Acceptability and safety objectives, use of concepts through various areas

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Summary

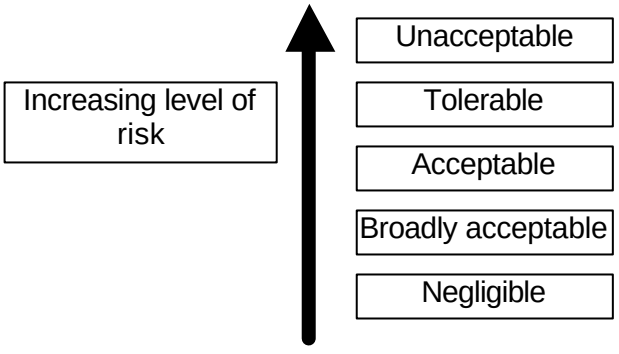
The definition and use of the acceptability concept has not been developed in an homogeneous way among all sectors of activities, and various interpretations have emerged. Many policy documents have been issued that allow to identify goals and criteria for safety policy. However, such documents may fail to reveal the practical use of the concepts, and complementary information may be available in administrative guidance and in some studies already made by research teams. The purpose of this study is to review these existing acceptability concepts and to suggest, if possible, some harmonization in the concepts and the vocabulary used in the different areas.

Though this review cannot be exhaustive, one must agree that there are many words and values in different areas for the definition and quantification of risk acceptability. Figures found in the literature search in are not all presented, but the examples given here are representative of what was found.

The figures for the individual lifetime risk of death due to a life long exposure cover many orders of magnitude, ranging from 10^{-8} to 10^{-3}. However most figures for an acceptable or a tolerable risk range between 10^{-6} to 10^{-4} but either for one year of exposure or a whole life exposure. Clearly enough two acceptability concepts emerge behind such figures, the "negligible" level and the "intolerable" level.

One fundamental condition for a proper definition and use of quantitative risk acceptability criteria is to be really convinced that numbers and figures do not solve all issues. After the increasing use of quantitative assessments, there is now a trend to moderate this approach by giving more importance to all the qualitative aspects of risk management. In its recommendations, the US Presidential/Congressional Commission on Risk Assessment and Risk Management insists on the weight of the qualitative information of a risk to make it acceptable.

Finally, and in order to suggest some harmonization of the acceptability frame, it can be drawn from this study a proposal hierarchy of terms to qualify risks. This is a suggestion that is consistent and more or less used in different sectors. It needs to be approved by all risk assessors and managers. If agreed and used, this qualitative hierarchy would give some consistency to all risks analysis and without associated figures, it would still allow the integration of specific quantitative aspects in a particular situation, for a particular risk.



Proposal for a qualitative hierarchy of acceptability risk adjectives

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1. Introduction

Most of human activities that have contributed to the economic progress present also some disadvantages, among which are the risks of different kinds that adversely affect the human health. This threat can occur through air or water pollution due to industrial activities (chemical plants, transportation), through food containing chemical additives and pesticides, through the use of radioactivity to produce electricity,... Despite all the possible efforts to reduce the threat, it is now well recognized that the zero risk objective is unobtainable or simply not necessary for human and environmental protection and that a certain level of risk in a given situation is deemed "acceptable" after considering the benefits obtained besides. Risk managers must cope with some residual risks, and thus define acceptable risk levels, concepts and criteria defining what can be neglected and what must be taken into account when defining safety policies for the protection of health.

The definition and use of the acceptability concept has not been developed in an homogeneous way among all sectors of activities, and various interpretations have emerged. Many policy documents have been issued that allow to identify goals and criteria for safety policy. However, such documents may fail to reveal the practical use of the concepts, and complementary information may be available in administrative guidance and in some studies already made by research teams.

The purpose of this study is to review these existing acceptability concepts and to suggest, if possible, some harmonization in the concepts and the vocabulary used in the different areas. Going back to definitions in risk assessment and risk management is important because of the wide range of uses of the acceptability approach, and the different meanings of terms used by different groups of experts and practitioners. This study consists of a literature search and collection of findings and aims to provide references on the concepts and the associated vocabulary and numbers in safety policies. It collects definitions and numerical applications of concepts such as acceptable risk, negligible risk, tolerable risk, safety objective, virtually safe exposure, in various areas (e.g. major hazards, polluted sites, food, air pollution, occupational carcinogens) and in various countries (e.g. USA, UK, The Netherlands, France) or by various institutions (e.g. International Commission of Radiation Protection-ICRP-, U.S. Presidential Congressional Commission, Health and Safety Executive in the UK). Practical approaches developed for the application of the concepts are investigated through administrative guidance, analyses of research teams, IPSN own experience. The definition and use of quantitative indicators of risk levels are described and compared to get some opinion on their practicability.

Risk acceptability can be defined as the predisposition to accept the risk, or as defined by the Health and Safety Executive (HSE) "the willingness to live with a risk so as to secure certain benefits and in the confidence that it is being properly controlled" [17]. The definitions allow various interpretations of the acceptability. As a matter of fact, one can distinguish the "technical" acceptability defined by technicians, scientists, economists and decision-makers from the public acceptability, that is lay people who are judging, each one with his/her individual view of the situation, the acceptability of a project, an activity, a product, a natural or industrial disaster[1]. Of course the acceptability of one particular risk depends on a good fit between the two types of acceptability and on the degree of interaction between decision-makers, bodies in charge of risk management and the public. In the literature, this difference in risk characterisation is often described through the concepts of "acceptability" for the professional/governmental judgement and "acceptance" for the public judgements [2]. Thus, a risk deemed acceptable for the professional and governmental bodies, can be defined as not accepted due to public resistance (e.g. nuclear industry in some countries) and on the contrary, a risk considered unacceptable by a government can be accepted by the public (e.g.

car driving, smoking). However, this study focuses mainly on the "technical" acceptability, as it is defined and used by scientists, policy makers, regulatory bodies. The public perception and acceptance have voluntarily been kept aside of this review.

Quantitative Risk Assessment (QRA) has been increasingly used since the early 70's. In the general process of risk assessment (hazard identification, exposure assessment, dose response assessment, risk characterisation) the use of numerical values has pushed the definition and choice of reference values or acceptable values to compare the quantified risk to. The present study does not look into QRA methods. Risk assessment and risk quantification are not discussed for themselves here. Acceptability concepts discussed here are the link between the risk assessment phase and the risk management decision making process. It is assumed that the risk is quantified by whatever model and one wants to tell whether it is acceptable or not. However, there is one aspect of QRA that has a great importance in discussing the acceptability : like all assessment techniques, whether QRA is experimental or by mathematical modelling, it is an uncertain process and any numerical result has a certain range of uncertainty, because of some lack of data, some specific choice of hypotheses and some approximations. It is not always possible to quantify this error, but it is essential to keep this uncertainty in mind when comparing apparent exact values of risk estimates to standards, limits, or thresholds.

This study covers a wide range of areas and several countries, but does not pretend to be exhaustive. Many references are drawn from the radiation protection area, due to the experience gained by the authors in this field.

2. Definitions, concepts, historical evolution and general findings

2.1. Semantics

Quantification of risk and criteria of acceptability, before giving rise to numbers, are always expressed in a more qualitative way, using qualifying adjectives. Indeed, in policy documents dealing with risk assessment and management, either for general statements or specific recommendations in a particular field (pesticides, food additives,…), a large number of wordings can be found to express the quantification and the level of acceptability of a risk. Wordings found in this research are collected in Table 1. The adjectives apply to risk, but some of them are also used to qualify the exposure to some toxic substances, to carcinogens, the dose received during an exposure, even the harm or injury caused by an event.

Table 1 : Qualifying risk acceptability

Risk criteria :	**Derived criteria :**
Unacceptable risk	De manifestis level
Unreasonable risk	Reference dose
Acceptable risk	Reference concentration
Tolerable risk	Acceptable daily intake (ADI)
Admissible risk	Tolerable daily intake (TDI)
Residual risk	Virtually safe dose
De minimis risk	Absolute safety
No-significant risk	Permissible dose
Zero risk	

The various risk qualifications of Table 1 will be commented in the following chapters. However, a few definitions are already given to precise some concepts.

