the search for third solutions can help without, however, being able to convincingly solve this conflict in principle to the same degree for all (Szejnwald-Brown et al., 1993).

These considerations lead to some important conclusions for the matter of the application of ethical principles to the issue of human action with regard to risks to human health and the natural environment. First of all, it contradicts the way ethics sees itself to develop ethics of its own for different action contexts. Just as there can be no different rules for the logic of deduction and induction in nomological science, depending on which object is concerned, it does not make any sense to postulate an independent set of ethics for risk management concerning effects on human health or the environment (Galert, 1998). Justifications for principles and moral systems have to satisfy universal validity (Nida-Rümelin, 1996b).

Therefore, it is not helpful to call for a special moral system for evaluating risks since this - like every other moral system - has to be traceable to primary principles. Instead, it makes sense to specify the generally valid principles that are also relevant with regard to the issue of how to deal with risks and benefits of human activities. At the same time standards should be derived from these principles that provide concrete guidelines of how to balance risks and benefits.

Categorical versus compensatory principles and standards: With regard to risk and benefits of human activities, different goods have to be weighed up against each other. There is no magic formula available indicating how much risk can be traded for how much valuable commodities. Humans alone are responsible for the resolution of conflicts between competing objectives. Appreciation and negotiation processes are therefore at the core of the considerations about ethical principles and standards of risk acceptability.

But this does not mean that there is no room for categorical judgements along the lines of "this or that absolutely must be prohibited" in the matter of risk evaluation. It follows on from the basic principle of conserving human life that all human interventions that threaten the ability of the human race as a whole, or a significant number of individuals alive today or in the future, to exist should be categorically prohibited. This refers to risks that threaten the systemic functions of the biosphere. Such threats are one of the guiding principles that must not be exceeded under any circumstances, even if this excess were to be associated with high benefits. In the language of ethics this is a categorical principle, in the language of economics a good that is not capable of being traded.

A second non-negotiable categorical norm is the protection of individual human lives unless other lives are jeopardised There are many exceptions to this categorical law. It is, for example, morally not justified to kill one person and use his or her organs to save two other persons. Without going into much detail here, imposing risks which are very likely to kill other individuals or to seriously damage their health are not justified regardless what economic benefit is associated with these risks. However, below the threshold of serious risks, some imposition of risks onto others (ideally with their informed consent) is legitimate if these risks are balanced with major benefits to society (Shrader-Frechette 1991). In this case risk to life can be compensated with other goods. In the past, a number of authors have tried to specify the minimum requirements for acceptable risk levels (from which compensation is legitimate). These so-called "safe minimum standards" specify thresholds for the measurement scale of risks (between 0 and 1) that may not be exceeded even if there is a prospect of great benefits (Randall, 1988; Randall and Farmer, 1995).

For most risks caused by chemical substances or radiation one can assume that compensatory rules apply. If indeed a risk would exceed the tolerable risk level set by societal consensus a release of such a chemical or physical risk would not be permitted. In all other cases the risk of being harmed by a substance or a release of radiation needs to be compared with the benefit of the activity that is associated with the risk in question. In order to evaluate partial infringements of compensatory principles or standards, society needs rules for decision-making that facilitate the balancing process necessary to resolve compensatory conflicts. In the current debate about rules for risk management it is mainly teleological valuation methods that are proposed (Hubig, 1993; Ott, 1993).

These methods are aimed at: estimating the possible consequences of various options for action at all dimensions relevant to potentially affected people, recording the infringements or fulfilments of these expected consequences in the light of the existing standards and principles and then weighting them according to an internal key so that they can be weighed up in a balanced way.

On the positive side of the equation there are the economic benefits of a risk-inducing activity and the cultural values created by its application, for example in the form of income, health enhancement or an aesthetically attractive landscape (parks, ornamental gardens, etc.); on the negative side there are threats to human health, the natural environment or the violation of aesthetic, cultural or religious attributes associated with the respective risk taking.

