

Health risk assessment in zone analyses

Utility, methodological
issues and interpretation

Collection
Documents

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HEALTH RISK ASSESSMENT IN ZONE ANALYSES

UTILITY, METHODOLOGICAL ISSUES AND INTERPRETATION

Report by the Special Commission on Environmental Risks

December 2010

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|--|---|--|
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| Jonathan LEVY | Harvard University United States | General framework: proposals of the National Research Council Committee on improving risk analysis methods used by the US-EPA |
| Thomas MCKONE | University of Berkeley, United States | Multiple sources of pollution: methodological options for complex exposure characterisation |
| Denis ZMIROU- NAVIER | EHESP/University of Nancy | Discussion |
| Gary GINSBERG | Connecticut Department of Public Health, United States | Population effect measures in zones of complex and cumulative exposure |
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| Philippe HUBERT | INERIS | Risk assessment and risk management: coping with attributable fraction |
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| William DAB | CNAM | Stakeholder's involvement: when? What for? |
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| Patricia BLANC | MEEDDM | Conclusion |

Literature reviews

Vincent Nedellec Conseil (VNC)

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Title: Literature review on practices focussed on quantitative health risk assessments conducted in the framework of zone assessments, 2010, 74 pgs.

Study Centre for Applied Social Sciences (CESSA)

Authors: Jean-Stéphane Borja, Stephan Castel, Pierrick Cezanne-Bert

Title: Literature review on the roles of stakeholders in risk assessment in contexts where multiple activities are present, 2010, 150 pgs.

Glossary

| | |
|--------|---|
| Anses | National Agency for Health Safety (food, environment and work) |
| ARS | Regional Health Agency |
| COS | Steering and Monitoring Committee |
| Dreal | Regional Environment, Planning and Housing Directorate |
| DGS | Directorate General for Health |
| EHESP | School of Higher Public Health Studies |
| RA | Health Risk Assessment |
| Z-RA | Health Risk Assessment in Zones |
| Z-QRA | Quantitative Health Risk Assessment in Zones |
| UR | Unit Risk |
| Ineris | French National Institute for Industrial Environment and Risks |
| Inrets | French National Research Institute on Transport and Safety |
| INRS | French National Institute for Research and Occupational Safety |
| InVS | French Institute for Public Health Surveillance |
| IRSN | French Institute for Radiological Protection and Nuclear Safety |
| PNSE | National Health Environment Plan |
| HR | Hazard Ratio |
| NRC | National Research Council |
| TRV | Toxicological Reference Value |

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Summary

Currently, zone studies, i.e. in the setting of multiple economic activities, are not subject to any regulatory requirement, unlike "*impact studies*", which are carried out in accordance with *classified installation regulations*¹. They can, however, be a part of the main course of action identified in the second national health and environment plan (NESP 2) on "environmental grey areas".

On 21 May 2008, the Health Directorate General made two requests to the High Council of Public Health (HCSP), one relating to "the development of an assessment methodology regarding health risks in the context of zone studies", the other one relating to "helping interpret the results of risk assessments conducted in the framework of impact studies".

The HCSP established a multidisciplinary working group made up of experts from various institutions, which, in order to progress on their expertise mission, relied on: (1) hearings with external individuals who have been involved in a zone health risk assessment (Z-HRA); (2) the presentation of specific and methodological work on Z-HRAs and on the involvement of stakeholders in other studies; (3) an international seminar organized by the HCSP; (4) a literature review of quantitative practices used to assess health risks in the framework of zone studies; and (5) a literature review of the roles of stakeholders in risk assessments where multiple activities are present.

In France, the approach of health risk assessment is conducted within a regulatory framework, for installations or facilities that are subject to a request for authorisation to operate. This "single site" approach does not usually consider other sources of polluting emissions (vehicles, other industrial and agricultural sources...) present near the installation. In recent years, and in various regions, State services wanted health risk assessments to take into account, within an entire area of economic activity, the total emissions arising from the various activities that operate there in order to better reflect the exposure experienced by those living around such environments. At the same time, these services are also considering issues of interpretation of HRA results, of thresholds for action as well as a comprehensible interpretation of the indicators resulting from such assessments.

In this report, we will speak specifically of "zone analyses" when the issue at hand deals with an overall grasp of the situation, with its health and scientific stakes, as well as economic and political ones. Also, we will speak of "zone studies" to apply a structured scientific approach to summarise the available scientific knowledge (HRA-Z) aiming to assess the health risks that populations encounter in a zone.

¹ The regulations: the French law of 10 July 1976 regarding the preservation of nature, referring to works, facilities and installations, the French law of 30 December 1996 regarding the air and the rational use of energy and the 1985/337/CE EU directive regarding the assessment of the effects of certain public and private projects on the environment.

This report², in response to the request sent to the High Council of Public Health, is structured by the following topics: defining a zone as being a relevant area to assess health risks and devise risk management options; the utility of a zone analysis from a health risk management viewpoint; involvement of stakeholders and their roles in these situations; the main methodological principles of a Z-HRA; interpretation of the results of an HRA (notably on the same scale as the zone); and the benefit of regulations to guide zone assessments. Although this report questions the relevance of conducting a Z-HRA, it is not, however, intended to be a methodological guide to do so.

Definition and description of a zone, the relevant area where health issues and risk management options will be studied

Several aspects must be taken into account in order to define and delineate a zone within a Z-HRA:

- an economic facet via a labour and activity pool;
- a political facet via the territory's various political players and their various interests;
- a population facet via the way the inhabitants occupy the territory and how they use it (residential housing, education, housing for the elderly, recreational activities, services and commercial activities...);
- an environmental facet through knowledge of the environment's physical, biological and natural characteristics, and the dissemination of chemical pollution via the different media that people come into contact with.

Accordingly, a general definition of a zone has been proposed as part of a Z-HRA. It is "*a solidary area, in terms of economics, physical attributes and population, where a range of economic activities (industries, transportation of people or goods, agriculture...) took place, are taking place or will take place, contributing significantly to the emission of potential hazardous agents in the environment, that may, alone or when combined, affect health in the short or long term, given the way that the diverse populations occupy the area*".

The operational delimitation of the study zone must be a separate step of the Z-HRA and it must involve all stakeholders. A first qualitative approach will make it possible to determine the potential exposure of the populations while considering all of the sources present in the activity zone and the population basin. Then, in a second step, a quantitative approach will make it possible to delineate the assessed area by considering, in particular, the results of modelling air pollution throughout the territory. It is proposed that one includes the entire zone whose peripheral area amounts to 10% of the environmental quality target regarding the modelled concentration of the observed pollutants or tracers, as long as this territory is in continuity with regard to economic activity and population pool.

² The report and its appendices are available at: <http://www.hcsp.sante.fr>

Utility of zone assessment in managing health risks

Conducting a Z-HRA may prove to be useful on several levels, thereby justifying its implementation in the event of partial or total overlap of activities. This will require that they be assessed jointly in order to measure the overall impact and to pool management measures. These uses are on different levels and their assessment results from an analysis of the situation:

- improvement of knowledge as concerns the assessed zone's exposure and risks;
- decision-making assistance, which posits the HRA in its political context;
- the involvement of the relevant stakeholders in order to promote the collective benefit of conducting a Z-HRA, even in the event where such a process would require a longer amount of time;
- communication between the parties that are directly involved as well as toward the entire population, which ensures transparency and consistency of the work.

Three situations may trigger a zone assessment: 1) the launch of an impact study in a regulatory context (for a new facility, for a new or modified process in an old facility, for an existing facility); 2) a response to a public concern about the possible health impact of a given industrial activity or environmental situation; 3) the observation of an excess of certain pathologies in the area. In each of these contexts, the initial analysis is a crucial step that is needed in order to understand each entity's various needs and expectations and to identify their stakes and goals.

Commitment and roles of stakeholders during the ERS-Z procedure

Stakeholders are defined as any group of people that are likely to be directly concerned by an approach to health risk knowledge and reduction that affects a delimited area. These stakeholders may have different roles and interests. The involvement of multiple players within the Z-RAs may tend to slow the process down, but this downside is more than offset by the overall positive impact that this active involvement generates (integration of various relevant data, conflict resolution, mutual acculturation, the search for acceptable and effective solutions). The debate is therefore no longer focussed on the relevance of this commitment, but on the forms that it might take.

When a health or environmental issue arises in a territory, and when it requires that a situational analysis be implemented, the HCSP recommends that a steering and monitoring committee (COS, for Comité d'Orientation et de Suivi in French) be established. Such a committee consists of six colleges (State, regional authorities, non-trading companies, employees, employers and qualified individuals) whose missions are (1) to deliberate on the type of assessment to be made to address the problem; (2) if a Z-RA is decided, they rule on the protocol to be used and the choice of the study consultant; (3) to monitor its progress and discuss the conclusions to be drawn in terms of risks and management measures and (4) to ensure that the recommendations are implemented.

The involvement of stakeholders must occur as soon as the problem is formulated, and their participation must be maintained throughout the work and research process, until the competent authority announces the decisions it has made, followed by the monitoring of the implementation of these decisions. It is proposed that a charter of good practice be established for the COS as soon as possible, explaining in detail the various rights and obligations that the various stakeholders have.

Interpreting the results of the RA and Z-RA

The two main quantitative results expressed in a RA, whether covering a single site or an area, are the hazard ratio (HR) and the unit risk (UR). Interpretation of these figures is based primarily on their comparison with conventionally accepted benchmarks established by national or international authorities (benchmark value of 1 for HRs and, often, 10^{-5} for the URs). The exceeding or non-exceeding of these benchmark values usually leads to the conclusion that the risks are "acceptable" or not, and therefore leads to undertake actions aimed at controlling the source of the risk and, where appropriate, to provide a health response to the population. A number of shortcomings were identified in this approach in cases where the computational exercise would replace an analysis of the RAs finality. These shortcomings affect the way results are presented and made understandable for both policy makers and the general public. Moreover, lack of consideration regarding the study's contextual and qualitative elements hampers the assessment of the HR and UR in terms of health consequences on the population.

Based on this, the HCSP makes a number of proposals designed to improve the readability, understanding and use of the results. First of all, it recommends that the benchmark values of interpretation that it proposes be used after a critical assessment of the uncertainties linked to the exercise of the RA (data quality, realistic aspect of the scenarios and calculation methods...). Secondly, it abandons the "acceptable risk" concept, and it suggests that value ranges should be used rather than absolute thresholds, and holds three areas to guide the interpretation of the risk estimates in anticipation of its management and whose practical meanings are defined in the full report. These are, respectively:

- a rapid action area = $UR > 10^{-4}$ or $HR > 10$;
- an active vigilance area = $10^{-5} < UR < 10^{-4}$ and $1 < HR < 10$;
- a compliant area = $UR < 10^{-5}$ and $HR < 1$

Thirdly, it recommends that risk assessors better understand multi-exposure situations and thus recommends that all effects related to the noxiousness of pollutants and harmful nuisances be taken into consideration, not just the critical effect which characterises each of them in the TRV (French acronym for Toxicology Reference Value) databases. Research is also encouraged in order to establish composite indices which "measure" the cumulative exposures and risks.

Methodological principles used for quantitative health risk assessments for zone studies

In France, the health risk assessment approach, in the context of single-site RAs, is governed by two methodological guides respectively produced by the InVS and the Ineris. In contrast, Z-RAs, so far, have no specifically defined methodological framework. The HCSP's objective was not to prepare a new methodological guide but to present, for each of the conventional stages involved in the risk assessment approach, the methodological characteristics of Z-RAs. They relate to (1) the hazard identification stage, where the entire area of activity's sources of pollution or nuisance are identified; categorisation and selection of hazardous agents; consideration of the acute effects resulting from the possible differences in temporal sequences of the various nuisances; (2) the dose-response assessment stage, with the standardisation of the choice of the toxicological reference values; taking into account all the potential effects arising from substances, and not just their critical effects; (3) the exposure assessment stage, with the mapping of the various populations' potential exposure within the area; implementation of environmental quality measurement campaigns coupled with pollutant dispersion modelling; characterisation of background noise and identification of either an initial state or a control environment; (4) risk characterisation, with consideration given to aggregate and cumulative exposure, and the search for the estimated share attributed to each source, in order to ensure that risk management measures are optimised.

In order to achieve progress in better taking into account these singularities, upstream research efforts are required, notably to establish multi-exposure composite indices and to reinforce toxicology training.

Value of a regulatory framework for the zone assessment

The high stakes involved in conducting risk assessment studies, whether for single sites or for entire zones, justifies their inclusion within a regulatory framework, as it is already the case with single-site ERSs conducted within the framework of impact studies. This regulatory framework has to be, at the very least, both prescriptive and flexible, adaptable to various local situations and, in particular, should focus on the need to proceed with a zone analysis beforehand, on the Z-RA interpretation criteria, on stakeholders' minimum commitment requirements, on the action plans design terms, on the capitalisation on various local experiences through an annual or biennial report, on the obligations of the managers of the various activities which generate the pollution and nuisances, in terms of control, corrective measures and funding. The Z-RA aims to assist in the decision-making process regarding the protection of public health in an area of dialogue that is suited to both the situation as well as those who are involved.

In the future, the streamlining of the framework within which these assessment studies will be conducted will heighten their legitimacy, and therefore their effectiveness.

Conclusion

The HCSP, in response to the requests it received, suggests a number of improvements, in terms of Z-RA, which aim to:

- restore to its rightful place the purely quantitative approach to RA, with reference to its purpose and the uncertainties related to the selected data, methodological choices and orientations;
- explain in detail the expected utility of a Z-RA with regards to an activity zone, by including it in local elaboration on planning policy, in terms of its health, economic, social and environmental issues;
- establish dialogue between the various involved parties in order to allow them to: assess - from different viewpoints - the stakes of the study, gather relevant shared and non-shared information, ensure that the approach is transparent and that all stakeholders understand it and make an inventory of all foreseeable management options based on the results obtained;
- identify the contributory shares of the various past and present activities on the territory so as to try to identify each of the emitter's respective environmental accountability;
- gradually move towards the systematisation of Z-RAs, which will replace the current single-site Z-RAs.

With these developments, the RA will fully satisfy its purpose, which is to provide the information required for informed discussion between the various stakeholders regarding risk management options.

Summary of recommendations

Over the course of this work, many recommendations have been made. They appear in the report in the section deemed to be the most appropriate. It became necessary to bring them together in a summary section in order to appreciate their coherence and their complementarity, not just their diversity.

These recommendations are of different natures. Some are them are of methodological while others have political overtones or are more principles-based. The organisation of these recommendations could therefore have been achieved in different ways. It was decided that they would be ranked within each chapter according to their nature. Each recommendation develops a way of thinking that retains autonomy and its own logic even though it is part of a whole. To assist the reader, each of the recommendations listed below has an active link which directs him/her to the report's *ad hoc* paragraphs. It is important to note that the wording of the recommendations in this summary sometimes features differences with the original text, because the ideas that are reproduced here are more fully developed further in the text and are summarized here in a more conventional manner.

These recommendations, each of them in its own field, will be analysed and used by the competent bodies and entities. Also apparent, from all the hearings and literature reviews, is the need to foster progress of all those involved in the risk analyses and assessments. Didactic and pedagogical support allowing such exchanges to take place should be established, so that everyone can learn to understand the thinking and the methods that are involved.

Recommendations taken from chapter 2, entitled: Definition and description of a zone, a relevant area for a health study and risk management

Proposals in terms of public decision

This is the definition itself, which, based on the concept of a solidary area, revealing its political dimension.

"A zone is a solidary area, in terms of economics, physical attributes and population, where a range of economic activities (industries, transportation of people or goods, agriculture...) took place, are taking place or will take place, contributing significantly to the emission of potential harmful agents in the environment, that may, alone or when combined, affect health in the short or long term, given the way that the diverse populations occupy the area."».

Proposals regarding principles

- economic, political, population and environmental aspects are taken into account when defining and delimiting a zone for an Z-RA;

- specific funding must be planned for the determination of the zone to be studied, especially if there will be measurement campaigns. Such funding must be obtained prior to the effective launch of the Z-RA ;
- delimitation of the zone can only be achieved with the involvement of all relevant parties.

Methodological proposals

- delimitation of the zone assessment occurs in two operational steps:
 - o The first step, which uses a potential exposure map, aims to determine the zone's first boundaries according to all of the sources of present activity, the population pool and stakeholder expectations;
 - o In the second step, the pollutants dispersion (air or water) modelling results and the limits of the zone are defined as those where concentrations of a tracer, from one or more sources, is equal to 10% of its environmental quality objective in the relevant environment.
- delimitation must occur before starting the actual study.

Recommendations taken from chapter 3, entitled: Usefulness of a zone assessment from a health risk management standpoint

Proposals in terms of public decision

- to propose, prior to the assessment, the drafting of an environmental and health management plan that identifies the various courses of action that could be implemented according to the results stemming from the zone assessment.

Proposals regarding principles

- to conduct an analysis of the situation in order to help understand the various expectations and needs and to identify each stakeholder's issues and goals;
- to express the various type or types of utility expected from a zone assessment.

Methodological proposals

- to gather the information needed to quantify the populations' potential exposure.

Recommendations taken from chapter 4, entitled: Stakeholders' involvement and roles in the Z-RA process

Proposals in terms of public decision

- a stakeholder is defined as *"any group of people that are likely to be directly concerned by an approach to health risk knowledge and reduction that affects a delimited area, even if the roles and interests of each are different"*;
- the COS will be co-chaired by the ARS³ and the Dreal⁴; its president will be appointed by consensus. If no consensus is reached, the president will be chosen from within the college of qualified persons;
- the COS will be a setting where the RAs stakes, issues and protocols can be discussed; and explained, but it will not be a setting where risk management measures will be negotiated; and arbitrated.

Proposals regarding principles

- stakeholders will be involved as far ahead of time as possible, as soon as a problem is formulated up until the announcement of the decisions made by the competent authorities and the follow-up of their implementation;
- the COS's missions relate to the choice of the type of assessment that is to be done, the assessment's preparation, which may or may not be backed by a consultant and, lastly, completion of the assessment as well as monitoring of the recommendations;
- the consultant that is chosen to draft the specifications must not be the one later conduct the risk assessment study;
- decisions on the choices to be made during risk assessment shall be borne by those in charge of activities that pollute, and decisions regarding the terms under which situations will be handled will be the public authorities' responsibility;
- the funding of Z-RA and pre-assessments will be borne by the parties which are at the source of the problem, according to allocation criteria that are defined locally. Funding of the COS's operations will be provided by the state and any relevant local authority or authorities;
- after the Z-RA has concluded, results must be announced publicly immediately;
- the COS drafts an operational charter that explains the rights and duties related to the various stakeholders' commitments.