- The *reference dose* describes a lifetime exposure or intake rate judged small enough to cause no detectable injuries in a large population so exposed (see chapter 2.4).

- The term "*de minimis*" is derived from the roman principle "de minimis non curat lex", or "the law does not concern itself with trifles". The basic concept is that, for any environmental agent or condition, there should be a level that is so low that efforts at further reduction are unnecessary. Concepts related to de minimis include "threshold limit" and "below regulatory concern" [3]

- *Residual risk* is defined as "the health risk remaining after risk reduction actions are implemented, such as risks associated with sources of air pollution that remain after the implementation of maximum achievable control technology" [14].

- The *de manifestis level* of risk is a concept largely commented by Travis[4]. He defines it as a "ceiling above which events are inherently unsafe and should be regulated without regard for cost." An interesting study made by his research team on regulatory decisions concerning air pollution is presented in chapter 3.3.

- The *virtually safe dose* appeared in the earliest US Food and Drug Administration (FDA) proposal for risk acceptability and was associated with an incremental lifetime cancer risk of 1 in 100.000.000 (10^{-9}).

- The *permissible dose* was commonly used by ICRP in its first publications[5]. It was defined as the dose that "involves a risk that is not unacceptable to the individual and to the population at large."

- In its guidelines for drinking water quality, WHO distinguishes ADI and TDI : "acceptable daily intakes are established for food additives and pesticide residues that occur in food for necessary technological purposes or plant protection reasons. For chemical contaminants, which usually have no intended function in drinking water, the term tolerable daily intake is seen as more appropriate than acceptable daily intake, as it signifies permissibility rather than acceptability" [32].

2.2. Threshold and non-threshold substances risk quantification and acceptability

Behind the vocabulary presented above, there is a distinction between two concepts of acceptability that has to be explained before any further discussion. It is the distinction made between carcinogens and non-carcinogens, for which two different methods for the dose-effect relationship are applied.

For non-cancer risk assessment and definition of acceptable levels, the threshold dose method is applied. The threshold is defined as the dose of the toxicant below which no adverse effect occur and above which adverse effects occur. To identify the threshold of a toxicant, traditional methods include the identification of the Lowest Observable Adverse Effect Level (LOAEL) and the No Observed Adverse Effect Level (NOAEL) by experiments on animals. The threshold dose is assumed to be between these two levels. To establish the safe human dose, the NOAEL is divided by various "security factors" (also called "safety factors"). Those factors represent a default approach to account for animal to human extrapolation and for average to sensitive population extrapolation from inadequately designed

experiments. Typical factors are : 10 to pass from animal to human, 10 to consider inter-individual variability and another 10 for security margin, but there exists case by case adaptation of these factors, which will not be presented here[8]. The threshold approach is used by toxicologists, in order to define tolerable exposure values [6]. In its guidelines for drinking-water quality[32] and air quality[7], WHO uses the term "uncertainty factors" instead of security factors or safety factors, adding that "the uncertainty factors were essentially determined through scientific judgement in consensus". This semantic precaution emphasizes the fact that the approach, even if based on experiments, still contains some approximations, due to some lack of knowledge.

This methodology leads to the definition of acceptable daily intakes (ADIs) or tolerable daily intake (TDIs) and concentration. It was first used by the US FDA for additives and contaminants in food. The definition of ADI is "an amount that can be ingested daily for a lifetime without harm"[8]. With this approach, it is assumed that when exposure remains below Adis and TDIs, there is no risk of adverse effect.

Dose-response evaluation for carcinogens (or suspected carcinogens) differs from that used in traditional toxicology. The no-threshold model is prominently used in cancer risk assessment. Advocates for this model often postulate that cancer can arise from a single change to the DNA of a single cell but they may also rely on models where many steps are necessary between the exposure and the alteration of DNA. Assessors of cancer risk assume that any dose of a carcinogen, even small, increases the probability of tumour formation. Indeed, it is generally considered that the initiating event in the process of chemical carcinogenesis is the induction of a mutation in the genetic material (DNA) of somatic cells. Because the genotoxic mechanism theoretically does not have a threshold, there is a probability of harm at any exposure. Therefore the development of an ADI or TDI is inappropriate and mathematical low-dose extrapolation models are used, to extend the dose-response curve from the high doses to which animals are exposed in the laboratory to the lower doses to which humans are exposed in the environment. The linearized multistage model is generally adopted, but other models can be used in specific cases. These models allow to play with numbers and associate a level of cancer risk to a particular dose, or conversely to calculate the maximal “acceptable” dose to respect a maximum acceptable risk of developing a cancer. Due to the no-threshold model, it is clear that the definition of an acceptable risk does not mean that there is a definite no-adverse effect zone, as it is assumed for non-carcinogens.

This distinction between carcinogens and non-carcinogens naturally raises the question of the carcinogenicity of a substance. The major reference to this issue is the classification of the International Agency for Research on Cancer (IARC) . Substances are classified into three groups:

Group 1: Proven human carcinogens.
Group 2: Probable human carcinogens. This category is divided into two subgroups according to higher (group 2A) and lower (group 2B) degree of evidence.
Group 3: Unclassified substances.

Based on this classification, institutions decide what model they use for a substance. For instance, in its air quality guidelines, the general rule followed by WHO is that for all chemicals not categorized in groups 1 and 2A, the non-carcinogenic threshold methodology must be applied.

Since there is much less variability among various risks in the definition of acceptable exposure to threshold substances (the levels of acceptability differ, but the methodology is

always the same), this study will focus on the acceptability of carcinogens, for which various approaches are used to derive some numerical reference values.

2.3. The acceptability versus tolerability debate

There are many documents defining what an acceptable risk means. Among the several definitions collected by a working group of the French "Observatoire de l'opinion sur les risques et la sécurité" [9], the most general comes from the HSE TOR document (see chapter 2.5) [17] : "For a risk to be acceptable means that for purposes of life or work, we are prepared to take it pretty well as it is."

But when considering aspects of risk management other than technical knowledge, i.e. perception by the public or ethics, the adjective "acceptable" appears to be too strong. Therefore the adjective "tolerable" is proposed by several people and seems to have been taken up by most of the risk managers.

To illustrate this important refinement we report here what R. Kasperson[10] states : "The term risk acceptability carries the inference that society knowingly and willingly accepts risks as the reasonable price for a beneficial technology or activity. But most risks are imposed or imperfectly informed risk bearers who often lack the freedom to accept or reject the risk….Hence the term risk tolerability more adequately describes the nature of the problem."

A similar statement is maid by Paul Makin, chairman of an ISO group the task of which was to prepare a new version of an ISO Guide related to the inclusion of safety aspects in standards [11]. He says :"We all live with the fact that, for practical purposes, the product, process or service will not be risk-free. How do we describe this state ? Our first approach was to use the term "acceptable risk". But we quickly rejected this term from the philosophical point of view that no risk is "acceptable" although the individual or society may choose to live with that level of risk because of the perceived benefits. In practice we are always seeking to reduce the risks and what would be acceptable to one generation becomes unacceptable to the next. Looking for a term that would identify a stage in the risk reduction process,(…) after much discussion, the term that would satisfy our requirements was : tolerable risk - risk which is accepted in a given context based on the current values of society."[11 12]

As demonstrated, the difference between acceptable risk and tolerable risk is well agreed by all. However, in practice, both terms are often used equally.

2.4. Types of criteria for judging acceptability

Despite the great variability in quantitative risk assessment methods and the numerous indicators calculated, the criteria on which acceptability is judged are very few.

Individual risk is the major acceptability criterion. The indicator retained is usually the full life incremental risk of death of a particular person from the exposure, expressed as the probability of dying of, lets say, "1 chance in a million" or equally a risk of 10^{-6}. It can also be explained as the chance that a person in a million population will die because of the exposure. This indicator refers usually to either a lifetime exposure or a year of exposure.

When considering the risks associated with a plant or an operation, the risk to an individual is not necessarily an adequate measure of the total risk: the number of individuals at risk is also important. The presentation of the combined risk to a number of people is called the societal risk. As defined by the English Institution of Chemical Engineers, it implies the "realisation of a specified hazard". That is why it is often used to characterize the acceptability of an acute

risk, a disaster, like the explosion of a hazardous storage, and not for the continuous exposure to a toxic substance. It is usually expressed by the combination of the number of fatalities and their probability of occurrence and represented by the so-called F/N curves (obtained by plotting the frequency F at which an event might kill or harm N or more people, against N). Societal risk is mainly derived when many individuals are at risk but each one being at low risk. Good examples for using societal risk estimations are the acceptability judgements related to the proposals of new developments in the vicinity of existing major hazard installations.