In risk-benefit assessment there are frequently related categories on both sides of the equation: With the same or similar categories on the credit and debit side of the balance sheet the decision is easy when there is one option that performs better or worse than all the other options for all categories. Such a *dominant* (the best for all categories) or *sub-dominant option* (the

worst for all categories) is, however, rare in reality. If we disregard the dominant or sub-dominant solutions, an appreciation between options that violate or fulfil compensatory standards and principles depends on two preconditions: best possible knowledge of the consequences (what happens if I choose option A instead of option B?) and a transparent, consistent rationale for weighing up these consequences as part of a legitimate political decision process (are the foreseeable consequences of A more desirable or bearable than the consequences of option B?) (Akademie der Wissenschaften, 1992).

Knowledge and values as a basis for risk assessment and management: In order to conduct such an informed balance one needs, first of all, adequate knowledge about the likely consequences in order to reveal the systemic connections between a human activity and its impacts on all dimensions that humans value (Wolters, 1995). This requires interdisciplinary research and cooperation. The task of toxicology in this multidisciplinary exercise, for example, is to show the consequences of using a specific substance on human health and ecological systems. The economic disciplines provide a benefit-oriented valuation of the application of this substance in different products and demonstrate the impacts for economy and well-being of all affected individuals. Cultural and social sciences investigate the feedback effects between this application, social development and cultural selfperception. They illustrate the dynamic interactions between exposure, socio-cultural lifestyles and control Interdisciplinary, problem-oriented options. and system-related research is needed to contribute to forming a basic stock of findings and insights about functional links in the relationship between riskinducing human activities and their consequences on human health and the environment (WBGU, 2000).

But knowledge alone does not suffice. In order to be able to act effectively and efficiently while observing ethical principles, it is necessary to shape the evaluation process between the various options for action according to rational criteria (Gethmann, 1998). To do this it is first of all necessary to identify the dimensions that should be used for the evaluation of risks. The discussion about the value dimensions to be used as a basis for evaluation is one of the most popular subjects within environmental ethics. To apply these criteria in risk evaluation and to combine the knowledge aspects about expected consequences of different behavioural options with the ethical principles is the task of what we have called risk governance (IRGC 2005). Within risk governance the main criteria are:

- Effectiveness: Does the activity and/or the risk management option achieve the desired effect?
- Efficiency: Does the activity and/or the risk management option achieve the desired effect with the least resource consumption?
- Minimisation of external side effects: Does the activity and/or the risk management option infringe on other valuable goods, benefits or services such as competitiveness, public health, environmental quality, social cohesion, etc.? Does it impair the efficiency and acceptance of the governance system itself?
- Sustainability: Does the activity and/or the risk management option contribute to the overall goal of sustainability? Does it assist in sustaining vital ecological functions, economic prosperity and social cohesion?
- Fairness: Does the activity and/or the risk management option burden the subjects of regulation in a fair and equitable manner?
- Political and legal implementability: Is the activity and/or the risk management option compatible with legal requirements and political programmes?
- Public acceptance: Will the activity and/or the risk management option be accepted by those individuals who are affected by it? Are there cultural preferences or symbolic connotations that have a strong influence on how the risks are perceived?

Measuring risk-inducing activities or risk-reducing management options against these criteria may create conflicting messages and results. Many measures that prove to be effective may turn out to be inefficient or unfair to those who will be burdened. Other measures may be sustainable but not accepted by the public or important stakeholders. There are many excellent guidance documents available that demonstrate how to handle painful risk trade-offs and how to employ decision analytic tools for dealing with conflicting evidence and values (c.f. Viscusi 1994; Wiener 1998; van der Sluijs et al. 2003; Goodwin and Wright 2004). The following section will present a framework for applying these principles to risk management with special emphasis on hormesis. The main line of argument is that risk management requires an analyticdeliberative approach for dealing effectively and prudently with complex risks.