³ ARS (Agence Régionale de Santé) is the Régional Health Authority

⁴ Dreal (Direction régionale de l'Environnement, de l'Aménagement et du Logement) is the Regional Direction for Environment, Planning and Housing

Methodological proposals

- the established COS will be made up of 6 colleges (State, local authorities, community bodies, company employees, local employers and qualified individuals);
- a steering committee with a more operational vocation will be created, as needed, to discuss technical issues.

Recommendations taken from chapter 5, entitled: Interpretation of RA and Z-RA results

Proposals in terms of public decision

- the "acceptable risk" concept must be abandoned and replaced instead with the "management thresholds and intervals" one whose concrete proposals include:
 - o A quick action response for an $UR > 10^{-4}$ and/or a $HR > 10$;
 - o Active vigilance for a $10^{-5} < UR < 10^{-4}$ and/or a $1 < HR < 10$;
 - o Compliant status for an $UR < 10^{-5}$ and/or a $HR < 1$.

Proposals regarding principles

- to enhance the readability, understanding and usage of HRA's results;
- a clear separation of results and their interpretation;
- variability and uncertainty must be fully taken into account when presenting results;
- the RA must provide a quantitative view as well as a qualitative risk analysis.

Methodological proposals

- to improve the presentation and the expression of the results: (1) zone iso-risk maps will be established; (2) one of the HRA report's chapters will be dedicated to the assessment's strengths and weaknesses; (3) iso-concentration maps of non-TRV substances will be conducted; (4) their statistical distribution within the population will be presented; (5) uncertainties will be taken into account in an improved manner;
- in order to improve the interpretation of the results, multiple exposures and cumulative risks will be taken into account, for both carcinogenic and non-carcinogenic effects.

Recommendations taken from chapter 6, entitled: Methodological principles of quantitative health risk evaluations for zone assessments

Proposals in terms of public decision

- to take into account the possible acute health effects that may result from the combination of temporal sequences of exposure to the various sources of pollution and nuisances present in the territory;

- to consider the critical effect associated with the TRV, and also keep track of all other types of effects (both chronic and acute) associated with the substances at hand and organise the categorisation of these substances according to their different effects;
- to take into account, both quantitatively and qualitatively, the aggregate and cumulative exposures so as to be able to describe the health risks;
- to strive to determine the share of exposures and risks attributable to each source.

Proposals regarding principles

- to implement" an iterative procedure whose initial stages may be relatively brief, with more intensive action being justified for worrisome findings.

Methodological proposals

- to conduct a complete enumeration of pollution and/or nuisance sources in the delimited territory;
- to proceed with the categorisation of the substances according to current toxicological knowledge, and select the potentially hazardous substances that are considered most relevant according to the objectives of the assessment;
- to group the substances according to the individual effects that they are likely to generate;
- to map the potential exposure of the population within the assessment area;
- to perform measurement campaigns so as to evaluate the quality of the environmental media and to estimate the populations' exposure, in combination with the modelling exercise, in order to delimit the assessment area and to establish the respective contributions of the different sources of the pollution;
- describe the background noise and identify an initial state or a control environment.

Recommendations taken from chapter 7, entitled: Value of a regulatory measure governing the zone assessment

Proposals in terms of public decision

- a regulatory, prescriptive and flexible framework that, in particular, governs: the Z-RAs interpretation criteria, the organisation of interaction between stakeholders and the functioning of the COS, the terms under which action plans are to be established, the organisation required to capitalise on past experience and the obligation of timely information of the public regarding the Z-RAs findings;
- the gradual replacement of single-site RAs with Z-RAs (spanning a decade). At first, these zone approaches will appear to be more demanding in terms of resources, but they will quickly reveal to be an extremely wise investment.

Proposals regarding principles

- an update of the assessment will be conducted at least every 10 years;
- lessons learned from these studies (implementation and methods, management measures and action plans) will be capitalised, locally, on the one hand, and through a periodic national overview (annual or biennial), on the other hand.

Methodological proposals

- it will take no more than 2 years to complete a Z-RA;
- a critical analysis of stakeholders' participation will be made in order to gradually increase their involvement in the Z-RAs.

1 - Introduction

1.1 - Context

On 21 May 2008, the Directorate general for health submitted two requests to the HCSP (High Council for Public Health) (Appendix 1). The first one relates to "the development of an assessment methodology regarding health risks in the context of zone assessments". These studies aim to measure the aggregate emissions resulting from businesses, facilities and transport activities within an entire area of economic activity – usually an industrial zone – and they seek to find the most likely chemical pollutant exposure level that the local populations are subject to. Although inhalation is the most commonly analysed exposure route, the setting may justify interest in other routes. The second request relates to "helping interpret the results of risk assessments conducted in the framework of impact studies", as State agencies wonder about interpretation and decision threshold levels as well as what indicators should be used to make a proper interpretation of the assessment.

In recent years, State agencies have sought to proceed with health risk assessments of entire industrial zones. Indeed, the issue plant-specific authorizations in a local context where various sources of chemical pollutant emissions are gathered raises an increasing number of questions with regard to the cumulative environmental and health effects on people that are exposed, whether the victims are the general population or specific groups or subjects at their sites of employment. In addition, there is a growing social demand to identify and prevent health effects linked to chemical pollutants present in the environment due to persistent contamination of various media (ex: soil and polluted waters), to ambient air contamination due to new sources of pollution, and, in general, for a better understanding and mitigating of the cumulative effects of multiple environmental exposures.

In France, the first such study of this sort took place in Dunkerque's industrial zone in 2002. As of today, a dozen studies have been completed or are currently underway (Dunkerque, Calais, Fos-sur-Mer, Lacq, Ambès, Lavera...). These zone assessments are carried out at the request of industrial entities or as part of preliminary studies carried out before an authorisation request is approved.

However, these zone assessments are not currently subject to any regulatory requirement, unlike impact studies which are conducted facility by facility in compliance with Integrated Pollution Control facility regulations. The reference laws are the 10 July 1976 act overseeing nature preservation and deals with works, urban planning projects and plants, and the 30 December 1996 act relative to the air and the rational use of energy. These assessments can, however, be a part of the main course of action identified in the second national environmental health action plan (PNSE 2) on "environmental hot spots". EU Directive 1985/337/CE, which governs the assessment of the effects of specific public and private projects on the environment, also serves as a reference.

1.2 – Referred Case instruction - Organisation of the report

The request process identified important points that require a well organised argumentation in order to help the relevant authorities provide guidance to their decentralised departments and other public institutions.

The HCSP's contribution primarily aims to provide guidance to public authorities regarding the purposes and the utility of zone assessments and the key steps to follow before deciding whether or not to conduct a zone assessment. Undergoing such an assessment is but one option among others and, in any case, a preliminary analysis of the zone will be necessary before any decision is made regarding further action. This is especially true since public decision makers will need to consider, in addition to the requests made by industrial entities, those of other interested parties who need to know what health and environmental effects are present. Stakeholders are indeed numerous and they have legitimate motives since they are directly and locally affected by the cumulative exposures: regional authorities, users and associations, other economic entities.

With regards to the interpretation of the health risk assessment (RA) studies that were requested by the State's decentralised departments or by public agencies (ARS), we have identified several sources of difficulty for which the present paper strives to provide some answers beyond and in addition to the reference documents already published by the French institute for public health surveillance (InVS) in 2000⁵ and by the French national institute for industrial environment and risks (INERIS) in 2003⁶. Until now, the interpretation of results has often been limited to a comparison of benchmarks: a value of 1 for the hazard quotient (HR), and a probability of 10^{-5} for unit risks (UR). However, interpretation of a study must be guided by its context in order to take into account the origin and the nature of the environmental and/or health issues that are at hand, the regulatory environment, the expected health effects and the involved population. Consideration of any uncertainties and variability should influence the interpretation of the results. In any case, it must be considered in a local context to clarify the type of management that should be chosen, because this is the very purpose of a RA.

Following this instruction, the HCSP has identified five lines of argumentation, each of which is covered in a separate chapter:

- the **definition of a zone** as an area of that is relevant for a health study and risk management;
- the **value** of a zone assessment from a risk management viewpoint;
- the involvement of **stakeholders** and their roles in the zone analyses and, in particular, in zone health risk assessment studies;

⁵ French institute for Public Health Surveillance (InVS), 2000, Guide for the analysis of impact studies' health components, 49 pgs.

⁶ French National Institute for Industrial Environment and Risks (INERIS), 2003, Evaluation of health risks in impact studies pertaining to classified facilities - Risks arising from chemical substances, 152 pgs.

- the **interpretation** of the results of a RAs on a local scale, including those conducted on a zone-wide scale;
- the main **methodological principles** of an RA on a zone-wide scale.

In addition to these five initial areas for exploration, a sixth one has now been set out: consideration of the value of a statutory provision to govern these zone assessments.

1.3 - Brief Comments on Vocabulary

Initial discussions within the HCSP quickly brought to light the vocabulary difficulties with which we can run into. The preceding introduction is not exempt from such semantic difficulties. Also, it seemed important to provide definitions of the following key terms:

- we talk about a "**Zone analysis**" instead of a "**zone assessment**" in order to indicate that we are proceeding with a global approach regarding all of the elements necessary to understand the situation, both in terms of its scientific and health stakes as well as its economic and political ones. This analysis is not just a preliminary stage before a study is launched. It relates to all of the attention that must be dedicated to the situation, from its assessment to its management.
- we speak of Zone health risk assessment (Z-RA) or "zone assessments" for a structured scientific approach that summarises the scientific knowledge available in order to evaluate the health effects resulting from exposure of a population or of individuals to hazardous substances, agents or situations (NAS, 1983)⁷ across a zone.

As necessary, other terms will be defined throughout the text, as they appear.

1.4 - Work method

In response to these two requests, the HCSP has established a working group made up of experts from various institutions, some of whom are members of the HCSP's special commission on environmental risks (CSRE), the list of which is presented at the beginning of the report. This interdisciplinary work led to the implication of expert skills for areas such as, among others, risk assessment, epidemiology, sociology, political science, toxicology and environmental quality measurement.

The achievement of this expertise was based on interviews of external experts, an international seminar and two literature reviews. The work group met 14 times between June 2009 and September 2010. During each session, minutes were written to keep track of what was said during the meeting.

⁷ 1983. Risk Assessment in the Federal Government: Managing the Process. Committee on the Institutional Means for Assessment of Risks to Public Health, Commission on Life Sciences, National Research Council, Washington, DC. This document is often referred to as the "Red book".

All of this material, rich in experience and in methodological thinking, was taken into account during the drafting of this report, but it has not been deemed necessary or possible to always specify the specific origin of each point retained by the HCSP's work group.

1.4.1 - Presentation of specific works and methodologies

During three sessions, members of the work group were able to attend a presentation of Ineris's specifications relating to zone assessments and feedback from six zone assessments⁸; an analysis of the feedback from the Chenôve school case study⁹ and of the stakeholders' involvement; finally, a presentation of the Intarese¹⁰ programme as well as a discussion on Ineris's ComRisk project¹¹.

1.4.2 - Hearings with outside experts involved in a Z-RA

A certain number of stakeholders who had been involved in conducting a Z-RA were invited to contribute to this expertise. A total of seventeen hearings took place over seven separate days, between October 2009 and February 2010, the list of which is presented on pages 5 and 6 of this report. These hearings took place in three different sites, in Paris, Marseille and Bordeaux, by videoconference or in face-to-face.

The individuals that were interviewed work for industrial entities, government agencies, communities and elected officials, associations and consulting firms. Before each hearing, the person being interviewed received a hearing grid that allowed him/her to prepare the testimony and helped guide the session's exchanges. Five interview grids were prepared by the work group, one for each area of specialisation: industrial, administrative, elected officials, consulting firms, associations (Appendix 2). Following the sessions, the hearings were transcribed in summary form and then validated by the interviewees (Appendix 3).

1.4.3 - International seminar

An international seminar was held in Paris on 12 January 2010 at the Ministry of Health and Sports, so as to contribute to the HCSP's appraisal of an approach to zone risk assessment and how to manage such assessments. The seminar, entitled "*Improved consideration of cumulative exposures during risk assessments*" was mainly focused on the issue of multiple sources of emissions and how the results of the risk assessments are produced and interpreted in this setting.

The seminar benefited from the participation of North American experts (list of speakers on page 5 of this report) who had been members of the committee on "improving the risk analysis approaches used by the U.S. EPA", which was formed by the National Research Council at the request of the environmental protection agency, which recently published a book on the subject entitled "Science

⁸ Grammont V. presentation on 19 March 2010 of the following reports: (i) Feedback on 6 zone assessments completed at the end of 2008 – report pending validation and (ii) Establishing specifications for zone assessments, available at <http://www.ineris.fr/>

⁹ Pirard P, Ormsby JN. Feedback on the Chenôve school case study, 21 May 2010

¹⁰ Philippe S. Formaldehyde: impact study on a health enforcement measure, 19 March 2010

Boudet C. Presentation of the tools used in Intarese's framework, 19 March 2010

¹¹ Hazebrouck B. ComRisk and a zone ERS, 21 May 2010

and decision. Advancing risk assessment"¹². This book, also referred to as the "silver book", is the follow-up to the now famous "Red book"¹³ on risk assessment, which was published in 1983.

This seminar has been documented via summaries written in both French and English, both of which were validated by the interviewees (Appendix 4).

1.4.4 - Bibliographic summaries

Two literature reviews by international authors contributed to the work group's situational analysis. The first one, conducted by the Vincent Nédellec Conseil (VNC) consulting firm focused on the quantitative assessment of health risks practices used within the framework of zone assessments. The purpose of this report was to:

- group together international reports on the subject;
- identify the objectives of the Z-RAs that are carried out;
- describe the methodological guidelines and the assumptions that were used in the Z-RA that were conducted.

This report was presented by Vincent Nédellec during a work group meeting on 19 March 2010 (Appendix 5).

The second review, produced by the Centre for Applied Social Science Studies (Cessa), is a bibliographic analysis of the roles of stakeholders in RAs when multiple activities are present. The purpose of this report was to:

- identify the stakeholders that had been implicated;
- determine the stakeholders' degree of involvement;
- determine the stakeholders' influence on results;
- determine the stakeholders' influence on the way the risk is managed.

This report was presented by Jean-Stéphane Borja and Stephan Castel during a work group meeting on 21 May 2010 (Appendix 6).

1.4.5 - Report proofreading and validation

The report established by the HCSP's work group was subjected to review by two outside experts, both of them risk assessment practitioners (Dominique Laurier, from the IRSN and Philippe Glorennec, From the EHESP). The amended version was then presented to the members of the HCSP's CSRE on 21 October 2010. The modifications proposed by this commission have been incorporated into this report.

¹² National Research Council (NRC), 2009, Science and decision. Advancing risk assessment (National Academy Press, Washington, DC) 404 pgs

¹³ National Research Council (NRC), pg .26

2 - Definition and description of a zone, a relevant area where health and risk management can be assessed

The industrial planning of the territory has led a number of polluting activities, with varying degrees of specialisation and concentration, to be grouped together across geographically defined areas. The populations that are located in the vicinity of these areas are subjected to multiple exposures. Regarding the assessment of their impact on health, these activities have not, until now, been taken together as a whole, except in rare cases, because each activity has been analysed separately in the context of impact studies.

The zone concept remains blurry due to the very wide range of activities that are considered: industrial plants, farming, road, sea and river transport, wastelands, etc... The cumulative chemical pollution and other nuisances generated by these activities is at the heart of the zone problem when it comes to assessing their cumulative impact¹⁴ on the population's health.

An expansive vision of a zone could lead, little by little, to the inclusion of a vast territory, as it is true that emissions into the atmosphere or into water environments barely have any limits as to how much can be spread. It is therefore suggested that we assign an operational character to the delimitation of the risk assessment zone because the objective is clearly utility-based: to enable sound management of the potential risks that the population is exposed to. In addition to the term "cumulative" (referring to pollution or nuisances), another key word to inspire this delimitation is "solidary area": an area where economic activities, physical environments and occupants interact. What are the links or the forces that establish this solidarity?

2.1 - Different facets of a zone

The importance of translating a RA into dynamic action leads us to consider the zone concept from different perspectives, whose compatibility is not immediately obvious. An economic perspective through an employment area that is based on activities that are more or less connected; a political perspective that is the result of the intertwining of local authorities' various hierarchical layers within this economic area, each one having its own regulatory prerogatives and areas of responsibility; a population-based perspective that helps us to understand the organisation of space into both residential areas that are more or less dense, as well as areas devoted to other functions (schools, homes for the elderly, recreational activities, commercial services and activities...), and this territory is often marked by an urban sprawl which pushes these areas close to polluting activities. Lastly, there is an environmental perspective which leads us to define the zone's boundaries according to the environment's physical, biological and natural characteristics, and according to the dissemination of chemical pollution through the various channels that people are in contact with. It is with the interaction of these different perspectives that the definition and the delimitation of a "zone" must be conducted when proceeding with a Z-RA.

¹⁴ This term will be defined in greater detail further on, in section 6.2.4 – Risk characterisation stage

2.1.1 - Economic facet

First of all, the territory is marked by the presence of different production and service activities, along with connecting routes that allow people and goods to be transported. Although they are sources of wealth-creation, they are all also, more or less, the cause of nuisances and pollution. The establishment of a new business, the changes made to an existing one (increased volumes or changes in processes or technologies) will modify environmental conditions. For example, because one of these businesses submits an application for expansion, which will entail an impact study, or because the law mandates that such a study be conducted on a decennial basis in older facilities, questions will arise regarding whether it makes sense to consider this single source of pollution or nuisance emissions, or whether this contribution, in conjunction with the associated "background noise", is likely to affect the health of a particular fraction of the exposed population. This overall assessment of pollution and nuisances thereby creates another form of solidarity. We therefore need to ask ourselves: is it this source that we need to reduce or even ban, or should we instead moderate or question the existence of other sources?

2.1.2 - Political facet

Life within a territory is governed by a rich set of communities and community networks which each (sometimes jointly) possess a set of responsibilities relating to different activity sectors: economic development, transportation, waste management, housing, facilities for the elderly, etc. Nuisances and pollution generated by an activity pool will most often affect several local authorities. Therefore, they will all more or less be interested in assessing the resulting impact. In addition, the measures that are likely to be implemented, if the impact on the area and on health is considered to be excessive, may involve one or the other of these communities, precisely because it is responsible for one of the problem's sources, or simply because the activity of concern is located within its territory and it provides them with revenues and jobs.

This conclusion commands the inclusion of the territory's various political stakeholders and their various interests for the sake of consistency in the public decisions.

2.1.3 - Population facet

As is the case with administrative and political districts, the population that is likely to be affected by the nuisances involved is not distributed across the territory in the same way that the pollutants are emitted. This is especially true as populations are mobile and multi-active: residents, workers, users (or seekers) of services and themselves contributors, in part, to the pollution (through their usage of transportation or production of waste...). The distribution of exposure levels is highly unequal. This depends on where the ways that the main pollution emitting activities are implanted, the channels by which pollution is dispersed and the ways that the various population strata make use of their respective territories.