Derived criteria, such as the ones quoted in table 1, directly allow to judge the acceptability of the risk associated with some product or activity. In general, they are more operational than a number of expected death (i.e. concentration in food, in air, and any other measurable quantities) but are somehow correlated with the ultimate indicator that is the incremental risk of death.

In very few cases and depending on the area of interest, one may find non fatal issues in the design of acceptability criteria, such as loss of life expectancy, occurrence of non fatal cancers,... An interesting thought is made by HSE in its guide "Risk criteria for land-use planning in the vicinity of major industrial hazards "[13]. Because in a population all individuals may not have the same vulnerability towards a pollutant, because of the complexity of the pollutant dispersion, all individuals may be exposed differently, and because society is concerned about risks of serious injury or other damage as well as death, HSE suggests, for major hazards, to use an injury criterion other than death. "For example, it is possible to define a dose of toxic gas, or heat, or explosion overpressure which gives all the following effects :

- severe distress to almost everyone;
- a substantial fraction requires medical attention;
- some people are seriously injured, requiring prolonged treatment;
- any high susceptible people might be killed.

This might be described as a " dangerous " dose. " Examples are given in the chapter 3.5.

2.5. The evolution of the acceptability concepts

- The Federal Food Drug and Cosmetic Act (FFDCA) and the Delaney clause

The original FFDCA dates to 1906, making it by far the oldest among US federal laws concerned with the regulation of public health risk from toxic substances. The Delaney clause, section 409 of the Federal Food Drug and Cosmetic Act (FFDCA) is the classic example of the zero-risk statute. Enacted in 1958, the Delaney clause prohibits any pesticide residue " if it is found...to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal ". This stipulation prohibits consideration of the quantitative level of risk that an additive might pose, effectively avoiding the quandary faced under other environmental laws of defining " acceptable " levels of cancer risk. Anything else than zero risk is unacceptable. The Delaney clause was first used by the Food and Drug Administration (FDA) but under the FFDCA, also EPA sets, but not enforce, maximum allowable levels of pesticides residues for raw agricultural commodities, animal feed and processed food.

From the beginning, implementation of the Delaney clause was problematic. Since a finding of cancer risk under the Delaney Clause would trigger complete prohibition of the residues, EPA was reluctant to identify cancer risks under the clause. One of the reason why EPA could not keep this concept any longer, at least in such an abrupt way, was its concern about

the relative carcinogenicity of older and newer pesticides. Because pesticides approved in earlier decades were not adequately tested to identify their carcinogenic potential, EPA is concerned that strict application of the Delaney Clause to new pesticides, tested with more severe standards and thus proven to be carcinogenic (but still less than older ones), prevents the replacement of more dangerous older chemicals with safer new ones. Thus EPA implemented a negligible risk policy. Pesticides were divided into those that pose only negligible risk (defined as a quantitative level of lifetime individual excess risk of 10^{-6} or less) and those that pose a greater risk and hence must be carefully considered. This is called the " de minimis " interpretation of the Delaney Clause. It calls for more quantitative risk assessments, to differentiate the negligible risk pesticides from the non negligible risk ones, and gives rise, after the zero risk acceptable to the " bright line " acceptability concept.

- The "bright lines" levels

The concept of the "bright line" acceptability level consists of a quite drastic separation between the unacceptable risks and the acceptable risks, without any further refine considerations in the acceptable region. The definition given in the glossary of the final report of the US presidential/congressional commission on risk assessment and risk management [14] is "specific level of risk or of exposure that is meant to provide a practical distinction between what is considered safe and what is not". It is seen as a very pragmatic tool for those making risk management decisions and those in charge of the enforcement of the decisions. Some practical examples of the use and interpretation of bright line criteria are presented in chapter 3. Among the controversies about bright lines, it is argued that a "strict bright line approach to decision-making cannot explicitly reflect uncertainties about risks estimates, population variation in susceptibility, community preferences and values, economic consideration"[14], and any case-specific parameter. Bright lines can give the impression of an exact boundary between safety and risk. However, this simple dichotomy between acceptable and unacceptable is not really abandoned but a more subtle frame has spread over and is described below as the multi-level scale of acceptability.

- The multi level scale

In the early 80's, a study by Kastenberg[15] et al. made a review of proposed quantitative risk assessment criteria of that time. They suggested a classification of the criteria into three categories :

1. point criteria,
2. frequency-consequence criteria,
3. risk benefit criteria.

"The criteria of the first category take the form of an upper non-acceptance limit, a discretionary range and a goal level of risk. The compliance with the upper limit is required. Within the discretionary range, many factors are considered in the decision, and risk estimates below the goal level are considered to be in compliance with the risk limits".

The second category corresponds to the well known curves (also called Farmer curves or F/N curves, see chapter 2.4) showing the relationship between the frequency of occurrence and the magnitude of consequences for a wide spectrum of accidents. These curves make a frontier between an acceptable and a non-acceptable zone on a graph of frequency versus consequences of an accident. Several examples in the civil nuclear energy are given by the author.

Finally, the third category proposes a gradual limit on individual risks as function of the benefits that can be gained from the risky activity. Here again figures are given to illustrate the concept, for example the "de minimis approach" of C.L. Comar [16] .

He proposed to :

1. eliminate any risk that carries no benefit or is easily avoided,
2. eliminate any large risk (1 in 10000 per year or greater) that does not carry overriding benefits,
3. ignore for the time being any small risk (about 1 in 100000 per year or less) that does not fall into category 1,
4. actively study risks falling between these limits, with the view that the risk of taking any proposed action should be weighed against the risk of not taking that action.

In 1986, HSE published the first version of the document "The tolerability of risk from nuclear power stations" that would later become the world-wide known "TOR document" very often quoted as a reference. After several years of discussion, the final version of the document[17] was published in 1992. It was originally dedicated to the nuclear community, but since it is now referenced among many risk areas,it is presented it in this part of the review and not in the nuclear section of chapter 3. The TOR philosophy is not a revolution nor a big innovation in the international debate on risk acceptability, but it must be given credits for laying down the most widely used approach. Indeed, with slight differences in the vocabulary, other countries or organisations advocate for a similar approach in different fields (Switzerland [18], the Netherlands [19] [20], ICRP,…).

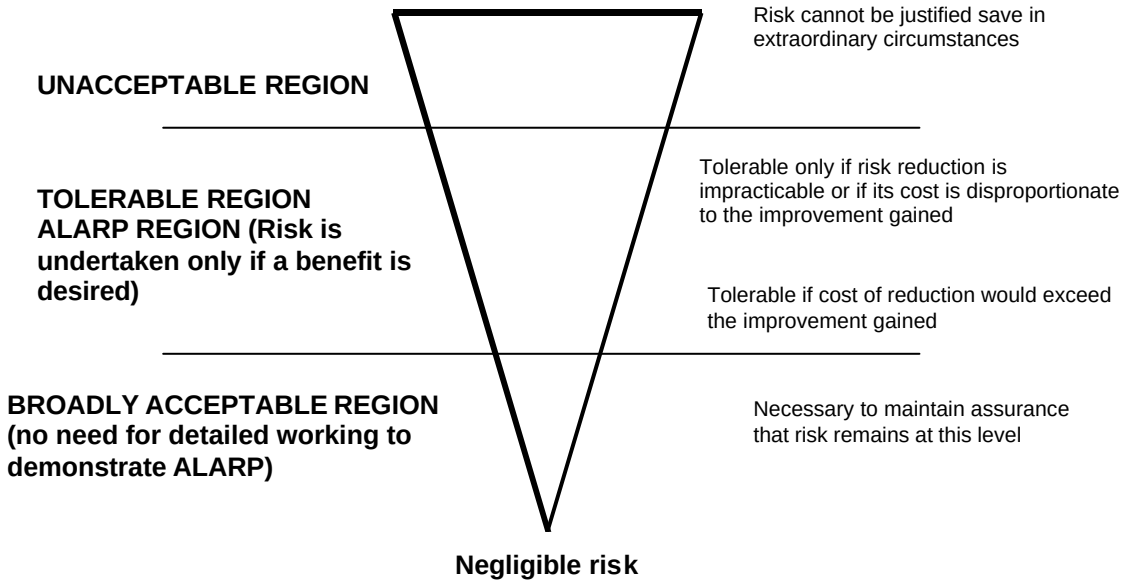


Figure 1 : HSE criteria for the tolerability of risk [21]

As shown on Figure 1, the acceptability level of a risk can be judged with a three regions scale : the unacceptable region, the tolerability region and the broadly acceptable region.