An analytic-deliberative approach to evaluating complex risks:

Combing ethical evaluation and risk management: Assessing potential consequences of human interventions and evaluating their desirability on the basis of subsequent knowledge and transparent valuation criteria are two of the central tasks of an risk governance process. However, the plural values of an heterogeneous public and people's preferences have to be incorporated in this process. But how can this be done given the wealth of competing values and preferences? Should we simply accept the results of opinion polls as the basis for making political decisions? Can we rely on risk perception results to judge the seriousness of pending risks? Or should we place all our faith in professional risk assessment and management?

If we turn to professional help to deal with plural value input, economic theory might provide us an answer to this problem: If environmental goods are made individual and suitable for the market by means of property rights, the price that forms on the market ensures an appropriate valuation of the good. Every user of this good can then weigh up whether he is willing to pay the price or would rather not use the good. With many goods that could pose a health threat to humans, however, this valuation has to be made by collective action because public health good is a collective good that cannot be governed by individual action. In this case a process is needed that safeguards the collective rationale in valuation and justifies it to the collective. However, this valuation cannot be determined with the help of survey results. Although surveys are needed to be able to estimate the breadth of preferences and people's willingness to pay, they are insufficient for a derivation of concrete decisionmaking criteria and vardsticks for evaluating the tolerability of risks to human health and the environment (Shrader-Frechette 1991).

Firstly, the individual values are so widely scattered that there is little sense in finding an average value here.

Secondly, the preferences expressed in surveys change so much within short time whereas ethical valuations have to be valid for a long time.

Thirdly, individual preferences are frequently based on flawed knowledge or ad hoc assumptions both of which should not be decisive according to rational considerations.

What is needed, therefore, is a gradual process of assigning trade-offs in which existing empirical values are put into a coherent and logically consistent form.

In political science and sociological literature reference is mostly made to three strategies of incorporating social values and preferences in rational decision-making processes (Renn, 1997). Firstly, a reference to social preferences is viewed solely as a question of legitimate procedure (Luhmann, 1983; Vollmer, 1996). The decision is made on the basis of formal decision making process (such as majority voting). If all the rules have been kept a decision is binding, regardless of whether the subject matter of the decision can be justified or whether the people affected by the decision can understand the justification. In this version, social consensus has to be found only about the structure of the procedures; the only people who are then involved in the decisions are those who are explicitly legitimated to do so within the framework of the procedure decided upon.

The second strategy is to, rely on the minimum consensuses that have developed in the political opinion-forming process (muddling through) (Lindbloom, 1959, 1965). In this process, only those decisions that cause the least resistance in society are considered to be legitimate. In this version of social pluralism groups in society have an influence on the process of the formation of will and decision-making to the extent that they provide proposals capable of being absorbed, i.e., adapted to the processing style of the political system, and that they mobilise public pressure. The proposal that then establishes itself in politics is the one that stands up best in the competition of proposals, i.e., the one that entails the fewest losses of support for political decision-makers by interest groups.

The third strategy is based on the discussion between the groups involved (Habermas, 1971, 1991; Renn 2004; 2008). In the communicative exchange among the people involved in the discussion a form of communicative rationality that everyone can understand evolves that can serve as a justification for collectively binding decisions. At the same time, discursive methods claim to more appropriately reflect the holistic nature of human beings and also to provide fair access to designing and selecting solutions to problems. In principle the justification of standards relevant to decisions is linked to two conditions: the agreement of all involved and substantial justification of the statements made in the discussion (Habermas, 1981).

All three strategies of political control are represented in modern societies to a different extent. Legitimisation conflicts mostly arise when the three version are realised in their pure form. Merely formally adhering to decision-making procedures without a justification of content encounters a lack of understanding and rejection among the groups affected especially when they have to endure negative side effects or risks. Then acceptance is refused. If, however, we pursue the opposite path of least resistance and base ourselves on the route of muddling through we may be certain of the support of the influential groups, but, as in the first case, the disadvantaged groups will gradually withdraw their acceptance because of insufficient justification of the decision. At the same time, antipathy to politics without a line or guidance is growing, even the affected population. The consequence is political apathy.