The representation of risks in society is also multifaceted. Collective action, initiated to reduce a perceived threat, will therefore build networks that will mobilise themselves to influence decision makers, or, where appropriate, to participate in the decision.

The delimitation of a health risk assessment zone shall include the different ways by which the population using the territory is concerned with the quality of its living environment and is interested in its preservation.

2.1.4 - Environmental facet

Of course, it will also shape the distribution of risk across the territory, through the environment's physical, biological and natural characteristics and through the areas in which the pollutants are emitted and through the pollutants and nuisances' properties. Knowledge of these technical and scientific elements is necessary to determine the demarcation of the area.

2.2 - Definition of an assessment zone

A RA assessment zone is therefore the complex result of various forms of interaction between sources of emissions of both pollution and nuisances, a population pool that is hosted and active in its territory, organised according to plural administrative and political boundaries, and, lastly, channels through which nuisances and pollutants are transferred to the locations where vulnerable individuals will be exposed. Thus, one understands that this delimitation is not based solely on technical criteria.

2.2.1 - Different names

The various zone delimitation facets demonstrate the extent to which its influence may depend on the various involved stakeholders. The name that different people use is not a trivial matter. Although not complete, the following list of terms has been used: "emitters' zones", "assessment zone", "exposure zone", "impact zone", "effects zone". Accordingly, it is difficult to settle on a universal definition, or at least a shared one.

Importantly enough, these different names clearly illustrate the lack of a consensus, which is not confined solely to semantics. Discussing a zone of emitters may lead one to limit the boundaries of a zone to the regulatory jurisdiction of the activities being considered. Discussing an effects or an impact zone may lead one to expand the zone to a relevant limit where pollutants are concentrated, from a sanitary point of view. Obviously, this results in a relevant population with a highly variable size.

2.2.2 - Definition put forth by the HCSP

Having considered these factors, the HCSP has proposed the following general definition of a zone, subject to a Z-RA:

"A zone is a solidary area, in terms of economics, physical attributes and population, where a range of economic activities (industries, transportation of people or goods, agriculture...) took place, are taking place or will take place, contributing significantly to the emission in the environment of agents with hazardous potency, that may, alone or when combined, affect health in the short or long term, given the way that the diverse populations occupy the area".

More specifically, and by way of example, a zone can *at the very least* be defined whenever two distinct sources of emissions are likely to affect a local population, through changes in the quality of physical environments.

2.3 - Qualitative and quantitative assessment zone delimitation criteria

Due to these different perceptions, the operational delimitation of an assessment zone must be a completely distinct step within a Z-RA. Later on, we will explain why it should take place in such a manner that all stakeholders are involved in its identification. This is the result of an analysis of the situation, the expectations of stakeholders, the objectives assigned to the assessment as well as the development of a conceptual exposure scheme. It is recommended that the identification of an assessment zone be done in an iterative manner and take place in two stages: in the first stage, through a qualitative approach, and in the second stage, through a more formal and quantitative approach so as to specify the limits corresponding to the criteria defined in the first approach.

2.3.1 - Qualitative approach

An analysis of the situation allows to develop a conceptual exposure scheme that establishes the relationships between sources of exposure, the transfer vectors and the exposed populations. This scheme lists all the exposure channels and vectors, but it does not correlate these channels and vectors with the size of the targeted population, nor does it identify their geographic location within the zone being studied.

It is nevertheless possible to go further by assessing the population potential exposure by overlapping the pollution dispersal map, exposure channels and vectors within this delimited area. The creation of a map illustrating the populations potential exposure thereby gives a more complete idea of the qualitative importance of the exposure expected in any point within the delimited zone.

Such a map will allow to define, during an initial qualitative approach, the boundaries of the zone while taking into account two criteria: (1) all of the sources present in the activity zone (industrial, transport, ...); (2) and the population pool, which must be continuous in terms of its presence across the territory.

Subsequently, one should consider the stakeholders' perceptions and expectations, not to mention the issues that have made headlines or that are likely to do so. Such information has an impact on the possible extension of an assessment zone.

2.3.2 - Quantitative approach

In a second quantitative approach, the boundaries of the assessment zone are specified, in what will be a preliminary study by modelling the dispersion of the emissions according to "tracer" pollutants or nuisances chosen according to the context and the relevant areas that are to be considered (air, water intended for human consumption...).

The tracers chosen for the delimitation of the territory are pollution tracers rather than health relevant tracers and they won't necessarily be used, ultimately, to calculate risks. They may be specific to each environment that is to be analysed. Until now, and in terms of air emissions, sulphur dioxide has been considered to be the most relevant industrial tracer to define the assessment zone. Other agents may be considered depending on the nature of the emission and/or nuisance sources as well as the transfer media (underground or surface water).

In practice, it is suggested that the zone's boundaries be those where the concentration of a tracer, attributable to one or more sources, is equal to 10% of the environmental quality objective for a given pollutant or agent, when that territory is continuous in terms of the activity and population pool, that is to say, it is included in the physical, economic and social space described above.

This empirical benchmark of 10%, which is already used in France for QRAs relating to incinerators, is deemed to be relevant because it can encompass, on the outskirts of the zone, areas where no unacceptable health impact is expected; in principle, it therefore represents a criteria leading to a broad definition of the territory included in the Z-RAs "zone". This approach assumes that the analysed environmental quality objectives, when they exist, are protective as far as health is concerned, and this should be documented.

Whether we are considering the 10% benchmark or the environmental quality objective, these two items can be modulated if local circumstances justify it. The results of the modelling depend mainly on the local dispersive conditions (meteorological ones in particular, and underlying or surface hydrological flows) and the characteristics of emission sources that are taken into account in the activity zone. These two criteria appear to be most important ones for the delineation of the assessment zone. On this basis, the occupation of the territory is an important adjustment variable that can induce changes in the zone that is delimited. Interested parties and/or the assessor are indeed likely to request an extension of the first assessment zone that was defined by modelling when densely populated areas are located at the edge.

In some cases, the results of dispersion modelling in the atmosphere, or on rare occasions in the aquifer or a river, can be tied in with measurements of pollutants in the environment's various compartments. These measures may already exist, in particular as a result of air quality monitoring networks or thanks to measurement campaigns (sensors or piezometers). The

implementation of such a campaign implies that specific funding for the assessment zone delineation stage has been anticipated and obtained before the actual start of the Z-RA. This preliminary work leads to a lengthening of the duration of the Z-RA, as the time required to complete a measurement campaign may stretch beyond several weeks, sometimes even months or more than one year.

Expansion of the assessment zone, in order to take into account densely populated areas on the edge of the territory or to align modelling results with the measurements, can also lead to the inclusion of new emitters on the outskirts of the zone.

This does not necessarily lead to an extension of the zone so as to include the territory affected by this (these) other emitter(s) because it is possible to consider only the contribution of these emissions to exposure within the initially delimited zone.

2.4- Organisation of work with regards to zone delimitation

The delimitation of an assessment zone therefore takes into account the many facets developed above and the criteria for this delimitation are of various types, both subjective and objective. Consequently, it can only result from a consultation involving all stakeholders. The proposal made by a Steering and monitoring committee (COS), justified and described in the section dedicated to stakeholders (section 4), brings together for discussion all of those who are involved, including, when appropriate, the representatives of emission sources located on the outskirts of the zone, as it is deemed necessary that they be taken into consideration. It is up to this committee to perform this delimitation work which may, if necessary, require that *ad hoc* studies be conducted to enhance the original data.

Specific funding should be planned for such delimitation. It is all the more necessary as measurement campaigns and modelling must be entrusted to consultants in order to be implemented.

In all cases, this zone must be delimited beforehand. An analysis of the situation may lead those who are involved to identify some sub-zones which will be studied particularly closely due to specific features (land configuration, tracts of land used for food crops, presence of vulnerable populations).

3 - Utility of a zone assessment from a health risk management viewpoint

3.1 - Concept of utility

A Z-RA must fall within an expected outcome in response to a triggering context. Like any other study which aims to evaluate the impact of an activity on the health of a population, it serves no purpose on its own. It relates to an objective identified in advance, since this scientific approach is defined first and foremost as being a decision-making aid in an uncertain situation. It is therefore important to identify in advance the range of decisions that can be taken based on the Z-RA results.

The presentation of the work outlined in the "Silver Book" published by the National Research Council (NRC) of the United States during the international seminar held during the process of this request clearly highlighted this using several examples, both American and French. In France, the quantification of risk has led to improved management of very diverse situations, as illustrated by the assessment of strategies seeking to optimise the reduction of emissions over a territory, the information of victims of growth hormones and the consequences following the sinking of the Erika tanker. On a local level, RAs conducted in the context of impact studies have a regulatory purpose, while others can, in emergency situations, help form the basis of decisions such as the banning of specific foods or the closing of a business.

Conducting a RA may serve several purposes. The first utility is cognitive in the sense that we are enhancing our knowledge in terms of exposure and risks in the assessed zone. The second utility, a central one, regards the decision-making support which places the RA in its political dimension, especially due to its contribution to the development of the territory's action plan. The third one relates to the involvement of stakeholders: proceeding with a RA in a zone can no longer be conceived without the participation of the various stakeholders, each one bringing relevant elements to the table for the examination of the case. Finally, the fourth type of utility focuses on communication, whether between those who are involved or targeting the general population.

These different utilities will be developed in the following paragraphs, while trying to distinguish between those which emphasize the analysis of a zone instead of the conventional "single-site" impact study approach. In any case, these utilities can only become tangible by relying on a key pre-requisite: a situation analysis.

3.2 - Pre-requisite: a situation analysis

At the local level, inquiries to authorities regarding environmental pollution or nuisances in connection with economic activities most often end up examining the health of the population, whether the origin of the inquiry is linked to the environment, health, the regulatory framework or the political will to be part of a regional health-environment plan, for example. Therefore, it is tempting to try to quantify the health impact of this situation in order to evaluate the basis of the expressed complaint or concern.

However, this first response is not necessarily related to the expectations and needs of local stakeholders, in particular the person or people responsible for the initial inquiry. Understanding the various needs and expectations is therefore very important to identify the issues and goals put forth by each stakeholder.

The situation analysis is a key step of dialogue and preparation for the implementation of a potential assessment, including RA, and therefore a Z-RA, whose objectives and terms will be defined according to a principle of reality and actions in proportion to the issues at hand.

3.2.1- Gathering of information

The situation analysis aims to gather and organise all of the information that is already available from archives, work already performed, etc... in order to identify the territory's environmental and health issues.

In a first stage, this information is restricted to the subject of the reported event. In particular, it covers the sources, details of the possible contaminations or exposures, the health problem and the effects that are described or implied and the characteristics of the exposed populations. Information is also available in various regulatory, political, legal and media areas so that the social dimension of an examined territory can be understood. For example, in terms of regulation, are industrial activities complying with currently applicable discharge thresholds? As for the media, one will gather the various events reported by newspapers at the local, regional and even national levels, while analysing the content of what is reported. Nowadays, the internet and social networks are two sources which should not be overlooked.

On the one hand, the organisation of this information allows to understand the degree of concern expressed by the various stakeholders regarding the health issue, whether this concern is that of the stakeholder and/or that which he thinks is reflected in the situation; on the other hand, it allows to create a preliminary conceptual exposure scheme which reflects all of the possible contact points between the pollutants and the population. This is an assessment of the population potential exposure.

3.2.2- Description of the stakes and questions relating to public health

All of this information should allow to understand the local context where health and/or environmental problems are present. These preliminary diagnosis elements will be even more useful when it comes time to guide future actions. We should then determine the environmental, health and socio-economic stakes and identify, formulate or reformulate more specifically the question(s) that arose, whether explicit or implicit.

Schematically, three types of situations can be at the origin of the request to undertake a zone assessment: 1) The implementation of an impact study within a regulatory context, knowing that this context may itself fall into one of two types of situations: 1.a- for a new facility (or a new or modified process in an existing facility); 1.b- for an existing facility; 2) in response to a concern regarding the possible health impact arising from a polluting activity or a given environmental situation; 3) in response to the discovery of the onset of an excess of certain diseases in the area.

Once the stakes have been stated and the issues identified, it is possible to define and formulate the objectives of the study or studies to be conducted in order to address them. It is a period during which the stakeholders can exchange their thoughts and concerns. The formulation of the objectives should be done with great rigour, as it then determines the methodological course of the study, the use of the gathered data and the interpretation of the results. These three entry points have a common root in terms of the questions, with three variables that follow. The root can be labelled as follows:

"Given the way that the various populations use the land, are the environments that are affected by previous, current or planned activities...", a root which is further broken down into:

▪ **regulatory points of entry**

"... likely to lead to health exposure and risks levels that are considered to be excessive in relation to conventional or regulatory benchmarks?"

▪ **environmental points of entry**

"... likely to lead to health exposure and risks levels that are considered to be excessive in relation to observed or estimated pollution levels?"

▪ **sanitary points of entry**

"... able to explain all or part of the incidence or prevalence of the observed or perceived health problem(s)?"

For each of these variants, we have common sub-questions in the event that a positive answer arises from the question: "If yes:

- *which is (are) the transfer media and route(s) and agents which most greatly contribute to these exposure and risk levels?*

- *which is (are) the past and/or current activity(ies) which contribute(s) the most?"*

Once the wording of these questions has been established, one must decide which type of assessment is the most appropriate (Sidebar 1).

Sidebar 1 - Analysing the relevance of the various types of studies that are possible in a given situation

The analysis of a situation allows to come to an understanding of the issues and the questions that have come up (or that the various involved parties have). In the context of this report, only RA-type studies will be explored, as these are the cases that have been referred to the HCSP. However, in a given local situation, great care must be given to a preliminary interrogation: what is (are) the most relevant type(s) of study(ies) available to address these issues and to answer questions raised by the situational analysis?

Indeed, there are many different types of studies that could be considered: RA, Health Impact Assessments (HIA), epidemiological studies, impregnation studies, etc. Consideration on the type of study to conduct is an important step because the wrong choice will prevent an adequate answer from being found. Prior work on the subject, which is still valid, has formalised this step. We refer readers to the following useful document "Guidelines for investigations in proximity to incinerators [InVS, 2003]¹⁵. The RA, which is the subject of this report, is therefore just one type of answer that is available.

Formalising such reasoning therefore assumes that an educational effort will be made to ensure that all those involved, including the population, will understand the legitimacy of the choices that are made. Indeed, the various issues raised do not necessarily require that an answer be provided by just one method. It is also worth noting that the RA may be a preliminary step before conducting a study of another kind (epidemiological study, bio-monitoring, environmental monitoring...).

3.2.3 - Benefits of a preliminary analysis on the zone's situation

The points mentioned above are not specific to a particular situation. At this point, it is therefore important that we highlight the elements that lead this initial analysis of the situation to demonstrate the singularities which provide the zone assessment with an original dimension as opposed to what you would obtain with a "single-site" study.

The definition of a zone, detailed in section 2, allows to highlight the "solidary space" concept. The value that one gets from a comprehensive situational analysis of a zone, which takes into account both industrial activities (and the pollution and nuisances that they cause) as well as all of the activities that ensure that a territory is able to function (other industrial activities, infrastructures, agriculture...), is the ability to understand the solidary character of this living space.

The taking into account of interaction between stakeholders, the estimate of an overall risk (and not just company-specific risk), the drafting of a comprehensive action plan covering the entire zone (and not the overlapping of single action plans which may be insufficient as a whole, and even contradictory) and, lastly, a statement which provides consistency over the entire area (rather than being scattered and sometimes out of phase or displaced) are all benefits to be obtained from a zone assessment.

¹⁵ Incinerators and health. Guide for how to proceed with a local request to launch a health investigation targeting a garbage incinerator. Institute of Sanitary Surveillance, St-Maurice, 2003, 104 pgs.

This is particularly relevant at a time when the theme of environmental inequalities is largely highlighted in the various national plans, the PNSE2 in particular.

3.3 - Different types of utility

3.3.1- Utility for knowledge

The RA consists in the organising and using of available scientific knowledge in order to describe the risks that a population faces; in doing so, it must allow to identify gaps in knowledge. These gaps may relate to the entire extent of the effort, from the source term (the emission of pollutants), to the transfers within the environment as well as toxicological data, including the description of the affected population and its exposure. This statement of knowledge provides an initial utility of great importance.

However, this organisation of knowledge and information allows to proceed even further. In particular, if one is examining several pollutants, one is able to identify those which are of greater concern and for which something must be done sooner. It also helps to identify the nature of the diseases involved, such as cancer, growth impediments... This represents the first diagnostic step which will help guide further efforts, whether in terms of environmental monitoring (where and when should we reinforce it?) or in terms of awareness of health conditions (which zones should we investigate? which pathologies should we be on the lookout for?).

The main objective of a RA in an activity zone is to seek the most comprehensive solution possible for the risks at hand, while taking into consideration, for example, all the exposure setting, not just the pollution generated by one specific source. This approach is considered to be more relevant than one that is derived from studies on each separate activity, thanks in particular to an awareness of the population overall exposure and the identification of areas of overexposure. This comprehensive approach also relates to cumulative impacts on health due to the possible interaction between the various effects derived from the agents that are present. This consideration regarding the various sources of chemical substances and their cumulative impact in areas where human activity is quite dense is an important insight.

3.3.2 - Utility for public action

The purpose of a RA is to provide information that helps policy makers understand what they need to do in order to manage identified risks. As was mentioned above, this first requires that we establish an environmental and health management plan that identifies the various courses of action that can be implemented and for which the RA can estimate the expected impacts. Indeed, the RA will allow to compare various management options from which the best choice can be made, especially in light of the sanitary improvements that are expected. For example, an estimate of the cumulative exposures and the impacts arising from the various sources is likely to optimise the allocation of resources, which will lead to a bigger benefit in terms of public health.

It is therefore important that we ask ourselves, beforehand, the following questions (among others): What action should we proceed with? What choices should we make between the various management options that we have? For which population(s)? What activities may be subject to an emission reduction? What activities may be subject to reduced exposures? These questions will guide the assumptions and the calculations of the Z-RA, which must clearly serve the risk management objectives and not be an exercise in and of itself.

Within the context of these zone assessments, a major expectation relates to the organisation of pollution regulation throughout the industrial basin as well as other activities to implement health risk management that is more in line with the populations' exposure distribution. Thanks to its comprehensive approach, it enables the identification of pollutants that shape risk as well as their primary contributors (in terms of sources and usage).