To define these concepts, HSE states that "Tolerability does not mean acceptability. It refers to a willingness to live with a risk so as to secure certain benefits and in the confidence that it is being properly controlled. To tolerate a risk means that we do not regard it as negligible or something we might ignore, but rather as something we need to keep under review and reduce still further if and as we can. To fit in the tolerability region, a risk must be kept as low as reasonably practicable (ALARP principle). It is also clearly stated that a risk is regarded as intolerable when it cannot be justified in any ordinary circumstances. Finally, the broadly acceptable region is set by the point at which the risk becomes comparable to those that people regard as insignificant or trivial".

In the TOR document, figures are clearly proposed to define the three regions. The numbers mainly refer to individual risks, for public or workers, but HSE has also included the societal risk dimension in the TOR philosophy and some examples are given below. HSE is also very cautious when giving numerical values, and stresses that they are guidelines to be interpreted with common sense and are not intended to be rigid benchmark to be complied with in all circumstances.

To distinguish the broadly acceptable and the tolerable region, "HSE believes that an individual risk of death of one in a million per annum for both workers and the public corresponds to a very low level of risk and should be used as a guideline for the boundary between the broadly acceptable and tolerable regions." The bases for such a value are, as usual, not very clear, except for the fact that HSE argues that a residual risk of one in a million per year is extremely small when compared to the "background level of risk" to which we are exposed in our daily environment (typically a risk of death from any cause of one in a hundred per year averaged over a lifetime).

To differentiate the tolerable and unacceptable regions, HSE states that "broadly, a risk of death around 1 in 1000 per annum is the most that is ordinarily accepted by substantial groups of workers in any industry in the UK. It seems therefore reasonable to adopt a risk of death of around 1 in 1000 as the dividing line between what is just about tolerable as a risk to be accepted by any substantial category for any large part of a working life, and what is unacceptable for any but fairly exceptional groups."

"Workers are aware of the risks they run, and have some choice in the matter. However, the public cannot choose whether to be exposed or not, that is why the acceptable level of risk for public is always set as a lower value than for workers. Thus, a value of 1 in 10000 per annum is proposed for the maximum tolerable risk for public".

In 1999, HSE published a discussion document to continue and broaden the debate around the risk acceptability issues, since the "TOR philosophy" is now referenced across the full range of risks. The document is called "Reducing risks, protecting people"[21] and was open for discussion and comments through the year 1999. This document does not modify the findings exposed in the TOR document, but suggests more flexibility for the boundary between the tolerable region and the unacceptable region. It says: "We do not have, for this boundary, a criterion for individual risk as widely applicable as the one between the broadly acceptable and tolerable regions. This is because risks may be unacceptable on grounds of a high level of risk to an exposed individual or to the repercussions of an activity or event on wider society." As the example of a railway disaster shows, the low level of average risk to any one individual does not necessarily make it acceptable in the affected population. However, the values given in the TOR document and mentioned above are not abandoned since they are still presented in this last document.

In addition to these individual risk levels, HSE also suggests some tolerability limits for risks giving rise to societal concerns. The comparison of probability-consequences curves (F/N

curves, see paragraph 2.4) of man-made accidents and natural disasters helped to define such values. “Thus, HSE proposes the following basic criterion for the limit of tolerability, particularly for accidents where there is some choice whether to accept the hazard or not, for example the risk of such an event happening from a major chemical site or complex continuing to operate next to a housing estate. In such circumstances, HSE proposes that the risk of an accident causing the death of fifty people or more in a single event should be less than one in five thousand per annum. ” (see chapter 3.5 for detailed value on societal risk).

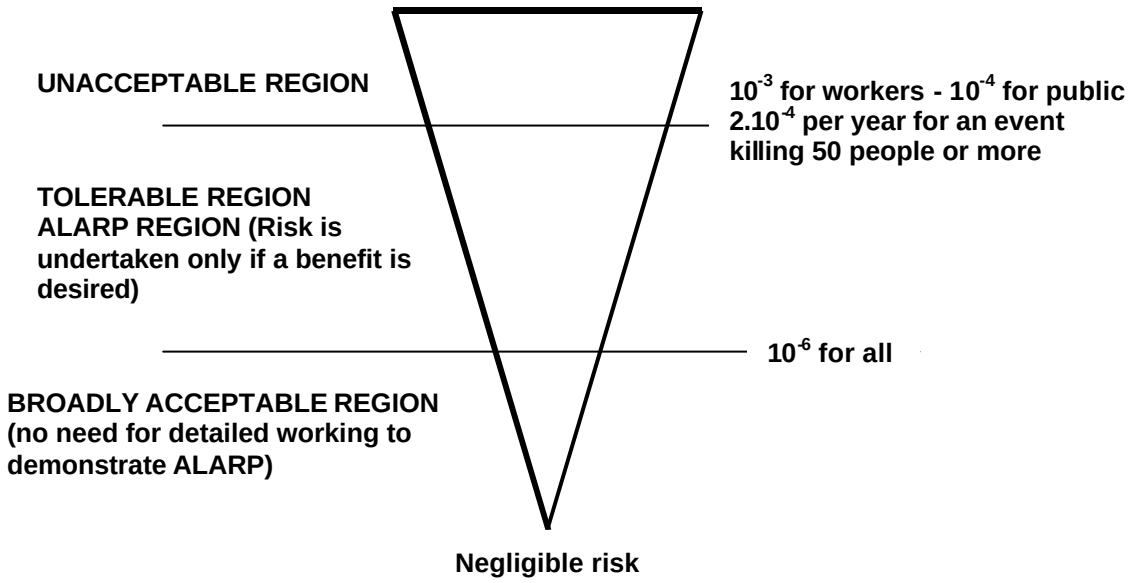


Figure 2 : HSE suggested figures associated to criteria for the tolerability of risk [21]
Numbers refer to one year of exposure

3. Practical approaches for the application of the concepts in different areas and countries

This chapter presents some practical approaches for the application of acceptability concepts in different areas and countries, with associated figures. It does not intend to be exhaustive and is based on documents made available to IPSN either by academic literature research or by its relations with other institutions.

For the description of the US approaches, the chapter rely mainly on the work done by the Presidential/Congressional Commission on risk assessment and risk management.

3.1. Nuclear industry

In its publication 60[22], the International Commission on Radiation Protection (ICRP) presents the current recommended radiation protection policy for both workers and the public. ICRP uses three words to characterise the scale of acceptability from radiation exposure. The first word is "unacceptable" and indicates that exposure would not be acceptable on any reasonable basis during normal operation. The bottom boundary of unacceptable exposure is very clearly defined by a bright line called dose limit. When not unacceptable, exposure is then "tolerable", or preferably "acceptable" when optimisation is completed. ICRP publication 60 sets the dose limits for workers and public. Since 1990, ICRP has introduced the concept of "dose constraint" to differentiate the tolerable and acceptable zones. It is a recommended maximum value (not a limit) for the exposure to one single source of radiation. It can be seen as an upper starting point to the optimisation of the exposure to that source. In publication 81[23], ICRP recommends an upper numerical value for the dose constraint. There is also a level of risk that is trivial, and the source of exposure will automatically be considered acceptable[24]. As shown on figure 3, the frame of acceptability of ICRP is very much similar to the TOR philosophy, at least for individual risks.

One particularity of the nuclear community is to define the acceptability in terms of dose (in Sievert Sv, mSv,….) more than of risk, but the reasoning is the same. The conversion factor used by ICRP to convert dose in fatal risk is 5.10^{-2} per Sievert. In addition, and only for public exposure, some additional considerations are integrated to choose round numbers for dose limit and dose constraint values, such as natural background radiation and simultaneous exposure to several sources of radiation.