The third strategy of discursive control faces problems too. Although in an ideal situation it is suitable for providing transparent justifications for the decision-making methods and the decision- itself, in real cases the conditions of ideal discourse can rarely be adhered to (Wellmer, 1992). Frequently, discussions among strategically operating players lead to a paralysis of practical politics by forcing endless marathon meetings with vast quantities of points of order and peripheral contributions to the discussion. The "dictatorship of endurance" (Weinrich, 1972) ultimately determines which justifications are accepted by the participants. The public becomes uncertain and disappointed by such discussions that begin with major claims and end with trivial findings.

In brief: none of the three ways out of the control dilemma can convince on its own; as so often in politics, everything depends on the right mixture. What should a mixture of the three elements (due process, pluralistic muddling through and discourse) look like so that a maximum degree of rationality can come about on the basis of social value priorities?

A report by the American Academy of Sciences on the subject of "Understanding environmental risks" (Stern and Fineberg, 1996) comes to the conclusion that scientifically valid and ethically justified procedure for the collective valuation of options for risk handling can only be realised within the context of -what the authors coin-- an analytic-deliberative process. Analytic means that the best scientific findings about the possible consequences and conditions of collective action are incorporated in the negotiations; deliberative means that rationally and ethically transparent criteria for making trade-offs are used and documented externally. Moreover, the authors consider fair participation by all groups concerned is necessary to ensure that the different moral systems that can legitimately exist alongside each other should also be incorporated in the process.

To illustrate the concept of analytic-.deliberative decision making consider a set of alterative *options* or *choices*, from which follow *consequences* (see basic overview in Dodgson et al. 2000). The relationship between the choice made, and the consequences that follow from this choice, may be straightforward or *complex*. The science supporting risk management is often complicated, across many disciplines of science

and engineering, and also involving human institutions and economic interactions. Because of limitations in scientific understanding and predictive capabilities, the consequences following a choice are normally *uncertain*. Finally, different individuals and groups within society may not agree on how to evaluate the consequences - which may involve a detailed characterization of what happens in ecological, economic, and human health terms. We shall describe consequences as *ambiguous* when there is this difficulty in getting agreement on how to interpret and evaluate them.

management inherently involve these Risk difficulties of complexity, uncertainty, and ambiguity (Klinke and Renn 2002). In some situations where there is lots of experience, these difficulties may be minimal. But in other situations these difficulties may constitute major impediments to the decision making process. To understand how analysis and deliberation interact in an iterative process following the NRC 1996 report, one must consider how these three areas of potential difficulty can be addressed. It is useful to separate questions of evidence with respect to the likelihood, magnitude of consequences and related characteristics (which can involve *complexity* and *uncertainty*) from socio-political evaluation of the consequences (i.e. ambiguity). For each of the three areas there are analytical tools that can be helpful in identifying, characterizing quantifying and cause-effect relationships. The integration of these tools of risk governance into a consistent procedure will be discussed in the next subsections.

Analytic-deliberative processes: Towards a procedural integration: The possibility to reach closure on evaluating risks to human health or the environment rests on two conditions: first, all participants need to achieve closure on the underlying goal (often legally prescribed such as prevention of health detriments or guarantee of an undisturbed environmental quality, for example purity laws for drinking water); secondly, they need to agree with the implications derived from the present state of knowledge (whether and to what degree the identified hazard impacts the desired goal). Dissent can result from conflicting values as well as conflicting evidence. It is crucial in risk management to investigate both sides of the coin: the values that govern the selection of the goal and the evidence that governs the selection of cause-effect claims.