The approach of a zone must allow one to pinpoint the relative contributions (to overall risk) by the various activities of an assessed zone in order to provide decision makers with information enabling them to measure the cost-effectiveness of available management options (ex: usage restrictions, infrastructure relocations, reduced emissions, adoption of the best available technology (BAT), etc.). Such judgement, though, occurs with constraints. As a result, it is typical for a new industrial activity to be implanted, whenever possible, on an existing industrial site, so as to not destroy wilderness area.

Similarly, it is important to combat urban sprawl. It is therefore essential that we know at the very start of the approach which areas for improvement can be discussed and implemented, both in terms of environmental and industrial development as well as public health.

The work group members' hearings and previous experiences have shown that this dimension hasn't always been clearly formalised. This dimension often intervened *after* the study. Yet, we clearly sense the progress that is made thanks to initial clarification of the desired outcome. This is an important point which needs to be reinforced in current practices.

3.3.3 - Utility for stakeholders

Hearings conducted with individuals who have already participated in a RA approach, within a zone containing several industrial facilities and other economic activities, have highlighted the substantial benefits that each party obtained from the confrontation of ideas, solutions, expectations and needs between the various stakeholders involved in the process.

It becomes apparent that there is genuine utility to be obtained when all of a territory's stakeholders take action. Of course, disagreements and differences will continue to exist, but such dialogue favours the coordination of action as well as the understanding of the issues at hand. This important topic is the subject of a specific section (section 4).

However, these hearings have also shed light on how much work Z-RAs require. A significant investment must be made in terms of human labour and time. It is therefore necessary that we plan for this obstacle: the time required to conduct these studies. Not all stakeholders, associations in particular, have the resources to cope with such a long schedule.

3.3.4 - Utility in terms of communication

The hearings have allowed to identify some gaps in terms of communication. It must be planned and prepared beforehand. It must not be subject to an inconsiderate obstacle or delay caused by any of the stakeholders, or the State, otherwise it could undermine the whole process and generate feelings of resentment.

The two principles of a RA are transparency and consistency. Transparency requires that the report provides all of the justifications, supporting arguments and criteria needed for the various hypotheses that are formulated as well as for the choices, both methodological and pragmatic, that are made. The report must also provide readers with the ability to redo all of the calculations and estimates that have been done, if he or she deems it necessary. Lastly, the report lists all of the bibliographic references that were used during the approach. The consistency reflects concerns regarding the relevance of the choices that were made, both on a comprehensive level, which ensures that the response corresponds with the question that was raised, as well as during each step of the process.

The Z-RA facilitates communication throughout the process. It calls for the sharing of information and implies an understanding (and even sharing) of the choices that are progressively made. It therefore creates a space for dialogue that is in line with the size of the activity pool's stakes. This allows the various stakeholders who are involved to be highly implicated, from the initial analysis of the situation up until the analysis of the lessons that can be learned from the outcomes (in terms of management options), including the establishment of a work method and the assessment's protocol.

Transparency between the stakeholders that are involved in the workflow must also be accompanied by the same level of transparency between those who are not involved but for whom the results and decisions will be important. The RA that is conducted within a zone must be accompanied by quality communication with elected officials and the general public. It should cover both its foundations - including the questions it seeks to address – as well as its results. The assessment schedule must take into account this communication phase.

3.4 - Conclusion regarding the utility of Z-RAs

A Z-RA stands apart from single-site RAs due to the comprehensiveness of its approach in territories where a range of economic activities (industries, transportation of people or goods, agriculture...) took place, are taking place or will take place, contributing significantly to the emission of potential harmful agents in the environment, that may, alone or when combined, affect health in the short or long term, given the way that the diverse populations occupy the area.

It has a number of benefits which demonstrate that the implementation of a Z-RA is fully justified and makes sense where the partial or total coverage of activities requires that they be studied together in order to assess the overall impact due to the accumulation of exposures and effects, and their respective shares, and to pool management measures.

Currently, these initiatives are taken quite easily and no obstacles arise which would block their implementation. We even see a willingness to repeat these studies after a few years in order to measure the progress that has been made. All of the stakeholders see it as an attractive opportunity to go beyond the analyses provided by single-site impact studies, by proposing an end result, for example, that provides a combined and concerted management effort at reducing pollution emissions. The freedom afforded by the absence of a regulatory framework is probably a contributing factor.

The Z-RA therefore represents a true decision-making tool for the protection of public health, within a forum for dialogue that suits both the situation as well as its stakeholders. Nevertheless, the heterogeneous feel of the hearings leads us to strive for harmonisation of the framework in which these assessment studies will take place in the future.

4 - Stakeholders' involvement and roles in the Z-RA process

This section justifies the benefit of involving all stakeholders involved by the impact on the environment and health that economic activities located in a local delineated area can have. These stakeholders have been identified, and the ways in which their knowledge of the context can be valued when conducting a RA are exposed. After this statement, a general framework for what can eventually become a stakeholder participation charter is proposed. The HCSP stresses that implementation of these principles must be aligned with local conditions.

4.1- Values and principles which justify stakeholder participation

The involvement of stakeholders in the analysis of risks linked to the environment has been the subject of extensive academic work, and this form of "environmental democracy" is now being implemented in many countries with approaches such as the "Environmental Impact Assessment" or "Health Impact Assessment", and oftentimes within a regulatory framework (in countries such as Canada, Wales within the UK, USA, Sweden...). France's "Grenelle Environment Round Table" in 2007 has given this concept a strong political foundation.

Why is it recommended that we make sure that stakeholders participate? Although the high involvement of multiple stakeholders may tend to slow down the process, for most authors and witnesses, this negative effect is largely offset by a range of positive effects linked to this active participation, such as the inclusion of various relevant data, the resolution of conflicts before they become irreversible and mutual acculturation. In addition to the positive impact that will be made in the quality of risk assessments, these debates between the various stakeholders are also likely to enrich the search for acceptable and effective solutions to problems that may arise. Today, the debate is therefore no longer about the relevance of this commitment, but rather the forms it might take on. Indeed, many references exist which illustrate the usefulness of stakeholders' participation in the ERS process.

For many authors, especially Anglo-Saxon ones, RAs are vectors of democratisation, which implies aspirations to improve the acceptability of decisions, to improve equality and to educate the general public. This entails a spirit of transparency which ensures that stakeholders have access to information regarding the ins and outs of the problem that has led to a RA, its stakes and its conditions of implementation. Although this practice is currently less widespread in France than in other countries, the HCSP endorses this approach and recommends that it be systematically implemented in the various forms of RA, especially in the context of a zone RA. It seems especially relevant and it bears specific characteristics due to the extent of the issue, both in terms of space as well as diversity of the stakes.

Nevertheless, one should not ignore the barriers to this development because, as of Rowe and Fewer's work (2000)¹⁶, the issue regarding the effectiveness of a participatory systems points to difficulties inherent in such an exercise. The HCSP now proposes to clarify the issues in light of the strong growth of participatory processes and their related procedures.

4.2 - Definition of stakeholders

Stakeholders participating in an Z-RA, or any other study designed to better assess the health risks of a range of activities in an area, in order to reduce them if necessary, can have various origins. In this document, the term "stakeholders" refers to a group of people that are likely to be directly interested in an approach to understanding and reducing health risks affecting a delimited zone, even if the roles and the interests of each are different. With this intentionally broad definition, the potential stakeholders are:

- those who manage facilities and activities which generate a nuisance in the territory being examined (industrial plants, road infrastructures, agricultural entities...);
- local elected officials (mayors, presidents of inter-municipalities or General or regional councils if applicable);
- public services publics (Dreal, ARS, administrative offices...);
- associations (environmental protection, as well as committees focused on neighbourhoods, parents, consumer protection, senior citizens, the sick...)¹⁷;
- employees working in the affected zone (Hygiene, safety and working conditions committee, inter-company committees,...);
- qualified persons or bodies who have been selected for their scientific expertise on the subject (risks related to the ecosystem or the populations).

Although everyone is clearly eligible for implication, not everyone is equal. It is obvious that the State's agencies, who by law have a mission to arbitrate and prescribe, are both stakeholders - providing technical knowledge and an expert analysis of the stakes – as well as being "above" such status, in the sense that they are defenders of the public's general interest, and in charge of submitting items for arbitration to the prefectural authority. The representative of the local authority which is directly involved (city or intra-community) will also have a special status, as will be discussed later on.

¹⁶ Rowe G and Fewer L. (2000), Public participation methods: a framework for evaluation. Science, Technology, and human values, vol 25, no. 1, 2000, pgs. 3-29.

¹⁷ We should not limit our reach to those associations which are the most committed to the subject at hand, and we should seek to elicit participation from diverse population segments.

4.3 - Terms of stakeholder involvement

This section is devoted to the statement of recommendations which aims to formalise the terms under which stakeholders are involved when we bring up the subject of consequences, via the environment, of the impact on public health arising from economic activities located within the territory. This statement does not intend to be a prescription for a uniform framework suitable for all circumstances since the activities involved and the diversity of stakeholders require terms of involvement which are adapted to each specific context. However, the general principles that are presented, which are largely inspired by both national and international experience, are likely to allow the various approaches that will be implemented on a national level to become both understandable and consistent, which is an important factor of trust and therefore participation.

Even though they are involved in this subject to varying degrees and for different reasons, the various stakeholders identified above are entitled to express their views throughout the RA process. Also, the involvement of stakeholders should be facilitated as early as possible, as soon as the problem which needs to be investigated and resolved, if need be, has been formulated ("issue framing"); their participation must be maintained throughout the work and assessment process, up until the decisions made by the competent authorities have been announced and their implementation has been monitored. This idea has been widely accepted as being necessary both in international literature¹⁸ as well as by French stakeholders who have been in charge of the problem (Cessa, 2010)¹⁹.

4.3.1 - The Steering and Monitoring Committee's formation and missions

When a local health and/or environmental issue requires that special investigations be conducted, the HCSP, based on the findings by Rowe and Frewer²⁰ (Sidebar 2), advocate the quick establishment of a Steering and Monitoring Committee (COS in French) by the State and the directly affected regional authorities in order to bring together the widest possible range of stakeholders affected by the problem. Any stakeholder that has a link to the case may initiate the request for such a committee to be formed.

This COS, whose size will vary depending on the contexts, will consist of 6 colleges with representatives:

- from regional authorities;
- from the State, competent government agencies and institutions;
- from the civil society (associations, neighbourhood committees, etc.);
- employees of companies or facilities located in the territory that is of concern;
- employers, of these same companies and facilities;
- qualified individuals, on an individual basis.

¹⁸ National Research Council (NRC), 2009. pg. 28

¹⁹ Cessa. Bibliographic analysis on the roles of stakeholders in the assessment of risks in contexts where multiple activities are present, 2010, 150 pgs.

²⁰ Rowe G and Frewer L. (2000), pg. 43

Because the issue that is raised is both of an environmental and a health nature, and because the State is entrusted with a responsibility to both regulate and represent public interests, the HCSP recommends that the COS be co-led by both the ARS and the Dreal (the health and environment public authorities in the regions), which oversee cases related to these issues which are referred to the State. All of the COS's participants will appoint, by consensus, a president whose responsibility is to ensure that everyone's voice is heard and that the Committee fulfils its role. In the event that a consensus cannot be reached, the ARS and the Dreal, in consultation with the regional council that is directly affected, will appoint a president from the college of qualified individuals, as they have no apparent direct interests at stake. During the COS's first meeting, it will be appropriate that everyone's opinion be gathered regarding the choice of the various categories of stakeholders that are invited.

As needed, and depending on the study and the questions that arise, the COS may elect to set up a steering committee. This committee, whose vocation will be more operational in nature, in order to discuss technical issues, will nevertheless be open to stakeholders who wish to participate. This way, no one will be under the impression that some are excluded. This committee will be held accountable and will have to justify its choices before the COS.

The COS's missions can be split into three phases:

- The first of these is decision-making support based on:
 - the environmental health issue that is at stake. This crucial work aims for stakeholders to have a shared vision, if possible, regarding the origin of the problem, its nature, its intensity, the questions that may arise regarding possible health and environmental consequences and the objectives that the government assigns to the participatory process;
 - the need, or lack thereof, to conduct an ERS-Z based on the situational analysis²¹.
- The second phase, occurring after the Z-RA assessment has been deemed appropriate, focuses on its preparation and includes:
 - determination, in a first approach, of the relevant assessment zone;
 - the choice of a service provider (usually a research firm, but any other type of competent body is also legitimate) that will draft specifications for the Z-RA that will be conducted²²;
 - validation of the Z-RAs specifications and, as required, any amendments that may seem necessary;

²¹ As was mentioned in section 2, a RA (basic or zone-wide) isn't necessarily the best solution for the issue at hand, and the COS will decide of this. It is possible that we will keep the COS active if the involved parties deem it useful (monitoring of action taken in order to control nuisances; awareness of a surveillance study regarding environmental quality, a bio-monitoring or epidemiological study...).

²² If need be, sufficient resources will need to be planned for in order to allow for the implementation of a preliminary study.

- the choice of the research firm that will be entrusted with conducting the Z-RA, after a call for applications. This research firm will not be the same one that drafted the Z-RAs specifications²³;
- The third phase involves the actual implementation of the Z-RA and the monitoring of the recommendations:
 - the conducting of the assessment, ensuring follow-up that complies with the specifications;
 - analysis of the results and formulation of recommendations pertaining to management measures;
 - once the arbitration has been performed and decisions have been made by the competent authorities, the monitoring of the action plan's implementation and the assessment of its impact.

It therefore appears that the COS is the occasion where the parties will agree upon the need to conduct an assessment (by definition, a Z-RA, in the context of this report) which aims to explore the health impact of economic activities (past, present or future) within a given territory, where a Z-RAs objectives and contents can be discussed. The COS will then follow the process and discuss the consequences that can be drawn from its conclusions, in terms of risk management options. It is not a setting, however, where political arbitrage regarding the action plan will take place (this issue will be clarified in the next section). Lastly, the COS will remain active in order to ensure the implementation of the management measures and to assess their impact.

The COS will also perform a role in terms of communication with the general public. It will ensure that the general population is made aware of findings, conclusions and recommendations resulting from the situational analysis and from the Z-RA which will have been conducted.

Throughout this effort, the COS's president will fulfil both a facilitating and a unifying role. The State's agencies will be as involved as other stakeholders in discussions. Nevertheless, at the end of the fourth leg of the second phase, the State's agencies will submit their recommendations, pertaining to risk management measures, to the competent decision-making authorities (departmental or regional prefecture), which will result from the consensus that has been reached or, in the absence thereof, fulfilling their mission by acting as a mediator for the conflicting interests.

²³ Indeed, the HCSP believes that it is key that steps be taken to ensure that the service provider in charge of drafting the specifications is not related to the party which conducts the actual Z-RA. This is to avoid any conflicts of interest from arising.

Sidebar 2 - Criteria for an effective participatory system, according to Rowe and Frewer²⁴

Based on an extensive review of essays on participation, the authors have established a set of standard criteria related to the effectiveness of a participatory process. These criteria are split into two categories, the criteria for legitimacy, which address the elements required for the public to adhere to the system, and procedural criteria, which relate to the process's progress, as well as the effectiveness of participation.

The legitimacy criteria:

1. The representativeness criterion: participants should include a sample that is roughly representative of the involved population.
2. The independence criterion: the procedure for participation must be conducted in an independent and impartial manner.
3. The early involvement criterion: the general public must be involved in the process as early as possible.
4. The influence criterion: the opinions and decisions that result from the procedure must have a genuine impact on policy, and the general public must be able to perceive this.
5. The transparency criterion: the procedure must be transparent in order for the general public to see what is happening and understand how decisions are made.

The procedural criteria:

1. The resource accessibility criterion: participants must have access to the appropriate resources in order to meet their targets (requested assessments, testimony by experts or other individuals).
2. The objective definition criterion: the nature and scope of the procedure's objectives must be clearly defined.
3. The structured decision-making criterion: participants must use/provide appropriate systems in order to structure and deploy (expose) the decision-making procedure.
4. The profitability criterion: the procedure must, in a certain sense, be cost-effective for the organisers.

²⁴ Rowe G and Frewer L. (2000), pg. 43

4.3.2- Stakeholders' rights and responsibilities

The COS is the setting where all subjects which affect the Z-RA will be discussed, from the wording of the questions which the process seeks to address in order to highlight the decisions made by the competent parties and authorities, to the selection of the health effects and target populations that are taken into account, including consideration of the environmental quality's "background noise". Some of these topics will be subject to negotiation (an extension of the assessed territory, inclusion of sources of pollution...); others, which are of a scientific and technical nature, are not subject to negotiation (selection of toxicological reference values, for a given critical effect, or benchmarks for the interpretation of calculated risk levels, for example), but they must all be explained and justified (for example, the wording of the criteria used for the selection of toxicological reference values).

Although the COS is a setting for discussion and clarification, it is not a setting where a majority vote leads to a decision. While it is expected that discussions occurring within the COS make it possible to precisely and jointly design the risk assessment study, in the absence of a general consensus, final choices regarding the actual conducting of the Z-RA will be made by the parties that are requesting and funding the study. It includes industrial entities as well as those who are responsible for the activities at the root of the nuisances at issue, with, if need be, appropriate input (in variable proportions depending on the context) from public entities (State, regional authorities and/or public institutions...). It is up to the study's backers to justify the choices made as a result of discussions that have taken place within the COS. Once a consensus has been reached, it is likely to greatly facilitate the use of the Z-RAs results as well as the acceptance of provisions that will be made to manage the evaluated risk. It is not a condition, except in the event that blocking power is to be given to a particular party. *A fortiori*, although it allows for informed discussion on the risk management measures that have been identified during the Z-RA, the COS is not a setting where they will be negotiated or arbitrated. It is up to the relevant public bodies and the economic entities that are involved to make these decisions, particularly on the basis of the work performed by the COS.

Mirroring this clarification regarding the final responsibility of the Z-RAs sponsor and the risk managers, it is important that the stakeholders be assured that they can retain freedom of speech and action during and after their participation in the COS. Although this instance of cooperation is likely to build a relationship of mutual trust and understanding between the various stakeholders, thanks to discussions on all matters relating to the Z-RA, each stakeholder retains his freedom to act and express himself publicly. Indeed, participation in the process does not mean that each stakeholder abandons his own stand; thus, for example, associations are entitled to maintain a certain critical distance, and even to dissociate themselves from certain decisions if they so desire. These "rules of the game" must be defined as soon as the COS is established, as should the terms under which the COS's work and conclusions will be published. In this regard, the HCSP, informed by the hearings and interviews conducted during this referred case, strongly expresses the view that a clear commitment be taken immediately by public authorities, and that the results of the Z-RA will be

made public as soon as it has been completed. The minutes of meetings, which are also intended to be public, will give way, if necessary, to the expression of divergent opinions. In these circumstances, stakeholders will not feel like they are being held hostage and the decision-makers will be able to make the choices they feel are appropriate, even in the event that one party objects. This applies to decisions regarding the conduct of the Z-RA and, even more so, to those concerning management measures that would result from the outcome of this analysis, which fall under the domain of competent public authority as well as management of the relevant companies and activities.