In terms of risk, ICRP considers that a risk of death of 1 in 1000 per year is the most that is ordinarily accepted nowadays for workers, and adopted this figure as the dividing line between what is just tolerable and what is unacceptable. For members of the public, ICRP, after discussions, finally retained a level of risk of death of 1 in 10000 as the bright line between unacceptable and tolerable risk. For all categories of population, ICRP agreed to consider a fatal risk in 1 in 1000000 per year as trivial.

In terms of doses, these maximum acceptable risk levels correspond to a annual limit for worker of 20 mSv. To be more precise, the actual recommendation of the ICRP for workers is an average dose over 5 years of 20 mSv/y and a maximum dose of 50 mSv each year. For the public, accounting for all considerations, the dose limit is set at 1 mSv/y and the dose constraint at 0.3 mSv/y [23].

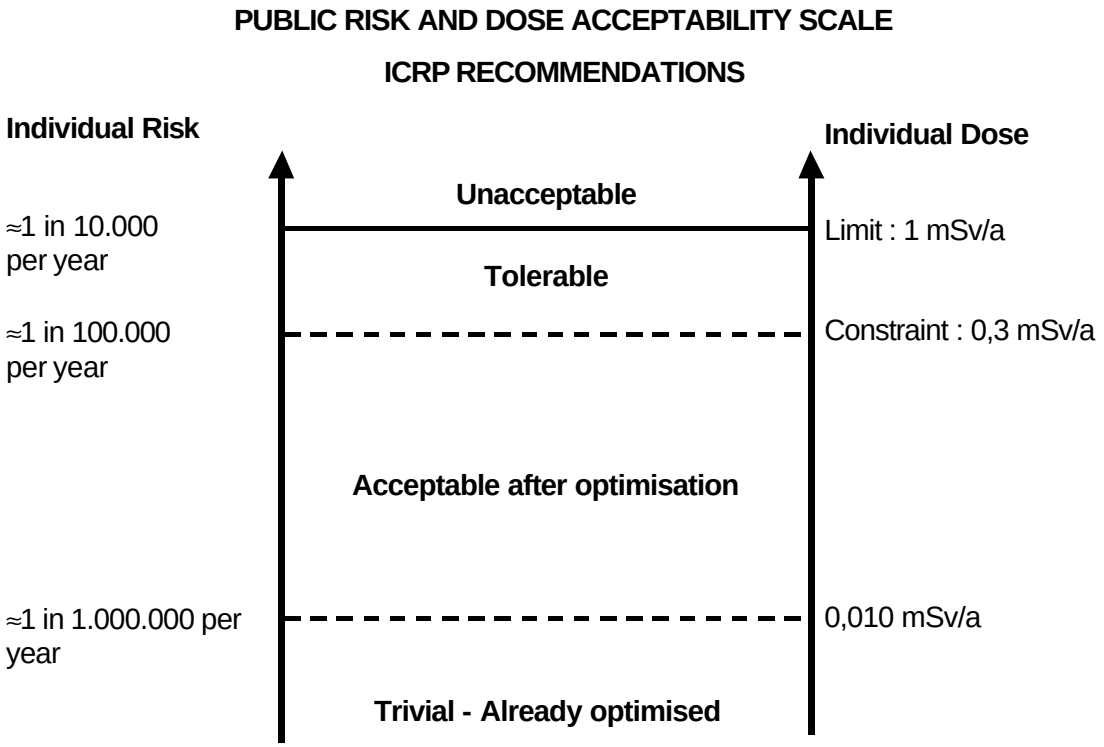


Figure 3 : Schematic diagram of the acceptability of risk according to ICRP [22] [23] [24]

ICRP states that the recommended values might be exceeded in some special circumstances, but countries usually follow ICRP recommendations and give a regulatory status to the values given above.

To conclude with the ICRP approach, we must precise that this frame concerns only normal operations. In case of an abnormal situation or accident, the acceptability frame is no more valid. ICRP elaborates a different radiological protection system for these "intervention" situations with no quantified acceptability levels. The recommendations can be briefly described by the two following principles :

> "Any intervention must do more good than harm so the reduction in radiation detriment must exceed the harm and social cost of the intervention"
> "The scale and duration of the intervention should be optimised such that the net benefit of the reduction in dose, i.e. the benefit of the reduction in radiation detriment less the detriment associated with the intervention, should be maximised."

Concerning the consequences of nuclear accidents, ICRP[25], IAEA[26], the European Commission[27], among others, recommend intervention levels, which are indicative values of exposure on which one can decide to take some protective action. However, these dose levels (or averted dose levels) are not based on any acceptability judgement. The derivation of these levels results from generic considerations and compromises between advantages and costs of implementing the protective actions. These quantitative indicators are not meant to define some acceptable or tolerable risk level. They are only tools for emergency response planning and emergency management.

Despite this lack of international recommendations or regulations to characterise the level of acceptability for accidental situations in the nuclear industry, many operators, for their design objectives and their safety demonstration, have used F/N curves. Either on a continuous way or by steps, these curves plot the probability of occurrence of a spectrum of accidents against their consequences (in terms of fatalities, doses, number of thyroid cancers,…) and thus define an acceptable region and an unacceptable region. As in other fields, this approach is usually associated with the probabilistic quantification of the risk. An illustration of this approach, quite old but very representative, is "the Index of risk exposure and risk acceptance criteria"[28], which is a review of literature on years 1975-1980 covering all articles relevant to nuclear power plant risk assessments and to the possible establishment of the acceptability of calculated nuclear power plant technical and environmental risks.

In France, this approach has never been accepted as a standard for safety demonstration and the authorities claim for a deterministic assessment of the consequences of some reasonably envelope accidental scenarios. The acceptability of the so called "design base accident" is judged on a case-by case basis and no generic criteria are used.

In Germany the situation is different. The design base accident scenarios, the methodology to calculate the consequences (either deterministic or probabilistic), and even the dose values that determine the maximum acceptable consequences are fixed by a radiological protection ordinance[29], which is a regulatory document. In that frame, as long as an operator demonstrates that the whole life dose received by a member of the public after an accident (under well defined conditions) is below 50 mSv, its plant is deemed acceptable. If we used the dose-risk coefficient of ICRP (5.10^{-2} per Sv theoretically not applicable in the context of an accident) this gives a whole life incremental risk of death of 2.5 10^{-3}, which is quite a high value compared to the broad spectrum of existing values. However, this rough estimate must be balanced by the voluntary choice of a very conservative methodology for dose assessment and the much lower dose level actually computed by plant operators in their safety demonstration.

3.2. Hazardous waste, Polluted Sites

In the US, hazardous waste is defined by the Resource Conservation and Recovery Act (RCRA which is the national policy for solid waste) as a solid waste that may cause or significantly contribute to an increase in mortality or an increase in serious irreversible illness, or otherwise present a potential hazard to human health or the environment.

From the Rhomberg report[8], we can note that for the risk characterisation and regulation, individual risks are calculated and "individual lifetime cancer risk levels of 10^{-5} or so from unregulated disposal trigger listing of a waste as a hazardous substance and hence subject to RCRA controls on handling and disposal. Newer methods are adopting a range of 10^{-4} to 10^{-6} for the individual lifetime cancer risk, in which a decision can be made. Delisting a substance as a hazardous waste requires a lifetime risk estimate less than 10^{-6} for unregulated disposal. Incinerators permits have usually been granted if individual risks are below 10^{-5}. Remediation of active waste sites depends on many non-risk technical and other factors, some of them being site-specific, but a post-remediation risk level of 10^{-4} to 10^{-6} (lifetime cancer risk) is aimed at".

Still in the US, the rehabilitation of sites polluted by chemical substances is managed by the Superfund program. For carcinogens, risk is estimated as the excess individual lifetime risk of cancer. For noncarcinogens, exposure to individuals is assessed by comparison of estimated doses to the respective reference doses. Despite the fact that population risks are not formally considered under EPA Superfund policy, the magnitude of the potentially exposed

population sometimes informally affects remedial decisions. In the early 80's, when the Superfund program was started, the value of one in a million lifetime risk of cancer (10^{-6}) was the reference to decide upon a remediation action. Since a 1991 directive of the Superfund office, "for known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} to 10^{-6}." The presidential congressional commission does recommend the use of that same range. This evolution illustrates the move from a "bright line" criterion to what we called earlier a "multi level" scale, with a range of tolerable risk in which there is place for optimisation.