Separating the science issues of what will happen from the value issues of how to make appropriate tradeoffs between ecological, economic, and human health goals can become very cumbersome. The separation of facts and values in decision making is difficult to accomplish in practical decision situations, since what is regarded as facts includes a preference dependent process of cognitive framing (Tversky and Kahneman 1981) and what is regarded as value includes a prior knowledge about the factual implications of different value preferences (Fischhoff 1975). Furthermore, there are serious objections against a clear cut division from a sociological view on science and knowledge generation (Jasanoff 1996). Particularly calculating risk estimates, value-based when conventions may enter the assessment process. For example, conservative assumptions may be built into the assessment process, so that some adverse effects (such as human cancer from pesticide exposure) are much less likely to be underestimated than overestimated [52]. Similarly the decision to include or exclude potential hormesis effects may alter the final judgment about acceptability of a given exposure. At the same time, ignoring major sources of uncertainty can evoke a sense of security and overconfidence that is not justified from the quality or extent of the data base (Einhorn and Hogarth 1978). Perceptions and world views may be very important, and difficult to sort out from matters of science, especially with large uncertainties about the risks in question.

A combination of analytic and deliberative processes can help explore these differences of opinions relating to complexity, uncertainty, and ambiguity in order to examine the appropriate basis for a decision before the decision is made. Most risk management agencies go through an elaborate assessment process and provide opportunities for public review and comment. Many controversial risk decisions become the focus of large analytical efforts, in which mathematical models are used to predict the environmental, economic, and health consequences of different management alternatives. Analysis should be seen as an indispensable complement to deliberative processes, regardless whether this analysis is sophisticated or not. Even simple questions need analytic input for making prudent decisions, especially in situations where there is controversy arising from complexity, uncertainty, and ambiguity.

Conducting deliberations on risks issues: In the course of practical risk management different conflicts arise in deliberative settings that have to be dealt with in different ways. The main conflicts occur at the process level (how should the negotiations be conducted?), on the cognitive level (what is factually correct?), the interest level (what benefits me?), the

value level (what is needed for a "good" life?) and the normative level (what can I expect of all involved?). These different conflict levels are addressed in this subsection.

First of all, negotiations begin by specifying the method that structures the dialogue and the rights and duties of all participants. It is the task of the chairman or organiser to present and justify the implicit rules of the talks and negotiations. Above and beyond this, the participants have to specify joint rules for decisions, the agenda, the role of the chairman, the order of hearings, etc. This should always be done according to the consensus principle. All partners in the negotiations have to be able to agree to the method. If no agreement is reached here the negotiations have to be interrupted or reorganised.

Once the negotiation method has been determined and, in a first stage, the values, standards and objectives needed for judgement have been agreed jointly, then follows the *exchange of arguments and counter arguments*. In accordance with decision theory, four stages of validation occur:

In a first stage, the values and standards accepted by the participants are translated into criteria and then into indicators (measurement instructions). This translation needs the consensual agreement of all participants. Experts are asked to assess the available options with regard to each indicator according to the best of their knowledge (factual correctness). In this context it makes more sense to specify a joint methodological procedure or a consensus about the experts to be questioned than to give each group the freedom to have the indicators answered by their own experts. Often many potential consequences remain disputed as a result of this process, especially if they are uncertain. However, the bandwidth of possible opinions is more or less restricted depending on the level of certainty and clarity associated with the issue in question. Consensus on dissent is also of help here in separating contentious factual claims from undisputed ones and thus promotes further discussion.

In a second stage, all participating parties are required to interpret bandwidths of impacts to be expected for each criterion. *Interpretation* means linking factual statements with values and interests to form a balanced overall judgement (conflicts of interests and values). This judgement can and should be made separately for each indicator. In this way each of the chains of causes for judgements can be understood better and criticised in the course of the negotiations. For example, the question of trustworthiness of the respective risk management agencies may play an important role in the interpretation of an expected risk value. Then it is the duty of the participating parties to scrutinise the previous performance of the authority concerned and propose institutional changes where appropriate.