4.3.3- Funding issues

The issue of funding relates to both the Z-RAs operational costs as well as the running of the COS in order for it to function properly. The Z-RAs costs, and, where appropriate, those of preliminary studies (including the drafting of specifications) must be borne by the parties that are at the source of the problem – that is to say, all of the economic entities of the zone being assessed, according to contribution rules which they will freely agree to or, failing that, by decision of the public authority publique²⁵. Depending on the local context, regional authorities and the State can decide to contribute more or less.

However, the funds required for the COS to operate (its secretariat and support for its members' travel expenses and their compensation for any losses of income related to their participation in these proceedings) will be planned for when it is established and provided by the State and the relevant regional authority(ies).

This distinction between funding sources according to the objects of the expenditures ensures that support for costs is in line with the various stakeholders' responsibilities.

4.4- Striving towards a stakeholders' participation charter

In a given territory, when one is wondering about the impact that economic activities can have on the health of the local population, which justifies that specific investigations be carried out, with the possible implementation of a Z-RA, the HCSP recommends the early establishment of a COS which brings together all of the stakeholders related to a problem that has been raised. The COS, which does not replace the decision makers, aims to involve all those who are interested, to varying degrees, in an assessment of this impact, and who can contribute to discussion on the methods that could be implemented to minimise it. The HCSP recommends that one of the committee's first tasks is to draft an operational charter that explains, in particular, the rights and duties related to the involvement of the various stakeholders.

²⁵ For example, one zone assessment was funded in proportion to the turnover of the businesses located in the activity zone being studied. This approach, however, raises a question regarding the contribution of non-industrial activities (major roads, farming activities where applicable...). This calls for the responsibility of the public authorities regarding the determination of how the sources of funding will be allocated.

The drafting of this charter may take shape in ways that are specific to the various locations and situations. The stakeholders' commitments can be explained in a more or less precise and formal manner. The HCSP nevertheless wants to bring the following points to the attention of upcoming COSs, as they believe that they should be explicitly agreed to and drafted before the committee actually begins its work:

- 1- Precise and explicit establishment of rules overseeing the integration of stakeholders within the COS: advertising requirements regarding calls for candidates to complete, if the parties agree to it, the initially established COS; choice of how it will be organised, and, in particular, the meetings' dates and hours according to the various stakeholders' constraints;
- 2- Structuring of the COS: presidency, secretariat, definition of the agenda, etc.;
- 3- Financing of the COS: for its internal logistics (including support for costs related to participation in the meetings) and the funding of preliminary assessments and/or assessments;
- 4- Transparency of discussions within the COS: organisation of the drafting and approval of the meetings' minutes, the format of these minutes (nominal presentation, or not, of the various stakeholders' statements; ways in which diverging opinions are expressed,...); terms under which minutes will be advertised outside of the COS;
- 5- Links (or lack thereof) between the COS and other possible settings for discussion within the same zone (CLIC, S3PI...); in principle, the use of such existing forums is advisable, if necessary by expanding them for this purpose;
- 6- Clarification of the COS and the steering committee respective roles: although the COS focuses on the implementation of a Z-RA and the creation of a mainly technical steering committee is decided by the stakeholders, we will need to define the relationship between the COS and the steering committee, especially regarding the methodological choices that may impact the ERS's results;
- 7- Terms of the various steps – for example, once an initial phase of a finished Z-RAs results has been obtained. Terms of the public presentation of the Z-RAs first results;
- 8- Terms of the public presentation of the conclusions reached by the decision makers regarding the Z-RAs results, in terms of the measures that must be taken;
- 9- Fate of the COS once the assessments have been completed: conditions for the monitoring of the implementation of the agreed measures.

5 - Interpretation of RA and Z-RA results

More specifically, this section addresses referred case DGS/EA1 no. 106 of 21 May 2008, which requests that the HCSP "help interpret the results of risk assessments conducted in the framework of impact studies". Its contents apply to any RA assessment, whether it is a conventional "single-site" one or part of a Z-RA which covers an entire economic area. In that respect, the HCSP has not discerned any fundamental difference between the two situations in terms of interpretation criteria. Nevertheless, when it will be appropriate, it will highlight certain issues that take on a specific dimension during a zone approach, which relates to the "combined" exposure question.

5.1- Current expression and interpretation of RA findings

The two main results expressed by a RA are the hazard quotient (HR) and the excess risk (ER). We are therefore dealing with a ratio that reflects exposure to the population that is above or below the toxicology reference value (TRV). For example, a HR equal to 2 means that the population is exposed to a dose or exposure concentration higher than the TRV by a factor of two. It does not mean that there is twice as much chance that a disease will occur. A HR result that is greater than 1 leads us to consider the possibility and the plausibility that harmful effects will appear within some individuals in the population.

The ER, on the other hand, represents the probability that a disease will occur, the result of a multiplied dose or concentrated exposure of the pollutant which is illustrated by a line that displays the dose-response function plotted by mathematical extrapolation, using data from the reference study. This slope is also called the unit risk (UR) as it expresses the probability that disease will occur if the population is subject to a unit of pollutant throughout its life, typically defined at 70 years.

In a previous expertise essay on the estimate of the health impact within a RA (InVS/Afsset, 2007)²⁶, other proposals for the expression of results were made. On the one hand, it was a calculation of the number of cancer cases that could appear within the population, an *impact* measurement obtained by multiplying the previously defined ER by the number of people in the population. On the other hand, it represents the percentage of the population affected by HRs or ERs which exceed the benchmark values. These expressions of results are not routinely included in the various RA that are conducted, either in France or abroad.

Currently, in terms of regulatory impact assessments, RA results are presented using the value(s) calculated for each population exposure scenario that has been established. Placed within a deterministic calculation approach, they are therefore limited to a single value, sometimes even two when a "risk management framework" is proposed, usually a mean value and a maximum value. In addition, in a first approach regarding the cumulative effect of pollutants in an assessed zone, the ERI or HR calculated per system are sometimes summoned.

²⁶ InVS/Afsset. Estimating the health impact of environmental pollution and quantitative assessment of health risks. Ed. InVS/Afsset 2007, 162 pgs.

The interpretation of these figures is based primarily on their comparison with benchmarks that are known as being "typically" or "usually" accepted by national or international authorities. The benchmark value is 1 for hazard quotients, and 10^{-5} for excess risk. The exceeding or non-exceeding of these values, a primarily binary method of reasoning, leads us to conclude that the risks are either "acceptable" or not. Therefore, actions must be taken to control the sources of the risk and, where appropriate, to provide a sanitary response to the population.

Usage and monitoring of a RA, following the principles outlined above, nevertheless have a certain number of shortcomings.

5.2- Identified shortcomings

These shortcomings affect the way that results are presented and therefore made understandable by the policy makers and the general public in order to enable them to make use of the risk assessors' results. They also affect the interpretation that is made of the HR and ER indicators, which help individuals understand a given situation's health implications. Shortcomings resulting from the lack of consideration of the study's contextual elements are also highlighted. They nevertheless are genuinely important for the assessment of the situation and for the formulation of recommendations arising from the RAs results.

5.2.1- Shortcomings in the presentation and expression of findings

Critical analysis of reports submitted to the authorities after RAs and hearings have been conducted has shown the need to reinforce the following items, in no particular order:

- Clarity and conciseness of the presentation of the assessment's results, regardless of the context which it is a part of²⁷. This seems all the more necessary in the context of a zone assessment, as the area is by definition larger than when looking at a single facility and the heterogeneity of exposures, risks and the population density merit consideration;
- The ability to identify and visualize possible locations that are more problematic than others ("hot spots"), whether in terms of the exposure level, the level of risk or the size of the involved population or a combination thereof;
- A detailed description of the population whose level of exposure was found to be potentially detrimental to its health;
- The qualitative or quantitative results, in terms of exposure, regarding pollutants for which it is not possible (with current knowledge) to calculate a risk indicator, in the absence of a TRV;
- The providing of exposure maps of pollutants which do not have TRVs, so as to identify areas where these exposures will become superimposed with those which are deemed to hold excessive risks according to the RAs conventional criteria;

²⁷ A very useful reference on this subject is the US-EPA's Risk characterization handbook (2000), available at <http://www.epa.gov/spc/pdfs/rchandbk.pdf>

- When justified, and after a first deterministic approach that is supplemented, if necessary, by a sensitivity analysis, the results should be expressed in a probabilistic manner and should, if possible, feature a confidence interval if we have the statistical information necessary to calculate it. Indeed, the results are based on assumptions, models and parameters whose variability and uncertainty should be taken into account as much as possible.

5.2.2 - Shortcomings in the interpretation of findings

Here, significant progress can also be made, in particular on:

- The meaning of the HR, which pertains to the over- (or under-) exposure with reference to a value that is determined to be "without harmful effects" and not to the probability that a disease will occur;
- The explanation of the meaning of an ER which does not reflect the risk incurred by a particular individual but rather reflects an ordinary "average" citizen within the study population, an individual whose characteristics and behavioural assumptions have been identified in the exposure scenario;
- The linking of the results with the contextual elements that have led to the assessment being conducted. Among these elements, we can note the consideration of the relevant population (presence of children or seniors or other vulnerability factors...), the time scale of the exposure at hand (past, present, future...), etc. These results are expressed as estimates of the occurrence of an event in the coming years, given the previously formulated assumptions²⁸;
- The linking of results within the context of knowledge: for example, the number of cases identified on the national level, the type of population that is affected, etc.;
- An effort to explain the assessment's findings in terms of possible decisions that authorities may make, or regarding the nature and extent of a health concern emerging from the examined situation, any element that is not subject to binary logic. In doing so, the assessor will not replace the risk manager; instead, he or she will provide information that will be useful for the manager to fulfil his or her responsibilities.

5.3 - Proposals

Observations of current RA practices, as well as shortcomings that have appeared, allow to make a number of proposals designed to improve the clarity, understanding and use of their results. This evolution is all the more necessary that, although RAs were initially primarily designed to prioritise public health problems, now increasingly applied to a local level, these results are expected to enlighten finer risk management reflexion rather than simply ranking such risk, for example to adjust the scope of a reduction in pollutant emission flows.

²⁸ In addition, these results are sometimes an indication of current risk that results from past exposures.

Their purpose is to guide potential environmental and health management measures which aim to reduce exposures, and to support, if need be, the health of the population residing in the assessment zone (through sanitary surveillance assessments, for example).

Similarly, enhancing clarity becomes a condition for the informed involvement of the stakeholders. Their "inexperienced" eyes (that is to say non-technical and non-expert) and their need to understand require that a presentation, expression or interpretation of results not be overshadowed by unfamiliar jargon or terms that are understood only by specialists.

The below proposals are intended to be as practical as possible, that is to say, they must be able to be put into practice quickly. If this is not the case, the following text will discuss areas or subjects that require additional work.

5.3.1 - In terms of the presentation and expression of findings

The evolution expected from the results presentation does not just focus on its visualisation, but on a clearer idea of the strengths and weaknesses as well. In addition, one must not neglect to express and present results other than those provided by HRs and ERs, as a RAs main objective is to organise the available knowledge in order to clarify the management of potential risks, and it must therefore present all of this knowledge in various appropriate forms. Lastly, the presentation of results should ensure that full consideration is given to variability and uncertainty (Sidebar 3), in particular by expressing the distribution of risk exposure within the population, including any sub-populations that are especially vulnerable. Their precise inclusion within the context of the assessment is also an important area for improvement as these results should be used to their full extent.

Sidebar 3 - Definition of variability and uncertainty

Variability: refers to differences in values that can exist for a given parameter due to the heterogeneity of the situations that relate to the parameter. Variability cannot be reduced since it reflects the "state of nature", but it should be described accurately.

Uncertainty: refers to the absence or lack of information regarding the parameter. The uncertainty depends on the quality, the quantity and the relevance of data as well as the robustness and relevance of the models and assumptions. Uncertainty can be reduced by using or gathering additional and/or more precise data.

- **The creation of "iso-risk" maps of the zone**

A numerical presentation of the results in a table format only provides partial information and does not allow the stakeholders to understand what they represent and, in particular, what part of the assessed zone is subject to the greatest impact. In the context of a Z-RA, this mapping is essential for all of the stakeholders to be able to share and take ownership of the results.

More specifically, creating maps of the territory allows one to quickly assess its possible heterogeneity in terms of risk level²⁹, especially for identification of problem areas. The presentation of the risk indicators' scale in a map format in addition to an indication of the proportion of the population that is covered by the highest indicators would better illustrate the Z-RAs numerical results and facilitate the prioritisation of management measures.

- **Highlighting the strengths and weaknesses**

In the final part of the Z-RA report, a section that identifies and lists the strengths and weaknesses of the approach is also necessary in order to facilitate the critical evaluation of their validity and strength. This section can also provide a reminder of the main assumptions and approximations that have been made throughout the process. Such a structure is consistent with greater clarity and conciseness in terms of the presentation of the results.

- **Separating the actual results from their interpretation**

There is sometimes confusion regarding the level of a health risk and the threshold where management is required. In order to avoid such confusion and to clarify the presentations, it is best that we clearly distinguish two separate parts in the report: the first part aims to describe the results and discuss them, especially their strength and validity, while the second part is dedicated to their interpretation, which requires that they be considered within the context of the territory and subject at hand.

- **The presentation of results other than HR and ER results**

The numerical results of a RA are mainly HRs and ERs. However, during the process, concentrations within the environments were measured or estimated using modelling. Exposure doses or concentration levels were calculated. These results must not be ignored during the final stage of the risk characterisation, especially regarding pollutants that do not have TRVs, as they can provide intermediary indicators of the potential risk. Their comparison with other data published in studies is possible, particularly in terms of exposure levels. Presentation of such data is necessary, and it should once again be done in an "iso-exposure" format, if possible.

- **Results presented as statistical distributions within the exposed population: variability**

The objectivity that is required when producing a single result is not only justified by the uncertainties inherent when conducting a RA. It is also required because of the statistical variability of many of the values used in the calculation, which reflects the diversity of the situations (emission conditions, population characteristics...). The individuals conducting the RA have access to the distributions of a number of the population's parameters (ex: body weight, ground ingestion, transfer factors, food consumption, water consumption, space-time budgets). This allows these parameters to be taken into account.

²⁹ This "iso-risk" mapping is obviously a simplified expression of a complex reality where the actual exposure level depends on factors that are difficult to describe with precision and where vulnerability, for a similar exposure level, is also subject to various factors (age, physiological state, etc.).

- **Better consideration of uncertainty**

The results of a health risk assessment are usually expressed with a single value, or even by a framework that describes a scenario that is qualified as being average and a scenario that is qualified as being high or "worst case". For many years, the need to discuss these results has been highlighted. Nevertheless, beyond words, there have been no efforts to code, standardise or take into account uncertainties or their expression in the results that are generated³⁰. Heterogeneity is very high across the risk assessment studies that are conducted and should be smoothed out. It is recommended that we take into account, as much as possible, any elements of uncertainty and variability, otherwise one may introduce a high degree of inequality in the usage made nationwide of the various ERS studies that have been performed.

The analysis of variability and uncertainty aims to find out if variations in the assumptions, model parameters, or the data that is used would alter the RAs results. This variability and uncertainty can be worked on in several ways: a qualitative analysis of the source term, the background noise, the modelling (including the identification of dose-response relationships) and exposure; quantitative analysis using different scenarios: sensitivity analysis, techniques that simulate and spread both variability and uncertainty (probabilistic approaches, such as a Monte Carlo analysis). All RA studies must lead to results that can be interpreted from a management standpoint. Nevertheless, not all require the implementation of complex uncertainty quantification approaches²⁹, according to the proportionality principle, but, given the multiple expectations that exist in terms of risk management, Z-RAs are clearly appropriate when initiating this type of approach.

A presentation of methods which allow for more detailed consideration and expression of uncertainty is outside of the scope of this report and was explicitly excluded from the request that was submitted to the High Council for Public Health. Those who have such an interest can find additional methodological work elsewhere, especially in the NRC's recent publication (the "Silver Book")³¹, as well as from other health and safety institutes and agencies.

- **Results that are more closely linked to the population that is genuinely at risk, and consideration of the context**

In order to provide a general direction for the work that is to be conducted, it is necessary that the population be described in detail. Indeed, the results of RA reports are generally presented to the entire population that is involved, irrespective of sub-populations. Sometimes, for some pollutants, the results are split into two groups: one for children and the other for adults. Given the local nature of studies and the practical answers that the involved parties expect, the use of assessment results would benefit from more detailed knowledge of the population and its characteristics in order to select, for example, toxicological data that are more appropriate.

³⁰ Risk characterization handbook, US-EPA (2000), pg. 52

³¹ National Research Council (NRC), 2009, pg .28

We would like to add that scientific progress, especially progress in toxicology and epidemiology, will probably allow for the more frequent adoption of TRVs that are specific to the population's various sub-groups, based on demographic criteria (young children, pregnant women, seniors...) or health criteria (victims of asthma, those with heart disease...), which will make it possible to have a better grasp of the population being considered.

Lastly, the broadening of the ways in which results are presented so as to include the spatial distribution of the percentage of the population that is subject to different estimated risk levels also tends to go in this direction.

This improvement effort is also noteworthy as it reinforces the ability to discuss results that relate to items within the study's context. This is all the more important since, during each step of the process, uncertainties, variabilities and poor judgements have been revealed which merited consideration within the conclusions that were drawn. In particular, the discussion can highlight, with more accuracy, the benefit of further studies designed to contribute to existing knowledge regarding exposure within the assessed zone or to increase the performance of the exposure's modelling. Other types of studies may be proposed, such as, for example, studies aiming to fill gaps in terms of knowledge of source terms for certain industries or for maritime traffic.

5.3.2 - In terms of the interpretation of findings

The proposals relate to discarding the "acceptable risk" notion in favour of the "management threshold" concept. The notion of acceptability leads us to a multi-dimensional social construct that does not just result from RA calculations. The proposals also address the consideration of multiple exposures and thus cumulative risks, which, although not a specificity of zone RAs, are nevertheless an essential aspect of these studies.

- **The setting of management thresholds and intervals**

Once the results have been obtained, the first interpretation that is made results from a binary reading, with the benchmark values of the risk indicators, which are exceeded or not, often being set at 1 for HRs and 10^{-5} for ERs. The reports' conclusion is thereby expressed in terms of "acceptable risk". It is possible to substantially improve this RA phase, particularly in the context of a Z-RA.