In France, a very recent instruction from the Minister of Environment[30] states very clear criteria to judge whether risks from polluted sites are unacceptable (and thus claim for remediation action) or "admissible". For toxic substances with a known reference dose, the exposure of the public must be below this threshold. For no-threshold carcinogens a goal for remediation at a whole life cancer risk of 10^{-5} is called for, "in accordance with WHO recommendations and already used for water potability standards." The minister's document states that a figure of lifetime cancer risk of 10^{-4} is " normally considered as unacceptable " therefore the risk must not be higher, and that it is necessary to reduce the risk at a level lower than the "goal" if available and affordable technologies exist. For cases where such a reduction is realistically not feasible, a residual lifetime individual cancer risk level between 10^{-4} and 10^{-5} can be accepted, provided that a detailed technical-economic study is done. To put it in other words, in France, there is an intolerable level and a target value, but no negligible level which is an intermediate stage between the "bright line" acceptability judgement and the TOR philosophy.

In the Netherlands, the tolerability frame set up by the Dutch Environmental policy Plan is used for risk assessment of soil quality[31]. "The Maximum Permissible Risk for intake is defined as the dose of a contaminant which forms a risk of one additional case of lethal tumour in 10.000 lifelong exposed individuals".

3.3. Air pollution

The regulation of air pollution in the United States has a long and varied history. Since the 1960's, the main regulatory text for air pollution has been the Clean Air Act. In the US, the federal agencies had to put forward risk criteria. In the eighties, the EPA proposed a rule based on two figures for the life-time risk due to a life time exposure : 10^{-4} for the most exposed person was deemed acceptable, the average figure within a population group of sensible size being limited to 10^{-6}. Changes in the " Clean Air Act " (about hazardous pollutants, requiring maximum available control technologies) put forward the figure of 10^{-6} for the most exposed individual, a figure above which EPA should take action. However, the new regulation allows the use of the former figures. Although it is a crude summary of a complex system, it seems that the acceptability range is from 10^{-4} to 10^{-6} for the individual lifetime risk.

In practice, Travis et al reviewed 132 federal regulatory decisions concerning environmental carcinogens (regulated under section 112 of the Clean Air Act) to determine the level of risk that led to agency action. The results of their study showed that every chemical with an individual lifetime cancer risk above 10^{-3} for small populations and 10^{-4} for large populations historically had been regulated. They call these values de manifestis levels since they appear to be the maximum acceptable risk values in the past. One of their strong statement is that "past regulatory decisions indicate that in many circumstances lifetime cancer risks greater than 10^{-4} are in fact tolerated", thus showing that their are differences between the recommendations and their application.

The approach followed by WHO for air quality guidelines is different. There is still the distinction between carcinogens and non-carcinogens substances. For non-carcinogens, the classical threshold dose-effect relationship is used to define guidelines values. For carcinogens, instead of giving air concentration levels corresponding to a generic lifetime individual risk, WHO gives the "incremental unit risk estimate". The incremental unit risk estimate of an air pollutant is defined as the additional lifetime cancer risk occurring in a hypothetical population in which all individuals are exposed continuously from birth throughout their lifetimes to a concentration of 1 $\mu g/m^3$ of the agent in the air they breathe. The definition of the acceptable risk, and thus the standards selected, is left to the regulator.

In the European Union, there is an on-going process to set up new directives on the ambient air quality. A first directive was adopted in 1996. It defines the basic principles of a common strategy to define and establish objectives for ambient air quality in the community designed to avoid, prevent or reduce harmful effects on human health and the environment as a whole. In particular, a "limit value" has to be set for a list of pollutants. It has to be attained within a given period and not to be exceeded once attained. The following directives in which numerical values will be given are still in preparation, except one. For example, the latest proposal for the directive on limit value for benzene gives a limit value of 5 $\mu g/m^3$ and explains that since benzene is a human genotoxic carcinogen there is no identifiable threshold and thus the unit risk concept has been used as a basis. Unfortunately no figure is given for the unit risk and the acceptable risk retained by the commission in its reasonning.

3.4. Water, Food and Consumer Products

In the directive setting the drinking water quality standard[32] (guideline values), the World Health Organisation (WHO) refers to a whole life excess cancer risk of 10^{-5} (one additional cancer per 100000 of the population ingesting drinking-water containing the substance at the guideline value for 70 years). WHO also presents concentrations associated with estimated excess lifetime cancer risks of 10^{-4} and 10^{-6} (guidelines values multiplied or divided by 10) to emphasize the fact that each country should select its own appropriate risk level.

The US EPA distinguishes the ambient water quality and the drinking water quality. Indeed there are two statutes regulating separately these "different" waters. The Clean Water Act has the goal to maintain and improve the cleanliness and biological integrity of the nation's waters, including lakes, rivers and navigable waters. The aim is to make these waters "fishable and swimable"[8]. In this frame, water quality standards are set on a health basis without cost considerations, but they are not themselves enforceable. They serve as a guide for judging the appropriateness and adequacy of state standards. For non-carcinogens, reference doses are the relevant criteria, for carcinogens, criteria are presented as water concentrations that would be expected to lead to lifetime cancer risk level of 10^{-5} to 10^{-7}. The Safe Drinking Water Act sets contamination level standards for "finished drinking water provided by all but the smallest public water systems." The basis of the standard are not only health risks but also technical feasibility. The standards correspond to a lifetime individual cancer risk in the range 10^{-4} to 10^{-6} .

In California, the state regulation for carcinogens risk assessment in water is driven by Proposition 65, the Safe Drinking Water and Toxic Enforcement Act. The proposition 65 regulations state that the risk level which represents "no significant risk" shall be one which is calculated to result in one excess case of cancer in an exposed population of 100.000, assuming lifetime exposure at the level in question. As W.S. Pease reports[33], the California Health and Welfare Agency has chosen the 10^{-5} standard because of the fairly conservative default assumptions required in the risk assessment, thus arguing that it can produce the

same results as applying a 10^{-6} standard to an assessment employing less conservative methodologies.

Still in the US, the principal legislation governing risk management issues in food products is the Federal Food, Drug and Cosmetic Act. This text contains the very specific statement about how the safety of potentially carcinogenic food additives is to be treated. This is the well known " Delaney clause ". It states that " no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. " As explains Rhomberg, this stipulation avoids consideration of the quantitative level of risk that an additive might pose, and prevent the legislator from defining an acceptable level of cancer risk. Anything above zero is unacceptable. Over time, there has been a "de minimis " interpretation of the Delaney Clause, setting a negligible level at 10^{-6} (see chapter 2 on the Delaney Clause). For agents that are not carcinogenic, the main issue is to ensure that the daily intake is below the ADI calculated by toxicity data.

World-wide, and more specifically within Europe, there are ongoing debates and discussions about food safety and the definition of food safety objectives. One key issue of these thoughts is to better frame the management of risks to human health due to microbiological hazards. Without anticipating the results that will come out of this research, we can briefly recall some statements about the current situation and the recommendations made by various working groups[34 35].

At present, many microbiological criteria exist for food safety, for example in European directives. Many of them were established about 10 years ago. They are operational criteria such as concentrations or number of bacteria per gram of foodstuff. These criteria were not based on a formal risk assessment and thus no acceptable risk criteria are associated with them. That is why it is now clearly stated that "microbiological criteria should be relevant and effective in relation to consumer health protection." "A risk assessment of microbiological hazards must clearly state both the purpose of the assessment and the form of the risk estimate that will be the output, which might take the form of an estimate of the annual occurrence of illness, or an estimate of the annual rate of illness per 100,000 population, rate of human illness per eating occurrence." When this formal risk assessment is implemented, the need for acceptable, tolerable and negligible level of risks comes naturally.

In the US system, there is a special commission in charge of the safety of consumer products others than food, drugs and pesticides, tobacco : the Consumer Product Safety Commission. The general methodology for risk assessment and acceptability judgement is very similar to those set by the other commissions, and the guidelines from this commission set an acceptable level of exposure to the individual of "one chance in a million during his or her lifetime of developing the deleterious effect, such as cancer."