Third stage: Even if there were a joint assessment and interpretation for every indicator, this would by no means signify that agreement is at hand. Much rather, the participants' different judgements about decisionmaking options may be a result of different value weightings for the indicators that are used as a basis for the values and standards. For example, a committed environmentalist may give much more weight to the indicator for conservation than to the indicator of efficiency. In the literature on game theory this conflict is considered to be insoluble unless one of the participants can persuade the other to change his preference by means of compensation payments (for example, in the form of special benefits), transfer services (for example, in the form of a special service) or swap transactions (do, ut des). In reality, however, it can be seen that participants in negotiations are definitely open to the arguments of the other participants (i.e., they may renounce their first preference) if the loss of benefit is still tolerable for them and, at the same time, the proposed solution is considered to be "conducive to the common good", i.e., is seen as socially desirable in public perception. If no consensus is reached, a compromise solution can and should be reached, in which a "fair" distribution of burdens and profits is accomplished.

Fourth stage: When weighing up options for action *formal methods of balancing assessment* can be used. Of these methods, the cost-benefit analysis and the multi-attribute or multi-criteria decision have proved their worth. The first method is largely based on the approach of revealed "preferences", i.e. on people's preferences shown in the past expressed in relative prices, the second on the approach of "expressed preferences", i.e. the explicit indication of relative weightings between the various cost and benefit dimensions (Fischhoff et al., 1982). But both methods are only aids in weighing up and cannot replace an ethical reflection of the advantages and disadvantages.

Normative conflicts pose special problems because different evaluative criteria can always be classified as equally justifiable or unjustifiable as explained in section 1 of this paper. For this reason, most ethicists assume that different types and schools of ethical justification can claim parallel validity, it therefore remains up to the groups involved to choose the type of ethically legitimate justification that they want to use (Ropohl, 1991; Renn, 2004). Nevertheless, the limits of particular justifications are trespassed wherever primary principles accepted by all are infringed (such as human rights). Otherwise, standards should be classed as legitimate if they can be defended within the framework of ethical reasoning and if they do not contradict universal standards that are seen as binding for all. In this process conflicts can and will arise, e.g. that legitimate derivations of standards from the perspective of Group A contradict the equally legitimate derivations of Group B (Shrader-Frechette, 1988). In order to reach a jointly supported selection of standards either a portfolio of standards that can claim parallel validity should be drawn up or compensation solutions will have to be created in which one party compensates the other for giving up its legitimate options for action in favour of a common option.

When choosing possible options for action or standards, options that infringe *categorical principles*, for example endangering human lives with a high probability and thus exceeding the limits of tolerability. At the same time, all sub-dominant options have to be excluded. Frequently sub-dominant solutions, i.e. those that perform worse than all other options with regard to all criteria at least in the long term, are so attractive because they promise benefits in the short term although they entail certain losses in the long term, even if high interest rates are assumed. Often people or groups have no choice other than to choose the subdominant solution because all other options are closed to them due to a lack of resources. If large numbers of groups or even peoples act in this way, global risks become unmanageable (Beck, 1996). To avoid these risks intermediate financing or compensation by third parties should be considered.

Application to hormesis: If one assumes that the hormesis hypothesis is correct and sufficient evidence has been collected to verify its basic claims. a thorough revision of the present paradigms in regulatory philosophy and actions is necessary. The minimization principle on which most of the traditional regulations rests would be in need of either replacement or refinement. If public policy is meant to improve public health and not only to prevent negative effects, there would be a necessity to seek exposure to small doses or at least to ensure that such an exposure is not prohibited by the minimization principle. In the case of toxic substances with a clear NOAEL, only little changes in the regulatory system are required. Individuals may then be advised to seek exposure rather than avoid it as long as the NOAEL threshold is not reached.