This binary reading appears simplistic. Given the precaution that is taken with the implementation of a factor of uncertainty in their construction, exceeding a TRV does not indicate that there is a risk that a detrimental effect will appear within the population, unless this excess is substantial and overpasses some of the factors of uncertainty. It is therefore inappropriate to speak of unacceptable risk in these circumstances. Similarly, the conventionally accepted risk threshold value of 10^{-5} was initially proposed to indicate an insignificant risk level. Work conducted by the Opersei³² has demonstrated that the criteria which allowed this 10^{-5} threshold to be applied are not always well known.

³² Opersei question 26. http://www.sante.gouv.fr/html/dossiers/etud_impact/626_ei.htm

Reference is often made to work conducted by Mantel and Bryan (1961)³³ and Kelly and Cardon (1994)³⁴.

The HCSP acknowledges the framework that is currently applicable in the context of the polluted soil policy³⁵ and its extension through proactive environmental efforts focused on "sensitive" facilities located on polluted grounds. This reference framework is as follows:

For soil :

- ER > 10⁻⁴ or HR > 5: reduction actions are required;
- ER between 10⁻⁶ and 10⁻⁴ and HR between 0.2 and 5: results are discussed on a case by case basis according to their context;
- ER < 10⁻⁶ or HR < 0.2: risk considered to be insignificant, no need for management measures.

For the air:

- HR < 1.

For the sake of consistency, regarding the benchmarks which inspire public health safety policies related to the environment, the HCSP recommends that three thresholds be used to interpret RA results. The differences observed with previous benchmarks, result from the framework in which risk estimates are made. In the context of polluted soil, risk benchmarks are used following a risk calculation that may be hastily obtained, and not from risk assessment efforts. However, this proposal can only be applied after a risk assessment effort has been rigorously conducted, the genuine (but essentially unknown) margin of uncertainty may be far higher than a factor of 5. We are therefore not just talking about a simple calculation that allows to quickly and roughly assess the concerns generated by a situation. These pragmatic and operational proposals are as follows:

- Areas requiring quick action: ER >10⁻⁴ or HR > 10

Risk levels (ER) or possibly adverse effects associated with exposures (HR) that have been explored in the context of the RA are considered to be of sufficient concern to warrant "fast" environmental and health protection measures. Such measures can include, for example, restricted use of (or forbidden access to) certain locations, or bans on vegetables in the event that they are produced there. In a secondary phase, and using these thresholds, a coordinated and coherent management plan will be developed. This plan will notably provide restoration options and support for the populations as well as an assessment of the relevance and feasibility of health monitoring efforts.

- Areas requiring active vigilance: 10⁻⁵ < ER < 10⁻⁴ and 1 < HR < 10

The risk levels are serious but they are not as disturbing and they require further situational analysis before any hasty management decisions are made. This vigilance will manifest itself in the following ways, in particular:

³³ Mantel N, Bryan WR. 1961. Safety testing of carcinogenic agents. J. Nat. Cancer Inst. 27:455-470.

³⁴ Kelly, K.A. and Cardon, N.C. 1994. The myth of 10⁻⁶ as a definition of acceptable risk. EPA Watch 3, 17.

³⁵ Paper published on 8 February 2007. Polluted sites and soils – methods of management and redevelopment of polluted sites - Ministry of Ecology and Sustainable Development

1. The results of the uncertainty analysis and the sensitivity analysis are accounted for: conduct the additional local studies that have been recommended; assess their impact on the RAs results. The findings will depend on the results of this thorough reanalysis of the RA;
2. Study and implementation of a management plan that is designed for the medium term and is calibrated for the following cases:
 - If a portion of the population that is deemed to be significant, or a sub-group that is considered to be vulnerable, is affected by these intermediary management indices (above 10^{-5} and 1, respectively);
 - If there are geographic areas that have exceeded the upper limit of these areas which require vigilance;
 - If there are geographical areas where other benchmarks have been surpassed, especially in terms of exposure for pollutants which do not have a TRV.

- **Areas that are compliant: $ER < 10^{-5}$ and $HR < 1$**

The risk levels are not considered to be disturbing, and it is not necessary to implement specific management measures beyond those that already exist and which fall under the general principle that the best available technologies be used.

• **Multiple exposure and cumulative risk**

In a zone assessment where emissions are obviously plentiful, it is essential that the interpretation of the results keep this multiplicity of sources in mind. This cumulative exposure and risk must be considered when one or more pollutants demonstrate results that exceed the upper limit of the range requiring vigilance. Section 6 provides recommendations on that subject. On the other hand, the discovery of lower values, below the threshold of conformity, indicates the absence of adverse effects according to current knowledge. This refined analysis will explore the dose-effect relationship of each pollutant. For non-carcinogenic effects, one must keep in mind that a TRV, for a given pollutant, was designed for its "critical effect". This is the first event considered as being harmful and occurring at lower exposure levels within epidemiological experiments or studies. It is the starting point of a dose-effect relationship. Currently, results are only expressed and interpreted in relation to this one effect. However, in the case of accumulation, it may be necessary to check for the existence of one or more other pollutants that can also induce this effect, even if it is not, for this or the other pollutants, the critical effect. This is particularly true as some effects occur at doses that are similar or very close to those producing the critical effect. Such a situation could "potentiate" the risk of the pollutant whose HR is "high". This assessment regarding cumulative effects in a complex exposure situation would help complete the analysis regarding the disturbing (or non-disturbing) nature of the situation.

This reasoning may also be used for carcinogenic effects and ERs. It is indeed rare that a pollutant is only carcinogenic within a single cancer site. An identical dose, or an increase in doses of exposure, leads to a multiplication of affected locations. Once again, having a greater amount of information in this area can help provide stakeholders with a choice of more targeted responses.

5.3.3 - Overview

The evaluation of a QRAs quantitative results, while keeping in mind the management thresholds and intervals arising from assumptions and calculations, is one of several benchmarks in the assessment of possible health consequences within the examined population. Qualitative information will necessarily complete, reinforce or temper the quantitative analysis's findings. Scientific uncertainties that were highlighted during the process will also be important elements of the interpretation. All of this information is put into perspective, within the context that led to the implementation of the study, in order to enlighten the management decisions that will follow.

6 - Methodological principles regarding quantitative risk evaluations pertaining to zone assessments

An analysis of the situation following a health or environmental signal, a regulatory request or political will allow to produce a conceptual exposure framework and to retain the approach that will be considered the most appropriate in responding to the signal, as was discussed in section 3. The QRA approach is one of these approaches.

The purpose of this section is not to draft a methodological guide on RAs for zone assessments, which falls under the responsibility of the Ineris in its work for the ministries in charge of ecology and health (scheduled to be released at the end of 2010), but to present the Z-RAS methodological specificities during each typical stage of the risk assessment.

In addition to being inspired by the opinions expressed during the various hearings, the methodological considerations presented below are drawn from the bibliographic study report on QRA practices conducted within the framework of zone assessments (written by Vincent Nédellec Conseil³⁶ at the request of the HCSP), a summary of the international seminar held on 12 January 2010, and from the Ineris's hearing on feedback that the institute had after evaluation from the first zone assessments.

6.1 - Current methodological framework of single-site RAs

The quantitative assessment of health risks is a structured approach that was developed by the National Research Council (NRC, 1983) which describes it as being "...the use of scientific evidence to define the health effects resulting from the exposure of individuals or populations to hazardous materials or situations". This approach follows a well defined four-step method that provides managers with health risk estimates, produced in acknowledgement of current scientific knowledge and according to scenarios and assumptions that should be clearly explained.

In France, this method was chosen to address the health component of an "impact assessment", and to be integrated into records relating to requests for the authorisation to operate a facility that is classified for the protection of the environment, so as to quantify the expected potential risk to populations who are in proximity of the site. The same goes for roads.

In France, two general methodological documents are referred to:

- the "Reading guide regarding an impact study's health component", published by the French Institute for Public Health surveillance (InVS, 2000)³⁷;

³⁶ Vincent Nédellec (2010) Bibliographic study of quantitative health risk assessment practices conducted in the framework of zone assessments. Report prepared for the HCSP. 74 pgs.

³⁷ « Guide de lecture du volet sanitaire d'une étude d'impact ». French Institute for Public Health Surveillance (InVS), 2000, pg. 25

- the Ineris's methodological guide: "Health risk assessments within ICPE impact studies - Chemicals" (Ineris, 2003)³⁸.

There are also methodological guides for each industry or source of pollution (polluted sites and grounds, biological risks, compost platforms, incineration plants, storage facilities for household and similar waste, refineries).

In contrast, and until now, Z-RAs have not had a specifically defined methodological framework. Previous initiatives have relied on the traditional approach to single-activity RAs, replicating the conventional four-step approach: (1) hazard identification, (2) selection of toxicological reference values, (3) assessment of exposure and (4) risk characterization. The hearings have allowed to identify a number of areas which distinguish the Z-RAs approach. This section describes the four health risk assessment steps, with emphasis placed on the peculiarities found when using this approach in the context of a zone assessment.

In all cases, it is recommended that a stepwise procedure, whose initial steps may be relatively "basic", be implemented. The use of more refined steps may eventually be justified if the results suggest that exposure and risk levels merit further examination.

6.2 - Singularities of the Z-RA approach

6.2.1 - Hazard identification step

A hazard is a substance's (or noxious agent's) intrinsic ability to cause an adverse effect on human health. It may result in: a change in the appearance of an organ or a temporary or permanent impairment of its functions, behavioural disturbances, a foetal malformation or stunted growth, a genetic mutation, a benign or malignant tumour, or death (Empereur-Bissonnet, 1999)³⁹.

This step involves both the identification and the most comprehensive description as possible of the substances emitted by sources present in the assessment zone and capable of generating one or more undesirable health effects, as well as a description of the resulting health effect(s). When a Z-RA is being conducted, the peculiarities of this step relate to the following items:

- the need for a complete inventory of the sources of pollution and/or nuisances present within the defined area;
- because this inventory will inevitably be of great size, it will be necessary to proceed with the categorisation and, later on, the selection of potentially hazardous substances considered to be the most relevant within the context that is being examined;

³⁸ « Évaluation des risques sanitaires dans les études d'impact des ICPE – Substances chimiques ». French national institute for industrial environment and risks (Ineris), 2003, pg. 25

³⁹ Empereur-Bissonnet P. Human health risk assessment: methodology. In glycol ethers – What are the risks to our health? INSERM collective expertise, 1999

- the taking into account, a priori⁴⁰, of the acute health effects that are likely to result from exposure to a combination of sources of pollution and nuisances present on the territory, some of which exhibit iterative emissions (boiler rooms...) while others are more constant.

These proposals illustrate the need for reinforced toxicological expertise when conducting RAs, and Z-RAs especially. It is therefore necessary that more training efforts be provided in this discipline.

6.2.1.1 - Identifying all sources of pollution and/or nuisances

With single-site RAs, only sources relating to the facility that is being assessed are inventoried and taken into account. However, in the context of Z-RAs, all of the emission sources present in the assessment zone must be identified. This inventory should include both industrial sources regulated by laws pertaining to environmental protection classified facilities (ICPE), as well as sources, industrial or other, that are not subject to such regulations, such as transport entities (rail, maritime)⁴¹, farming or urban heating.

These emission sources contribute to both present and future pollution. It is also necessary that past sources be identified, as their impact continues to be felt within the assessment zone. Consideration for past pollution will most often be found through its impact on land surfaces. Consulting the BASIAS⁴² database allows one to identify all of the previous industrial sites, abandoned or not, in mainland France and in overseas departments and territories, and the BASOL⁴³ database lists the concentrations of some substances that were found on polluted sites and grounds.

An overview of emissions is necessary for all the sources that have been inventoried, either by using facility or infrastructure-specific data, or, at the very least, by using published data. The heterogeneity of the activities that are to be accounted, however, can be a challenge when trying to define a common denominator of information. Wherever possible, the inventory must take into account the details of each industrial process, and it should also specify the categories of substances that are found.

6.2.1.2 - Categorising hazardous agents and establishing a selection

In the context of a Z-RA, different sources can emit a large number of substances. Vincent Nédellec Conseil's⁴⁴ literature review demonstrates that French studies consider the selection of "risk tracers" as being an obvious necessity within Z-RAs. The rationale that justifies this selection is based on the economy of resources, the simplification of the assessment, the proportionality of the study in relation to the stakes and therefore, ultimately, a clearer presentation of the findings.

⁴⁰ The prior situational analysis will have been able to eliminate the likelihood of such acute effects, but it is often during the actual exposure assessment that this hypothesis can be explored. Although the inclusion of short-term effects is generally required for single-site assessments, it is even more necessary in situations where several sources were active during different time periods

⁴¹ Road transport is already subject to regulation.

⁴² <http://basias.brgm.fr>

⁴³ <http://basol.environnement.gouv.fr>

⁴⁴ Vincent Nédellec (2010), pg. 61

However, this “tracer” concept calls for the representativeness of one or more harmful agents within a family of pollutants; different categories of pollutants may thus be taken into account, each one with its sources, its physical, chemical or toxicological properties, which may lead to different behaviours within the environment, as well as various detrimental processes. It is based on currently available knowledge, which allows one to quantify the risk at hand. The evaluator hopes that these tracers will serve as conclusive benchmarks which will help in terms of both decision-making and actions intended to serve public health at the end of this process.

The main objective of the RA approach, however, is to organise knowledge. Before considering the selection of any activities or substances, it is therefore important that one identifies the toxicological knowledge that is available for the widest possible range of substances that are emitted, or nuisances that are related to activities. It will therefore be necessary to categorise the substances according to the degree of knowledge that is available at the time of the study by grouping together those for which no toxicological knowledge is available, those for which only the health effects have been identified, with no established TRV (by separating the carcinogenic effects from the non-carcinogenic ones), and those which allow for a quantitative assessment to be performed, once again separating the carcinogenic effects from the non-carcinogenic ones.

In a second step, a selection will be made of hazardous substances believed to be relevant, using a method that will need to be clearly explained and justified within the report. This selection will lead to the retention of those substances that are in line with the study's objectives. Subsequently, the method will eventually limit the range of these substances, thanks to the use of criteria such as a vulnerable population, a specific effect, a preferred channel of exposure, the shared substances emitted by all sources or a large proportion of them, etc. Lastly, the method may introduce contextual elements, in particular those related to media efforts or stakeholders' expectations.

The selection of single substances that are emitted from the various emission sources, to the extent that they are relevant, is highly desirable in order to add up and rank their definitive emission and exposure levels, as well as estimate their total impact within the assessment zone.

6.2.1.3 - Considering acute effects

The overlap of geographical pollution dispersion and accumulation areas across different temporal profiles can sometimes lead to high concentrations of certain pollutants in certain areas and time periods (heating periods, relaunches of discontinuous activities, etc.). These cumulative instances of pollution result from emissions that are either simultaneous or successive over time. It is therefore conceivable that resulting concentrations may generate effects that appear rapidly, sometimes even immediately. Weather conditions may reinforce this consideration.

In the context of a Z-RA, it is therefore necessary to examine the possible onset of acute effects, which is usually not the case for site-specific RAs.

6.2.2 - Dose-response relationship assessment stage

Depending on the toxic mechanisms that are involved, two main types of undesirable effects may be typically distinguished: effects with thresholds and effects without thresholds. A single substance can produce these two types of effects across different endpoints, leading to various health effects.

- An **effect with a threshold** occurs beyond a certain administered dose of the product. Below such a dose, the probability that the effect will occur is deemed null. Non-carcinogenic effects are the main ones to be classified within this category. Beyond this dose, the intensity of the effect experienced by a given individual increases as the dose is increased. Similarly, the proportion of subjects likely to be affected at the population level also increases.
- An **effect without a threshold** is defined as an effect that appears regardless of the dose received. The probability that the effect occurs increases with the dose size, but its intensity does not. The assumption that is typically upheld is that a single molecule of the toxic agent can cause changes within a vulnerable individual's cells or tissue, and it can be the cause of the observed effect. Initially, the no-threshold concept was only associated with carcinogenic effects. This view has recently expanded.

The establishment of dose-response relationships provides an estimate of the link between the dose or the concentration of a substance that comes into contact with the body (which constitutes exposure) and the onset of a toxic effect. In the context of TRVs, this effect is referred to as being "critical" since it is the first effect, considered harmful, that appears within the population that is being evaluated. The term "critical" is not a judgement regarding the severity of the effect.

This step ensures that an inventory and a selection of TRVs is done for each toxic element that is examined – the inventory and selection are to be conducted in a transparent and reasoned manner throughout all ERS efforts. In the case of Z-RAs, in addition to the need to highlight the selected critical effect that is associated with the TRV, one should note the following peculiarities:

- for the various substances, consideration for the different types of effects they may induce other than their usual critical effect, in order to understand the possible cumulative effects;
- consideration of the toxicological benchmarks for short-term exposures and effects as well as acute effects (see previous section).

6.2.2.1 - Ensuring that the critical effect is highlighted

The search for and the selection of TRVs require that toxicological databases be used. Regarding single-site RAs, TRVs are selected following the recommendations that were published in the DGS/SD7B/2006/234 circular on 30 May 2006⁴⁵, an update of which will soon be

⁴⁵ DGS/SD7B/2006/234 circular regarding chemical substance selection procedures and the choice of toxicity reference values in order to conduct health risk assessments in the context of impact studies

released. It recommends that TRVs be chosen according to a proposed hierarchy of organisations which produce TRVs: the US-EPA, the ATSDR, the WHO/IPCS, Health Canada, the RIVM and the OEHHA. No regulatory or methodological framework exists in this respect for Z-RAs, but the differences between single-site RAs and Z-RAs do not preclude application of the circular in this context. In practice, it has been found that the choice of a TRV selection methodology can vary depending on the evaluator, and for a single evaluator, it can depend on the substance. Due to the current lack of a regulatory framework, a standardisation effort therefore appears to be necessary. Similarly, it appears to be important that the evolution of the French context be taken into account, especially regarding the Afsset/Anses's TRV production.

This response regarding the adopted TRVs should seek to highlight the nature of the effect that is linked to the definition of this toxicological benchmark. Indeed, in a public health effort, it is important that a quantified risk figure be associated with the type of effect that is expected.

6.2.2.2- Sorting substances into categories based on their chronic toxic effects

For single-site RAs, in particular, an inventory of the possible effects of various pollutants will sometimes be conducted without this information being systematically used during the process's later stages. This is because the interpretation of the findings, when they are expressed, mainly pertains to the critical effect associated with the TRV. This approach can be even more detrimental in a Z-RA since there are multiple sources and pollutants which are emitted, which means that one needs to be aware of the risks that can accumulate, and, as a result of this, the effects that can occur. This point will be discussed further in paragraph 6.2.4.1.

Also, beyond the critical effect associated with the TRV, which may be subject to a first grouping of substances inducing the same critical effect, the HCSP stresses the need to inventory all of the effects associated with the various pollutants (at least those pollutants identified in the Z-RA) that are emitted within a zone and to organise their categorisation according to these different effects.