3.5. Major industrial hazard, land planning

In Europe, the management of risks due to major industrial hazards and land planning is now based on the "Seveso directive", first published in June 1982. This European regulatory document defined the principles of what is named safety studies, risk analysis or danger studies in the various national regulations. The directive has pushed forward the quantitative risk assessment in the field of major industrial hazards.

The Dutch approach for risk management presents some interesting aspects, especially on quantitative indicators, since it is the only European country which sets up a systematic probabilistic analysis of industrial risks with the definition, after a Parliament debate, of

quantitative levels[36]. The main findings of a detailed analysis of the Dutch system by a French team[37] are presented below.

As mentioned in the presentation of the TOR philosophy, the Dutch government has set up a very similar approach for the environmental risk management to the TOR philosophy, with a three regions scale separated by a "maximally tolerable risk level " and a "negligible risk level" The middle region being the place for optimisation of the risk level. Both individual and societal risks must be assessed and judged through the acceptability grid. This approach, to be applied for all technological risks (major hazards, chemical substances, radiation, noise and odours), has found a practical application in the field of land planning and major hazardous industry siting [38]. For new installations presenting major hazards, the maximal acceptable level of individual risk was chosen so that it would increase the death risk from all other causes by only one per cent. The individual "natural" risk of dying of a ten years old group of population being 10^{-4} per year was used as a reference. Thus, the individual maximal tolerable fatal risk level was fixed at 10^{-6} per year and the negligible risk level was fixed at 10^{-8} per year. For societal risk, the maximal tolerable level was set to a probability of death of 10^{-5} per year with a maximum of 10 deaths, the negligible level was set to a probability of 10^{-7} per year with a maximum of 10 deaths. To draw the F/N curves defining the societal acceptability, it was decided that a consequence n times bigger must have a probability of occurrence n^2 times lower. Compared to the HSE reference values, these criteria were considered to be absolute values but in 1993, the use of the criteria changed, after discussion between the Parliament and the government. The negligible risk level concept was abandoned and the stringent status of the numerical values, at least for societal risk, became more flexible.

Table 2 : Risk acceptability criteria of the Netherlands[37]
Annual probabilities

	Individual risk	Societal risk
Original system	Maximally tolerable risk : 10^{-5} for existing installations 10^{-6} for new installations Negligible risk level : 10^{-8}	Maximally tolerable risk : $10^{-1}/n^2$ for existing installations $10^{-3}/n^2$ for new installations Negligible risk level :$10^{-5}/n^2$
Current system	Maximally tolerable risk : 10^{-5} for existing installations 10^{-6} for new installations below these levels, application of the ALARA principle	Maximally tolerable risk : $10^{-3}/n^2$ for new and existing installations, but the granting authority may accept higher values, if justified

In its guide for land-use planning in the vicinity of major industrial hazards[13], HSE suggests individual and societal risk criteria and actually uses them when giving advice for granting planning permission. For individual risk, HSE defines a lower bound of 1 in a million per year chance of a "dangerous dose" for the majority of the population, that is a 1 in a million per year chance of death for highly vulnerable people (c.f. paragraph 2.4). For developments where there would be a high proportion of highly susceptible people, a more stringent criterion might be appropriate. The upper limit used by HSE is 10 in a million per year of a dangerous dose (the most vulnerable members of the population are at risk of death of about 10 in a million per year). In using these values, HSE applies the TOR philosophy, considering negligible the risk below the lower bound and unacceptable the risk above the upper limit. For proposals where the risk lies between these values, HSE states that it "would consider whether there are features or details which tend to justify more or less stringent advice. "

For societal risk, HSE recognises that there is no clear consensus on quantitative criteria for judging the acceptability and that the use of F/N curves is not trivial. Its advises against developments near major hazards are based on a compromise between the individual risk values given above and the number of people affected. However, after some case studies including the major hazards transport study [17], it seems that HSE has moved one step forward since in the recent discussion document " Reducing risks, protecting people "[21], " HSE proposes that the risk of an accident causing the death of fifty people or more in a single event should be less than one in five thousand per annum " (see paragraph on the TOR philosophy).

In France[39], the management of hazardous facilities, in accordance with the Seveso directive, is based on a deterministic approach for the risk assessment and the definition of the "zone at risk" also called "coordination zone"(because it is the area for which the operator and the administration have to define the land planning restrictions due to the industrial hazard). A set of reference accidents is defined by the authorities and is used on all sites for the establishment of the zone at risk. The quantitative criteria for the delimitation of this zone are the "lethal threshold" (mortality rate of 1 % as a consequence of the accident) and the threshold of occurrence of irreversible injuries (severe burn, excessive pressure following an explosion,…). These health criteria are used to define the land planning restriction zones but do not, as such, classify hazardous facilities as acceptable or not. However in a case where the respect of the restriction zone is not possible due to existing houses for example, the authorisation of operating may not be granted, and the plant can thus be considered as a source of unacceptable risks. It must be noticed that these thresholds have a regulatory status and apply on the entire territory.

3.6. Risk at workplace

The US Occupational Safety and Health Administration (OSHA) is responsible for the regulation of workplace safety and thus has to manage the exposure of workers to toxic chemicals. The Occupational Safety and Health Act does not mention risk assessment as such, nor does it say much about the establishment of safe exposure. However it is interesting to see how in practice a quantitative criteria has emerged. J.D. Graham makes a good summary of the famous benzene case [41]: "In the late 70's, OSHA proposed a standard of 1 ppm for workplace benzene exposure. Industry petitioners challenged OSHA's emerging policy and argued for both quantitative risk assessment and benefit-cost analysis. In the 1980 benzene case the Supreme Court held that OSHA must determine that a cancer risk is significant before taking steps to reduce or eliminate the risk. Justice Stevens commented favourably on the developing discipline of quantitative risk assessment. He also opined that a reasonable person might regard a lifetime risk of 1 in 1000 as significant yet regard a risk of 1 in a billion as trivial. In 1981, Justice Brennan wrote for a majority of the Court (including Stevens) rejecting the legitimacy of benefit-cost analysis under the Occupational Safety and Health Act. Since these two rulings, OSHA has embraced quantitative risk assessment and uses 1 in 1000 as a threshold of significant risk."

4. Conclusions

Though this review cannot be exhaustive, one must agree that there are many values in different areas giving some quantification of the risk acceptability. All values found in the literature search in this study are not even all presented, but the examples given here are representative of what was found.

It is by far in the US that the quantification of risk acceptability has spread the most. The importance of the work done by the presidential/congressional commission shows very well the extent of quantitative risk assessment and risk characterisation.

The figures for the individual lifetime risk of death due to a life long exposure cover many orders of magnitude, ranging from 10^{-8} to 10^{-3}. However most figures for an acceptable or a tolerable risk range between 10^{-6} to 10^{-4} but either for one year of exposure or a whole life exposure. Clearly enough two acceptability concepts emerge behind such figures, the "negligible" level and the "intolerable" level.

Despite this general good agreement on figures, the justification of the values chosen either for unacceptable risk or trivial risk is rarely exposed clearly. There is a very interesting paper from Kelly[40] which explores the origin of the 10^{-6} as a definition of acceptable risk. The result of her research is that there is no serious written justification of this value, and more importantly, that it is not, as we also see in our study, the unique definition of acceptable risk. Like in the Travis' study presented above, it is interesting to see how this magical value of 10^{-6} has to be demystified, and yet, how much it remains a reference point. For upper values, when defining the limit between tolerable and unacceptable risks, the comparison to actual risks to which all people are exposed is usually the justification.

From a more practical point of view, one should not forget that such figures are quite meaningless when they are not associated with some elements on the corresponding assessment process. Regulations specify that they apply to the most exposed individual, with conservative assumptions, or to a realistic assessment for an average individual, or any other assessment mode, but they carefully avoid to leave open the assessment strategy. This is a general comment for all the quantitative risk assessment process, and a strong limitation to risk comparison.