Risk management becomes more difficult and controversial if hormesis is applied to stochastic risk agents. Most dose-response models assume a finite probability for developing a detrimental health effect (most often carcinogenic and/or mutagenic effect) as a result of any exposure above zero. These stochastic effects are due to the possibility of irreversible damage to the DNA at an exposure level of a single molecule. If the hormesis hypothesis is applied to carcinogenic substances or radiation, the probability for a tumor inhibition may outweigh the probability of a tumor induction. Under these circumstances the situation might occur that a single individual may develop a tumor as a result of an exposure to a very small dose of a carcinogen, while the majority of people may experience positive inhibitory effects. Similar dilemmas can also occur with simple toxic substances if individuals vary in their sensibility towards the beneficial range of exposure in which the positive effects are observed. One individual may experience the positive effects at a different dose range compared to another more sensitive individual. How should a regulator evaluate such a situation? Is it justified to endorse exposure to small concentrations of a proven carcinogenic or toxic substance if there is a chance that a small number of people will probably be negatively affected while the majority enjoys the potential benefits? This question raises equity concerns and leads to difficult policy dilemmas.

The popular question "how safe is safe enough?" would not only need the addition of "how safe is fair enough" but also "what degree of safety implies living less safe than possible". The paradigm of minimization would need to be replaced by a new optimality rule that allows for beneficial effects of low dose exposure. Instruments for reaching this new paradigm are not yet in place and would require more deliberation and policy studies.

What would be the ethical implications for risk management if faced with such dilemmas?

First, ignoring hormesis would be immoral as the principle of assigning trade-offs between comparable goods require that all (known) benefits and risks are included in the balancing procedure. This is also true even if the effects are still uncertain yet plausible.

Secondly, the juxtaposition of positive and negative impacts of a given risks (and the respective risk reduction measures) is central to finding a morally justified policy. The newly proposed MOE Approach may be a good approximation to structuring such a balance sheet. The factor between exposure level by which 10% of the test animals develop a tumor, and the actual exposure to humans provides a good indicator of the level of protection that society would like to impose on risk-causing activities. Similarly one could calculate a hormesis factor based on the maximum beneficial effect to public health in relation to the 10% exposure. One would expect either a logistical or a sinus function staring with the 10% level and then reducing the exposure level step by step until it reaches the proposed minimum divisor of 10,000. Such a juxtaposition of protection level and hormesis level could assist risk managers to look for the appropriate trade-offs.

Third, the assignment of trade-offs between the potential detrimental effect of a given stochastic risk and the beneficial effect of hormesis as indicated by the MoE approach needs to include equity considerations, basic human rights, and values pertaining to social cohesion, integration and peaceful conflict resolution. It is not sufficient to count the people most likely to receive a benefit and weight them against those that have a higher probability of being harmed. The complexity of finding the appropriate criteria for such a comparative review requires a discursive approach to decision making as explained in earlier sections of this paper.

Fourth, the discourse to find the appropriate tradeoffs need to include those who would benefit from the activity (economic actors as well as those who are most likely to benefit from hormesis) and those who would most likely suffer from an exposure (most vulnerable groups). The main objective of such a participatory discourse is the creation of an informed consensus. All parties need to learn what is known about the potential impacts of a risk and the choices among the risk reduction options. They need to be informed about the remaining uncertainties and ambiguities associated with each impact. Based on this common knowledge they can start deliberating about the relative weights to be given to each impact category. The tools of decision analysis can assist the participants to adhere to formal as consistency, coherence criteria such and proportionality. Yet the trade-offs themselves are not pre-determined and cannot be pre-determined according to our analysis on ethics and decision making. The discourse is the place where the various arguments are exchanged and a consensus or at least a compromise might arise from the exchange of ethically informed arguments.

Fifth, the outcome of such a discourse may not provide a general rule for treating stochastic risks with known hormesis effects. It may be specific to different contexts (for example: voluntary exposure versus non voluntary), to different agents (chemicals in food versus chemicals in consumer products) or to different target groups (general population versus special vulnerable groups). What should be expected from such a discourse is not unity but convincing justification for each case.