This analysis nevertheless requires reinforced toxicological expertise. Beyond a catalogue of undesirable side effects, it is a proper look at the possible interactions that must be provided, so that one can grasp this accumulation concept. This structuring is a first step, as research still deserves to be done before we can fully understand this point.

It is worth noting that this point could have been covered in the hazard identification step. It has recently been decided that it would be better to place it in the dose-response relationship step in order to make its role more visible in the interpretation of data in combination with TRVs and critical effects. It will also be necessary to identify the most appropriate time (during the process) to proceed with it (ie: before or after the selection of the substances).

6.2.2.3 – Searching for acute toxicological benchmarks and categorising substances according to effects

There are many toxicological benchmarks or TRVs that allow to understand the outcomes of high exposures over short periods of exposure. With regards to the air, they are developed to respond to either accidental situations or situations featuring pollution peaks resulting from industrial activity dysfunctions or extreme weather conditions⁴⁶⁴⁵. These latter benchmarks are the ones that are relevant for zone assessments. As an example, we could choose to retain short or intermediate-exposure TRVs (less than 1 year) for pollutants emitted by energy production facilities that are used on an occasional basis when demand exceeds capacity. These types of facilities experience a lot of downtime during the year and they are therefore subject to repeated resumptions of emissions.

Knowledge will be organised in the same way that chronic effects are organised, both in terms of the search for toxicological benchmarks and TRVs as well as the categorisation of substances according to critical effects and other potential effects.

6.2.3 - Exposure evaluation stage

Exposure assessments require two-step reasoning. The first step is qualitative in nature and requires that a conceptual exposure scheme be drawn up that illustrates all of the possible ways in which populations can come into contact with contaminated environments. It is partly achieved during the situational analysis, but it may be completed later on during the actual course of the process. The second step is quantitative in nature and seeks to estimate the dose or exposure concentration that a population is subject to.

In the context of risk assessment efforts and the conclusions that were reached during the HCSP's work group discussions, the perspective on current practices does not highlight any peculiarities with Z-RAs in relation to conventional efforts. However, this perspective requires that we emphasise the importance of the following three items:

- the spatial and demographic construction of a conceptual exposure scheme, which aims to visually represent where populations are located and the different ways in which they come into contact with contaminated environments;
- the implementation of environmental quality measurement campaigns in tandem with the modelling of the dispersion of pollutants within these different environments. In addition to the fact that the measurements can sometimes be used to verify the relevance of the modelling data, they help to make the population's total exposure more "palpable", and this is true for all sources of pollution. When they are well designed, they can also help

⁴⁶ For more information, you may refer to the following work published by the InVS: "Description of toxicological benchmarks used during acute exposure by inhalation by populations", available here: <http://www.invs.sante.fr/publications/default.htm> as well as the Ineris's acute toxicity threshold sheets, available here: <http://www.ineris.fr/fr/fiches-de-seuils-de-toxicite-aigue/fiches-de-seuils-de-toxicite-aigue/502>

determine the amount of pollution that each source generates (synchronous measurements both upstream and downstream of the pollutant emissions).

- consideration of background "noise", that is to say pollution that is not linked to the polluting activities examined within the analysis. The link to the previous point is obvious. Nevertheless, it goes even further by highlighting the idea that one should be familiar with the initial or "reference" state of the assessed zone.

6.2.3.1 - Creating a map which depicts an entire territory's exposure potential

Depending on how the various territories are used, populations that are likely to be exposed to emissions within the assessment zone are defined as those living in the area or coming into contact with it. People who come into contact with the assessment zone and who may demonstrate a greater sensitivity or vulnerability to certain substances are identified (day-care centres, schools, housing facilities for the elderly, health and social centres, sports facilities...). Whenever appropriate, dense locations of employment will also be examined, since the length of time that employees spend in an area may contribute highly to the overall exposure.

The measurement of individuals' exposure levels within the assessment zone also requires that we describe the different ways in which the environment is used. This way, we can identify the various possible transfer vectors that exist between the pollution and the population. Identifying the ways in which the environment is used involves making an inventory (and listing the locations of) potential farmlands, gardens and breeding operations which are subject to atmospheric fallout or aqueous discharges generated by all of the area's pollutant emitters. Atmospheric fallout on the ground and aqueous waste can also contaminate natural resources, such as sources of drinking or irrigation water, private wells and fishing and swimming areas, so it is necessary that they be identified as well. Indeed, these natural resources are also potential exposure vectors.

The gathering of such environmental and population data requires much more work for Z-RAs, due to the size and diversity of the assessment zones. However, there are often limits as to how much data can be gathered due to data availability constraints.

The creation of a scheme illustrating potential exposure brings these various elements together in a generic manner by listing the various environments and vectors that are likely to contribute to populations' exposure in a more or less pronounced manner. Description of populations, the places they frequent and their combination does not always clearly appear in the risk assessments that are currently produced. In a geographical area whose surface is in principle larger than in those of single-activity studies, in which the populations are linked to the multiple sources of emissions and pollution which blend together, it seems necessary to present the potential for exposure through maps which allow one to locate and overlay all of the involved components. It may be relevant to produce different maps which distinguish between different populations such as children and adults.

6.2.3.2 - Using the geographic environment measurement campaigns and the modelling of dispersion in a complementary manner

There are two approaches one can use when estimating exposures: doing measurements in the various environments and modelling the dispersion of pollutants within these same environments. The choice between these exposure estimation methods, which are complementary or alternative approaches, depending on the situation, is primarily guided by the objectives of the assessment. In terms of "absolute" quality, there is no competition between the two approaches. For example, concentration measurements are not possible for preliminary studies relating to the installation of a facility, since its activities have not yet begun. Nevertheless, they can be used to describe an initial baseline state⁴⁷.

- **The benefits of environmental measurements**

Regarding Z-RAs, the hearings have indicated that measurement campaigns have been systematically implemented or planned. Existing data was used as often as possible. Such data was generated by previous campaigns or by environmental monitoring systems that were already in place in all or part of the area.

The fact that such data provides knowledge of an area's overall pollution weighs strongly in favour of the use of such measurement campaigns. Estimates of the health risk associated with the quality of a living environment respond to the highly voiced needs of certain stakeholders, regardless of how much risk is generated by each specific source. This is especially true as the latter are often less familiar with modelling approaches whose "reality" is deemed to be less important.

The HCSP backs this practice, which has evolved naturally over time. It considers that measurement campaigns are necessary in order to both determine the quality of the environments located within the assessment zone and to estimate populations' exposures. However, it insists that these measurement campaigns should not only focus on the atmospheric environment, as other environments often show traces of past and present pollution. Obviously, conducting these multiple measurements means that the studies will take longer to complete and they will cost more. It is therefore necessary that they quickly be planned for during discussions on the assessment's process and funding.

- **The benefits of modelling the dispersion of pollutants that occurs within the environment**

Modelling objectives must be explicitly defined. The primary objective of modelling is to help delimit the assessment zone. It is not mandatory, but it can help identify areas that might have been neglected without modelling, for example because of specific local weather or topographical conditions.

⁴⁷ During a measurement, various conditions (weather, etc.) should always be clearly described, as they can influence the resulting figures.

A second objective is to help determine the respective contributions of the various sources to the measured pollution. With the exception of a very specific pollutant that evidently comes from a specific emitter, in all other cases, the pollutants are emitted by several different sources and it is important to distinguish their respective contributions. When decisions need to be made regarding currently emitting sources, modelling is préférable⁴⁸. This does not exclude the aligning of modelling results with measures that can be taken, as the latter can serve as inputs for the models or as data to verify the models' results.

Both approaches clearly provide elements that help complete zone assessments and risk evaluation efforts. An assessment of this sort of methodological complementarity must be accompanied by a review of the budgetary resources they respectively require. Indeed, although direct measurements are preferred when exposures are present and/or they result partly because of past contamination of the environments, this solution requires more resources than are needed for the modelling approach, and there may be a significant level of uncertainty regarding the spatial and temporal representativity of the measurements. As the representativity of a sample is mainly related to the number of measurements that are performed, the budget allocated to the exposure estimate is a major factor to keep in mind when choosing a method. These elements will be brought to the attention of the COS, which will make its recommendations based on its assessment of how one or both of these approaches will meet the evaluation's objectives.

6.2.3.3 - Describing background noise and identifying an initial state or a control environment

Background noise can be defined as the sum of diffuse sources present in the assessment zone (small businesses, commuting, residential and tertiary heating, sources located far away...) as well as past pollution. This background noise issue is dealt with differently depending on whether we are talking about a single-site RA or a Z-RA. In the first case, which focuses on a specific activity, impact study procedures recommend that the "initial state" be considered when evaluating a project. This approach can easily be extended for cases involving existing facilities by conducting measurements on physical environments that are "upstream" of the pollution and nuisance transfer flows (in the air, groundwater, soil and plants)⁴⁹. In the single-site approach, the goal is primarily to allow for a relative assessment of the examined activity's contribution.

For Z-RAs, evaluations focus instead on all of the sources that are deemed relevant. In most cases, the many sources of background noise, whether past or present, cannot be subject to modelling. On the other hand, their impact will of course be taken into account by the measurement campaigns' results.

⁴⁸ Cases with emitting sources are more complicated and measurements are justified.

⁴⁹ Regarding the ground, when an industrial activity has been operating for several years, it is impossible to find out what the pollution level was before the present contribution by the industrial sources, except if measurements were made before the start of operations.

In these circumstances, and during the scheduling of a measurement campaign within the various environments, it is important that measurements be obtained from the outset from beyond the various activities' zone of influence in order to have concentration benchmark levels that will be qualified as a "reference environment". This acknowledgement of "background noise" allows one to know how much additional pollution was generated by activities that justified or called for a Z-RA to be conducted and, therefore, it provides one with a relative measure of the effort required for greater control of this pollution, if need be. Furthermore, depending on how significant the background noise and the associated risks are, further work may be conducted and used so as to consider potential management options. This analysis and this recognition are crucial for clarifying the parties' judgement regarding the best pollution and identified risks management options.

6.2.4 - Risk characterisation step

Risk characterisation is a step that is based on the data that was put together in the previous steps. It leads to a quantitative analysis of the risks that the exposed population(s) is(are) subject to, on the one hand, and a qualitative data analysis, on the other hand.

The risk quantification results are expressed in a variety of ways. The evolution of their format was discussed in section 5 and will not be discussed again here. The same applies to the contextual elements which support the results' interpretation. However, the issue regarding simultaneous exposure to multiple pollutants is particularly important as there are multiple sources in Z-RAs. A comprehensive approach, inherent in a Z-RA, therefore leads one to consider the pollution generated by different emitting sources in a cumulative manner.

This risk characterisation step does not present any singularities for Z-RAs, but some elements become particularly important:

- the quantitative assessment of simultaneous or successive exposures to multiple pollutants;
- the qualitative assessment of simultaneous or successive exposures to multiple pollutants;
- the assessment of each source's respective contribution to the overall pollution.

6.2.4.1 - Aggregate or cumulative exposures - quantitative aspect

The health risks that may be associated with the complex pollution context result from aggregate or cumulative exposures or a combination of both.

To assess the first type of exposure, we must consider all of a single pollutant's emission sources and the various channels of transfer and contact with the target populations that result from its emission into physical environments. Therefore, the addition (for a single contact channel) of the exposures and their conversion, via the relevant TRV, during risk estimation does not pose any particular problems at first sight. For a given pollutant, this concept of **aggregate** exposure is particularly relevant in a zone approach instance.

Strictly speaking, the **cumulative** exposure concept refers to exposure to pollutants that are different but which act the same and can therefore produce the same types of effects. Today, the use of Z-RAs is regularly confronted with the cumulative exposure issue in areas relating to chemical mixtures. In the presence of multiple exposures, the risk additivity approach has been adopted, which follows an approach advocated by the United States' EPA and used by French institutions. It is a pragmatic approach, used when there is a lack of knowledge on the interactive relationships between substances.

With Z-RAs, we will progressively seek to take into account, in a broader manner, this multiple exposure context, while taking into account the diversity of pollutants and nuisances (noises, smells...) which have heterogeneous effects. The "Silver Book"⁵⁰ recommends that one go in this direction although it does not provide key solutions on how to combine these effects, which are expressed on scales which at first sight are incommensurable.

This extension of the cumulative exposure concept requires *ad hoc* methodological work in order to develop composite indicators. To this day, this limits the "multi-exposure" character of zone assessments where the only risks are chemically related. Methodological developments presented in publications propose that composite indices be established which include the different types of effects⁵¹. This point did not benefit from careful reflection within the work group, as this exercise would have exceeded its mandate. The work group recommends that the various ministries look over this issue and assign the task of developing appropriate methodological approaches to competent scientific organisations.

6.2.4.2 - Aggregate or cumulative exposures - qualitative aspect

Toxicological knowledge is incomplete for many substances. However, in the best of cases, even if we know the health effects that characterise the danger of a substance or one or more TRVs for this or these different effects, in many cases, we only know of the health effects, without TRVs, and we do not have complete information. For example, the effects on human development and reproduction have not been analysed much. For a given substance, not all effects have been systematically searched for or described.

An innovative approach would be to find out what the main effects associated with a substance are, not just the main critical effect that was determined during the TRV process. One should analyse the substance categories that are likely to lead to a given type of effect. These categories were created during the hazard identification stage. Currently, this approach can clearly be conducted in a qualitative mode if no TRV exists. However, if we wanted to consider adding together the "risks" for a single effect for all substances that can induce this undesirable effect, whether this effect is the critical one or not, multiple TRVs would be required for each substance. This calls for a detailed search of effect thresholds for the pollutant tracers of interest and the availability of databases featuring these results.

⁵⁰ National Research Council (NRC), 2009. pg. 28

⁵¹ <http://www.atsdr.cdc.gov/mixtures.html>

Work on reprotoxic TRVs is already going in this direction, but it is necessary to consider it for all of the effects that are of interest and which require a specific solution. The HCSP calls on scientific bodies (research laboratories or specialised agencies) to develop research and development on this subject.

6.2.4.3 - Share of exposures and risks attributable to each source

The need to take action to reduce both exposures and risks requires that one know the respective shares of pollutants which contribute to the risks. The analysis of cumulative and aggregate exposures will strive to address this issue, as well as determine the respective shares of the various sources that were considered when pollution was measured in the various environments. For single-site RAs, this attributed share is not always known, as the primary desired outcome is to find out whether the pollution generated by a specific facility requesting an operating license leads to danger quotients (HR) and/or excess risks that are above the usually authorised benchmark. In some cases, excess risks and/or HRs due to pollution represented by background noise or the initial state are estimated so as to determine if the emissions of a facility being examined add pollution that leads to an excess of risk or if the overall HR exceeds typically authorised benchmarks, even if the facility contributes only to a small fraction of this excess.

With zone assessments, however, industries and sources of pollution are taken together as a whole and the Z-RA must be able to trace each relevant source's contribution to the definitive exposures and calculated risks. This ability is one of the virtues of the comprehensive zone approach, which produces a more accurate view of each emission source's responsibility for an evaluated impact, and therefore provides a setting for rational discussion on the share that each party could take in resolving the identified problems. This strong recommendation will therefore lead to significant consequences in terms of responsibility identification.

7 - Benefit of a regulatory provision which governs zone assessments

The analysis of various types of utility demonstrates the benefits that are obtained from the implementation of such an assessment in a territory featuring polluting activities. The first zone assessments were launched as a result of local initiatives, oftentimes because the locals had a history that naturally led them to establish this type of approach. Others seem to have been launched due to elected officials' somewhat proactive vision regarding sustainable development.

The conceptual proximity between the Z-RA approach, in the context of activity zones and current conventional practices in the context of "single site" or "single-activity" impact studies, leads us to question the utility of including this emerging approach within a regulatory framework.

What are the advantages and disadvantages to be observed when enacting such a provision? Can we genuinely expect mandatory action to result in added value? These are important questions and the items in this section attempt to answer them. The various sections cover the length of time needed for these studies, the capacity for action after the study's outcome, the mobilisation of stakeholders and the added knowledge or feedback that is obtained from these studies.

7.1 - Time required to conduct the assessments

Based on the Ineris's experience, it usually takes four years to conduct such a study (Ineris, 2009)⁵². This lengthy amount of time, which is linked to the genuine complexity of such a study, has led to a gap between the conditions that existed at the beginning of the assessment (phase where one identifies the sources and emissions) and those that existed at the end of the study (reported results). Indeed, the zone's emissions or usage/occupancy conditions may have significantly evolved during this time. In these conditions, the calculated risk may no longer reflect the state of the area when the results are obtained. Furthermore, a zone assessment can sometimes directly point to problematic emissions and incite the implementation of measures to reduce them, which the modelling will be able to provide.

As more studies are conducted and experience grows, the assessment completion times will fall. For example, in order to facilitate the flow overview step, one could agree to either immediately establish the rules of inclusion (or non-inclusion) of the flow modifications that could occur or define a reasonable framework for the Z-RAs to be accomplished (2 years maximum) while providing the necessary resources from the outset. The flow overview should start when the administrative aspects of the study are completed (funding, technical specifications, choice of consulting firm).

⁵² Feedback on 6 zone assessments completed at the end of 2008. Ineris, 2009, 155 pgs. Report pending validation.

This period of implementation calls for the integration of this approach within a regulatory framework, as the extensive time required can make the stakeholders reluctant to proceed, and the need for a large budget can also have an adverse effect on their good intentions⁵³.

7.2 - Need for an action plan

Since Z-RA studies are conducted with resulting action in mind, is it possible that a management plan can be implemented without being part of a regulatory framework?

The Z-RAs results will allow one to both assess the need to take action as well as measure the magnitude of the actions that the various stakeholders will have to take. The Z-RA also allows one to assess the expected effectiveness of the different available ways to improve a situation that has been deemed likely to negatively affect public health. The terms of this strategy must therefore immediately be considered. Statements regarding possible action plans that can be implemented prior to conducting a Z-RA will not be effective if the individual polluters have no obligations to fulfil. Furthermore, the risk prevention department ($HR < 1$; $ERI < 10^{-5}$). These benchmarks, which were set in the context of soil pollution, have been extended to all areas. Concern for the effectiveness of policy and fairness therefore dictates that limits be defined regarding action so that society, in its various components, knows how to make decisions regarding risk levels in relation to environmental, health, economic and social issues, which are often in conflict with each other.

7.3 - Capitalising on past experience

All stakeholders consider this type of study to be tedious to carry out. The hearings have demonstrated the attention that these stakeholders have paid to other similar initiatives carried out elsewhere within the territory, when proceeding with their own efforts. These hearings have also highlighted the importance of thinking from the outset of the possible resumption of this type of study a few years later, in order for it to reflect the changes that have occurred within the area in terms of polluting activities, facilities and infrastructures and the population's territorial occupancy.