In all US federal regulatory programs, except Superfund, there is no accounting for the fact that people are exposed to more than one chemical at a time and that certain effects may be dose additive. In the Guidelines for drinking-water quality [32], WHO specifies that guidelines values were calculated separately for individual substances, without specific consideration of the potential for interaction of each substance with other compounds present (however it is stated that in circumstances where a number of contaminants with similar toxicological effects are present at levels near their respective guideline values, it is appropriate to assume that the toxic effects are additive). This peculiarity of systematic cumulative risks assessments in Superfund is attributable to the need of risk characterisation of the waste site as a whole and not just to assess risks from particular chemicals. This is also one of the major differences between the assessment and management of risks from chemical carcinogens and radioactive substances. For one installation, chemicals are regulated individually while radiation protection regulation always considers all sources of radiation (emitters and type of radiation). This is another important limitation to compare quantitative values and acceptability criteria.

One should also not forget that risk assessment is an uncertain process. There is variability in the laboratory experiments, there are strong hypotheses on the dose-risk relationship and also uncertainties associated with the estimation of risks below the range of observable events. Indeed the impact of one in a million cancer risk on a population cannot be detected, since one-fourth of that population is expected to die of cancer, even in the absence of well identified chemical exposures. Therefore, one must be cautious when trying to define too accurate criteria.

One fundamental condition for a proper definition and use of quantitative risk acceptability criteria is to be really convinced that numbers and figures do not solve all issues. That may be the temptation of "bright lines" defenders but it oversimplifies the reality. To go beyond these magical and universal risk levels John D. Graham has a clear statement [41]: "Although some observers see value in bright lines levels of acceptable risk, history suggests that acceptable risk will ultimately be defined on a case-by-case basis. Key decision factors such as the size of the exposed population, the resource costs of meeting risk targets, and the scientific quality of risk assessments vary enormously from one decision context to another. Administrative discretion is necessary to weigh these factors on a case-by-case basis. No magic risk number can substitute for informed and thoughtful consideration by accountable officials who work with the public to make balanced decisions."

When defining quantitative acceptability levels as standards, organisations and policy makers always claim that numbers should be regularly reviewed and revised as new scientific evidence on the effects on public health and the environment emerges. In practice, such reviews are always long and it may reveal to be difficult to modify values that were already the result of discussions, compromise, approximations, on which the present regulation may be based[42].

These critics of quantitative risk assessment and quantitative acceptability values are not aimed at completely rejecting them. After the increasing use of quantitative assessments, there is now a trend to moderate this approach by giving more importance to all the qualitative aspects of risk management. In its recommendations, the US Presidential/Congressional Commission on Risk Assessment and Risk Management insists on the weight of the qualitative information of a risk to make it acceptable. "Often, qualitative information is more useful and understandable than quantitative estimates of risk. Qualitative assessments include a careful description of the nature of the potential health effects of concern, who might experience the effects under different exposure conditions, …"

The Dutch case is also interesting in that sense, because the government who wanted to set a very strong regulatory and universal status to the acceptability levels defined, had finally to go back and acknowledge that risk acceptability is partly specific to each case and cannot be pronounced for all situations by applying a unique rule. The Health Council of the Netherlands' report: "Risk is more than just a number" [43] gives some good insight of this debate.

The already visible orientation toward less stringent quantitative criteria for acceptability is that the most widespread approach is now the definition of a range of acceptability, like the TOR and ICRP approaches, in which all case specific parameters can be considered and thus contribute to an optimised acceptable level of risk.

Finally, and in order to suggest some harmonization of the acceptability frame, it can be drawn from this study a proposal hierarchy of terms to qualify risks. This is a suggestion that is consistent and more or less used in different sectors. It needs to be approved by all risk assessors and managers. If agreed and used, this qualitative hierarchy would give some consistency to all risks analysis and without associated figures, it would still allow the integration of specific quantitative aspects in a particular situation, for a particular risk.

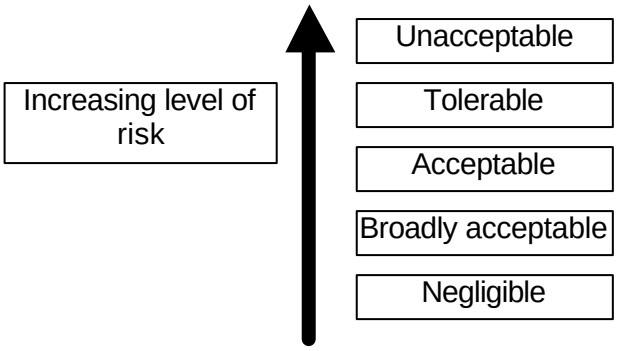


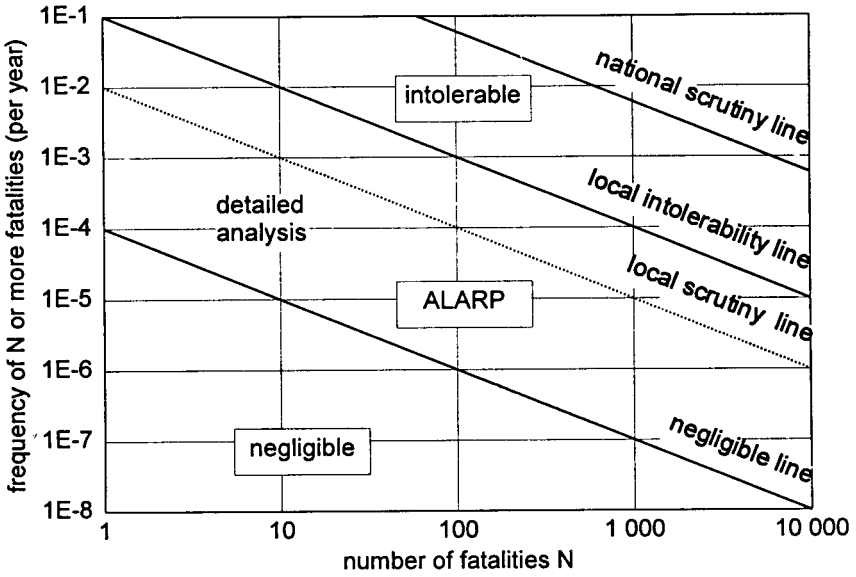
Figure 4 : Proposal for a qualitative hierarchy of acceptability risk adjectives

5. Appendix

- Level of fatal risk per year[17] :

  1 in 100 : risk of death from five hours of solo rock climbing every week-end
  1 in 1000 : risk of death due to work in high risk groups with relatively risky industries such as mining
  1 in 10.000 : general risk of death in a traffic accident
  1 in 100.000 : risk of death in an accident at work in the very safest part of industry
  1 in 1 million : general risk of death in a fire or explosion from gas at home
  1 in 10 million : risk of death by lightning

- Societal risk curve (F/N curve)



Societal risk criteria proposed for major hazards in transport in the UK [17]

♦ Summary overview of criteria in risk management by US federal regulatory agencies [8]

	Individual risk considered	Population risk considered	Usual acceptable residual risk (lifetime risk for lifetime exposure)
Toxics	Yes “ reasonable worst case for occupational exposure	Yes, indirectly	Unstated, but usually 10^{-5} to 10^{-6} for public, 10^{-4} to 10^{-5} for occupational exp.
Pesticides	No for carcinogenic additives; yes for residue tolerance	Yes for residue tolerance	Zero for additives (Delaney clause) 10^{-6} for assumed max residues in average diet, 10^{-6} for non-dietary exposure
drinking water	Yes, a standard exposure scenario in middle range	No	10^{-4} to 10^{-6} range considered to be adequate
water quality	Yes, a standard exposure scenario in middle range	No	10^{-5} to 10^{-7}
hazardous waste handling, active disposal	Yes	No	listing : 10^{-5} corrective actions : 10^{-4} to 10^{-6} incinerators : 10^{-5}
Superfund sites	Yes, “ reasonable maximum exposure ” using mix of midrange and conservative assumptions	Yes	10^{-4} to 10^{-6}, depending partly on anticipated future use of site
hazardous air pollutants	Yes	Yes	10^{-4} to 10^{-6}
food additives, colours and contaminants; cosmetics	No for carcinogenic additives; yes for additives, contaminants	No	Zero for additives; 10^{-6} for assumed max residues in “ high use ” diet
occupational exposure	Yes, for full working life at possible exposure limit	No	Feasible controls (in practice 10^{-3})

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