A regulatory system that has incorporated such a discourse for trading off positive hormetic effects against negative stochastic risks is not in sight. Until now any consideration about hormesis has been excluded from the regulatory systems worldwide, partially because the evidence is still regarded as insufficient to trigger any regulatory action, partially because agencies fear the complexity and ambiguity when faced with positive and negative impacts of the same effect. But with more and more evidence coming in it will be difficult for agencies to ignore the positive effects and, as mentioned before, it would become immoral to ignore such evidence that could help people to improve their health status. Therefore, it is ethically mandated that provisions for including hormesis effects in risk management are introduced and implemented. This being said, the inclusion would not automatically lead to lower standards or a lax regulatory practice. It may be the result of an analytic-deliberative process that the discourse participants agree to place more weight on preventing stochastic genotoxic risks than on positive immunization effects caused by hormesis. If the arguments for both sides are truly considered and weighted against each other the ethical rule of balancing is met.

CONCLUSIONS

The objective of this paper was to address and discuss the use of ethical principles and decision analytic tools for standard setting procedures in risk management with special emphasis on hormesis. Organizing and structuring discourses for assigning painful trade-offs goes beyond the good intention to have all relevant stakeholders involved in decision making. The mere desire to initiate a two-waycommunication process and the willingness to listen to stakeholder concerns are not sufficient. Discursive processes need a structure that assures the integration of technical expertise, regulatory requirements, and public values. These different inputs should be combined in such a fashion that they contribute to the deliberation process the type of expertise and knowledge that can claim legitimacy within a rational decision making procedure (von Schomberg 1995). It does not make sense to replace technical expertise with vague public perceptions, nor is it justified to have the experts insert their own value judgments into what ought to be a democratic process.

Decision analytic tools can be of great value for structuring and assigning complex trade-offs. They can provide assistance in problem structuring, in dealing with complex scientific issues and uncertainty, and in helping a diverse group to understand disagreements and ambiguity with respect to values and preferences. Decision analysis tools should be used, however, with care. They do not provide an algorithm to reach an answer as to what is the best decision. Rather, decision analysis is a formal framework that can be used for trade-off analysis and risk handling to explore difficult issues, to focus debate and further analysis on the factors most important to the decision, and to provide for increased transparency and more effective exchange of information and opinions among the process participants. The basic concepts are relatively simple and can be implemented with a minimum of mathematics (Hammond et al. 1999).

Many risk management agencies are already making use of decision analysis tools. This, however, need further refinement. It is necessary to use these tools in the context of an iterative, deliberative process with broad participation by the interested and affected parties to the decision. The analytical methods, the data and judgment, and the assumptions, as well as the analytical results should be readily available and understood by the participants. Both the risk management agencies and the interested groups within the public that government agencies interact with on risk management decisions should all gain experience with these methods.

With respect to hormesis it is ethically mandated that potential beneficial aspects of low exposure to potentially hazardous material are incorporated in the risk-benefit balancing procedure. The potential harm done by pollutants does not justify the invocation of a categorical principle. Minimisation of risk is not required if health benefits are also at stake. Society needs to find an informed consent on the threshold of risk below compensation of goods is legitimate and morally justified. Such a threshold can be defined context-specific but any human action associated with potential health impacts makes such an acceptability judgment - implicitly or explicitly. Incorporating hormesis into risk management forces regulators to make such thresholds explicit. Once as risk is below this threshold all positive and negative impacts are subject to a relative balancing towards reaching a final judgment on acceptability and necessary risk management options. This balancing risk cannot be reduced to body counts: equity issues, context specific circumstances (voluntary or involuntary exposure, for example), avoidance of risks, the nature of vulnerable groups and many other factors need to be taken into account. Such a complex weighing exercise is best

performed by an analytic-deliberative process by which the best available knowledge of impacts (including their uncertain ties) is fed into a deliberating body of individuals representing all sides of the debate. Such a debate would be inspired by the consensual and procedural school of ethics in which rational discourse seen as the most suitable instrument to come to a morally superior conclusion when facing conflicting values and principles. If such discourses were made effective in regulatory decision making, the debate about hormesis could act as a catalyst for need regulatory reform.

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