The HCSP therefore recommends that the conditions for capitalising on lessons learned from these studies, in both their conduct and their methods, and in terms of the implemented management measures and action plans, be consolidated. A second area of capitalisation, which is needed locally, consists of the regular updating of the Z-RAs.

⁵³ We would nevertheless like to point out that consideration of a set of activities within a coherent geographical area will ultimately result in economies of scale and resources compared to the sum of the individual impact studies that the same situation would have required in the end. Not to mention gains in relevance.

On the one hand, the idea is to collect descriptive information on the various studies conducted nationally in order to analyse the evolution of how Z-RAs are conducted, and their results, and to provide support that will help facilitate and enrich future studies. In order to meet this objective, it would make sense for a national report to be published on the various studies conducted within the territory during the previous year. Such a report could be released on an annual or a biennial basis. This work would be entrusted to a competent public organisation. The description of each study's context, the expectations, the organising of expertise efforts, the identities of the stakeholders participating in the established COS, the Z-RAs primary methodological characteristics and a summary of the resulting outcomes and courses of action would all be a part of the framework.

On the other hand, there is another objective to be pursued. At the local level, one must indeed consider the regular updating of Z-RA studies, as is done with single-site impact studies, because significant changes will inevitably occur over time and scientific progress will be made. In any case, it is recommended that an update be done at least every 10 years. Therefore, the idea is not to repeat the entire Z-RA process from scratch but to integrate and discuss, in relation to the initial assessment of consequences in terms of exposure and health risks, the changes in the area's activities and emissions during the reporting period and during any significant changes (halting of an activity or launch of a new one). One must be able to refer to the Z-RA as the initial state. We can now clearly understand the significant benefits obtained by capitalising on this process. The full benefit of this comprehensive approach requires that the Z-RA be saved over time and made available without restrictions and with full transparency. This applies to the conditions of its achievement as well as the assumptions used to enable this update (databases, figures used for calculations). As is the case with "operating diagrams" of contaminated sites and soil, it must monitor the zone's operations and the evolution of its emissions. This form of capitalisation is usually established on a local basis (perhaps regionally), and is entrusted to a specialised public or private agency that is subsidised or paid for this purpose. It acts as the "active memory" of the various Z-RA studies that are conducted on the territory⁵⁴.

A final facet of this capitalisation relates to the stakeholders' spontaneous feedback. In order to progressively improve the participation of stakeholders in Z-RAs, the HCSP encourages, in a realistic manner, this type of feedback. As the CESSA report highlighted gaps regarding information published on this subject, this valuation effort could lead to genuine social science research efforts to produce a certain amount of sociological data based on French Z-RA experiences. In addition, consideration should be given so that certain research programmes such as those conducted by the national agency for research (their public health research programme, in particular), the Anses, etc. are able to include these issues within their efforts.

⁵⁴ This organisation would therefore not become the owner of the databases created for the various Z-RAs. It would become the custodian of this record, responsible for its upkeep, and it would be obligated to make it available to any relevant stakeholders and, in particular, to any consulting firm responsible for updating or re-analysing a specific Z-RA.

7.4 - Mobilising stakeholders

Regulatory provisions, which oversee the establishment of local information commissions, exist in order to allow stakeholders to get involved. The extension of these provisions so that they cover zone assessments is justified in detail further on. It appears necessary that a minimum amount of parameters be defined in order to manage the ways in which the relevant bodies are established and operated in order to design, monitor and evaluate these zone assessments. The territory on which these studies are conducted is much more heterogeneous than the one which is defined for single-site impact studies. In a regulatory framework, this heterogeneity should be considered in terms of its actual value.

7.5 - Overview

Although single-site RAs are well regulated, it is currently worth noting that, in terms of Z-RAs, initiatives are taken with ease, without any constraints which would prevent their implementation. We have even noticed a willingness to repeat such studies after a few years, in order to measure the progress that has been made. All stakeholders agree that this is an attractive opportunity to go beyond the thinking generated by single-site impact studies. The freedom that is afforded by the absence of rigid requirements surely contributes to this viewpoint.

However, the evolution of currently used methods, the emphasis on grey areas and social and environmental inequalities in the state's environmental plans, the general public's increasing concerns regarding their health, advocate that harmonised solutions be provided for the entire nation. A minimum amount of prescriptive and flexible regulation is required, in particular regarding: the need for preliminary zone assessment studies to be conducted (inventories), Z-RA interpretation criteria, the organisation of the interaction taking place between the stakeholders, the terms under which action plans will be developed and the capitalisation of experiences. In this regard, it is essential that locally collected data be accessible to the relevant members of the general public. Furthermore, this data must also be transferred to a centrally located system that stores and capitalises on it. The management, organisation and resources allocated to such a system must be explained in detail. Forthcoming regulations should also plan on describing and enforcing the obligations that those who are responsible for pollution and nuisances are subject to in terms of control, compensation and funding.

Under these circumstances, the Z-RA represents a genuine decision-making tool for the protection of public health, in a setting designed for dialogue that suits both the situation as well as the stakeholders. In the future, the harmonisation of the framework within which these assessment studies will be conducted will reinforce their legitimacy and therefore their effectiveness. The more complete these studies are (taking into account, in particular, non-industrial sources of pollution, such as those related to transportation, infrastructures, etc.), the more they will gain in terms of credibility and help stakeholders be aware of their respective contributions to this pollution.

This awareness is a key component in the preparation of legislative measures. It is also a key argument in the recommendation that single-site RAs be progressively replaced by Z-RAs.

8 - Conclusion

During its preliminary investigation, the HCSP has decided to combine its consideration of the two requests referred by the DGS. These cases respectively relate to the benefits of conducting Z-RAs in the context of zone assessments, including the identification of their singularities, and the development of an interpretation grid which aims to improve the exploitation of RA results in general, regardless of the context that triggered the RA.

The full hearing of the two concurrent referred requests proved to be productive. It was based on feedback obtained in France and abroad (mainly from the USA), shared during hearings that featured various stakeholders and experts from relevant fields, and from an international seminar that was held on risk assessment. Research based on published works completed the information that was made available to the HCSP. This analysis of past experiences allowed for the identification of shared practices and distinct approaches, but it also highlighted shortcomings. On this basis, this report provides technical and organisational recommendations and it also identifies areas where these studies could benefit from further research and progress.

The "Grenelle Environment Round Table" debates, the extensions of environmental responsibility ruled by directive 2004/35 on 21 April 2004 (regarding the prevention and compensation of environmental damages⁵⁵), discussions focusing on safety and prevention principles, the implementation of national environmental health action plans, occupational health, nutritional health, the implementation of Z-RAs, etc. All of these actions are part of society's evolving attitude towards risks.

There is strong demand for these risks to be reduced, and even completely removed from our everyday lives, even though everyone knows that a zero-risk environment does not exist. However, even though there is nothing more comfortable than an equation that allows us to control everything, using a calculation that appears to wield absolute truth, a certain use of RAs, which many accounts attest to, imposes the almighty power of the number. Once it is revealed, it cannot be debated; the interpretation that is made is binary and reductionist, leading one to forget the choices that were made along the way, when building scenarios, assumptions and uncertainty factors. This work intends to demystify this approach and restore numerical results to their rightful place by providing a more equitable balance between what can be approached through quantification and the outcomes of shared and explicit choices and directions.

⁵⁵ Especially damage affecting the soil (any contamination causing "a serious risk of adverse effects on human health due to the direct or indirect introduction of substances, preparations, organisms or micro-organisms"). The directive is transposed into French law through law no. 2008-757, passed on 1 August 2008, which becomes applicable through a decree enacted on 23 April 2009.

This is because, at the end of the Z-RA, the idea will be to ultimately put into perspective the various kinds of risks up against each other and weigh the various options' pros and cons.

It is in this spirit that the HCSP recommends that we abandon the "acceptable risk" notion and instead use the "areas of management" one. This expression of a RAs results allows us to better integrate all of a given territory's stakes by paying more attention, beyond figures, to the identified health and environmental problems and the various population segments that are involved, and therefore the various possible actions that can be taken.

This development first requires that one explains (formulates) the utility that is expected from the use of a Z-RA in an activity zone, by including it into thought on territorial planning, while keeping in mind that the territory is a solidary area. This is the whole point of conducting a zone assessment, which is a decision-making tool for which consideration of the necessary actions implies that we identify health, economic, social and environmental issues at their sources.

This comprehensive analysis of the situation and the items that affect the management of a risk must be done under collaboratively agreed upon conditions. This cooperative dimension is now recognised as being key in the management of an environmental health problem, no matter what the scale is (administrative, geographic or political). As soon as the process is launched, and given the often conflicting interests that arise, the HCSP recommends that a steering and monitoring committee be put together featuring the widest possible panel of stakeholders linked to the problem at hand. Discussions on how to conduct the assessment and management options will be conducted within this committee. The HCSP postulates that this COS will be able to define guidelines through general consensus, even though differing views may be expressed. In situations where an agreement cannot be reached, the final choice will be up to the sponsors of the study or, where appropriate, relevant State agencies, as public authorities are supposed to guarantee the general public's interest. The HCSP also recommends that a charter be established during the very first meeting which outlines how the COS will operate.

This dialogue will substantially contribute to two important phases of the zone assessment. The first phase aims to more closely study the zone's issues by bringing together the events known, shared and non-shared by the stakeholders, and clearly identifying the possible decisions that can be made based on the results that might be produced by the Z-RA. The second phase touches upon the gathering and organisation of knowledge, within a defined area featuring significant human activity, regarding environmental (pollutant emissions, state of the environments, etc.), populational (characteristics of the exposed population(s)) and health issues, in order to describe the risks at hand.

Zone assessments are now complementary to single-site studies. The latter are mandatory in the processing of an application for permission to operate an ICPE (environmentally compliant facility) and they aim to prove that the implantation of a new facility will have an acceptable impact on the local population's health risks. The main difference between a single-site RA and a Z-RA is the comprehensiveness of their respective approaches. Such comprehensiveness targets territories where a group of economic activities operated, are operating or will operate (industry, transport of

people or goods, farming...) which will significantly contribute to emissions into the environment of potentially harmful substances that may, alone or in combination, affect health in the short or long term, given the ways that the various populations occupy the territory.

However, recent developments regarding the use of the "initial state" during single-site RAs (a new repository will be made available soon) also leads to a situation encouraging the participation of other potential contributors of harmful emissions around the assessment site. This calls for local efforts to pool resources in order to monitor the environment. Under these conditions, the ongoing evolution of regulatory single-site RAs naturally leads to an implicit consideration of the zone which surrounds the site being assessed.

One may question the benefit of maintaining both of these RAs in the long run, and in particular, the pursuing of single-site impact study efforts. When an area featuring multiple activities is the subject of a comprehensive study, the question is no longer whether a new installation (broadly speaking: a new facility, a new road, etc.) will have a health impact that can be kept under control on its own, but whether, in the context of the area, the emissions it will contribute will modify the balance between the environment's quality and how it is used. The corollary of this comprehensive approach is the need to capitalise on the first assessment in order to make it available to be used as the initial state of further studies, and to update it.

In these circumstances, the HCSP recommends that we gradually shift (over the span of a decade, approximately) to the systematic use of Z-RAs, which will replace single-site RA, while keeping in mind that these zone approaches will at first appear to be more demanding in terms of resources, but they will quickly reveal themselves to be an extremely wise investment.

This perspective requires that we improve and reinforce existing knowledge, methods and tools in order for the Z-RA to claim its rightful spot and meet its expected utilities. The areas of research that need to be developed mainly pertain to the combination of exposures and risks as well as the ability to identify the share of pollution contributed by each of the zone's emitters. This accumulation of exposures and risks does not relate solely to chemical pollutants. It must also consider potential physical and biological risks, which are usually simultaneously present within a zone. This implies the need to have a grasp of toxicological knowledge pertaining to the mixtures, both in terms of the expected effects as well as the numerical benchmarks - the toxicological benchmark values and any related parameters.

For a given study area, one must pay attention to background noise if one wishes to be able to identify the respective contributory share and environmental responsibility of each emitter. The RA will therefore fully satisfy its purpose, which is to provide all stakeholders with the information required to hold informed discussions regarding the management options for identified risks.

The result is a project whose scale can appear to be frightening. However, the work involved is extensive only because the desired solution must cover a wide area. The efforts that must be made are not just methodological in nature. An assessment of a zone and its related issues can sometimes take a much longer time to be established, expressed and shared than the actual Z-RA process itself. It can sometimes take a long time to provide an answer to a question; in this case the same outcome cannot be achieved using a rapidly conducted study. Ultimately, these zone assessments appear to be a genuine opportunity to achieve solid progress on both a political and scientific level.

9 - Appendices

APPENDIX 1: REFERRED CASES

APPENDIX 2: INTERVIEW GRIDS

APPENDIX 3: HEARING MINUTES

APPENDIX 4: SUMMARY OF THE INTERNATIONAL SEMINAR

APPENDIX 5: LITERATURE REVIEW BY VINCENT NEDELLEC CONSEIL

APPENDIX 6: LITERATURE REVIEW BY THE CESSA

Appendices 3 through 6 are to be found on a separate document (only in French), which you can access on the HCSP's website (<http://www.hcsp.fr>)

APPENDIX 1: REFERRED CASES

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and Community Life

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Paris, 21 May 2008

The Director General of Health
to
Secretary of the HCSP
Environmental Health commission

Subject: Risk assessment approach – Interpretation and use of ERS results
Attachment: - Esso case
- DDASS 13 note regarding this case and letter to the DGS on 17/08/2006

In the context of procedures that lead to impact studies, the environmental health division of the DDASS (regional social services department) issues an opinion regarding the health risks that were highlighted in the cases that were submitted to the prefecture by petitioners.

Health risk assessments that are conducted during impact studies are done according to guidelines outlined in two methodological guides:

- the InVS's (French institute for public health surveillance) guide, which helps interpret the health component of impact studies. It was published in June 2000 and is aimed at officers who analyse the health effects of activities/plans on health and issue an opinion on the cases that are submitted.
- the INERIS's (French national institute for industrial environment and risks) guide, which details how health risk assessments are done for impact studies conducted from 2003 on and aimed at petitioners.

Nevertheless, services relating to ERSs (health risk assessments) need to be harmonised, especially in the following areas:

- ERS results' interpretation criteria,
- the use of the final results in order to manage the health risks.

With this in mind, I am sending you a case which was processed by my department and which illustrates the type of assessments that are conducted for these cases.

I would like to obtain an opinion from the High Council of Public Health in order to have nationally applicable interpretation criteria pertaining to risk assessment results.

To this end, you will hereby find a health risk assessment case, including the opinion that was issued on this case by the Bouches du Rhône region's Departmental Directorate of Health and Social Affairs. This opinion, selected as an example, indeed illustrates the current use made of assessment results in order to manage the health risks linked to human activities.

I would be grateful if you would kindly provide me with a proposal, during the first half of 2008, describing the work to be done on this referred case.

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Paris, 21 May 2008

The Director General of Health
to
Secretary of the HCSP
Environmental Health commission

Subject: Risk assessment approach – Zone assessments
Attachment: - Fos sur Mer case

In the context of procedures that lead to impact studies, the environmental health division of the DDASS (regional social services department) issues an opinion regarding the health risks that were highlighted in the cases that were submitted to the prefecture by petitioners.

Health risk assessments that are conducted during impact studies are done according to guidelines outlined in two methodological guides:

- the InVS's (French institute for public health surveillance) guide, which helps interpret the health component of impact studies. It was published in June 2000 and is aimed at officers who analyse the health effects of activities/layouts on health and issue an opinion on the cases that are submitted.
- the INERIS's (French national institute for industrial environment and risks) guide, which details how health risk assessments are done for impact studies conducted from 2003 on and aimed at petitioners.

To date, the regulatory process provides for the application of this method, on an individual basis, to the activities/plans that are part of an authorisation request submitted to the prefect. Typically, such requests were authorised, given the absence of risk attributable to these activities/plans on an individual basis.

However, the issuance of these permits leads to the densification of human activities across certain areas with no knowledge of the impact that results.

In order to overcome this difficulty, the State's agencies have strived for assessments to be conducted throughout an entire industrial area, depending on the local context. These zone assessments allow for the combined emissions of an entire area to be accounted for. Such emissions are caused by activities and their layouts, but they are also caused by related transportation activities and they therefore reflect the local population's actual exposure.

I would like to obtain an opinion from the High Council of Public Health regarding this initiative and a proposal of how it can be generalised to all sites whose human activities are very dense. This will allow for better understanding of the general public's exposure to environmental pollutants.

I would be grateful if you would kindly provide me with a proposal, during the first half of 2008, describing the work to be done on this referred case.

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| Interview grid for government agencies |
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1. The benefit of a QRA within a zone assessment and the conditions which trigger such an effort

- The regulatory system is now planning to assess the health risks that are caused by a new activity, as opposed to those that are caused by previously existing activities. Do you think that this approach is relevant in areas where the density of human activities is high? Why?
- What regulatory tools do you have at your disposal to coordinate the management of emissions in areas where the density of human activities is high?
- Have you implemented this sort of coordinated management effort? If so, what are the practical modalities?
- What was it that triggered the use of such an approach?
- Do you think that such an approach should become widespread or should it instead be implemented only on high-priority sites? What criteria would you use to define the priority level?

2. Interpreting QRA results on a local scale

- In your opinion, what is the purpose of a RA conducted as part of an impact study?
- Can the results of a risk assessment be used as is in order to take action against a petitioner?
- What practical procedures have you implemented in order for the RA to help Prefects make decisions regarding authorisation requests?
- What steps have you taken that were driven by a RAs results?
- Do you believe that a RAs results can be communicated to the general public as is in order for the purpose of the studies to be well understood?

3. The definition of a zone

- In your opinion, what constitutes a zone?
- In your opinion, which activities should be taken into account within a zone? Does this include roads, for example?

4. The involvement of stakeholders and their role in zone assessments

- Which stakeholders do you think should be associated with such an approach?
- What will their role be?
- In which phase(s) should they be associated with the approach?

Interview grid for associations

1. Your experience with such a study/approach (whether you participated in it or not):

- Do you know in which setting, in which context and by whom such assessments are conducted?
- Have you ever been involved in such a study/approach?
If yes, what were the terms of your participation (periodic consultations, hearings, active participation, etc.)? Did you get involved at your own initiative or were you asked to participate?
- Do you know how the assessment zone was delimited/identified?
- Which emitters were involved/evaluated? What nuisances and/or discharges of pollution were evaluated?
- Do you know what information was sought for the implementation of the study? Who was it obtained from?
- Did you contribute to the supplying of information? If yes, what information? What were your sources?
- Do you know which stakeholders were involved in the assessment efforts? Do you think that some stakeholders were missing? If so, which ones?
- What were the findings of the study? Did you find them to be understandable? How do interpret them?
- Has a discussion system been set up? (meetings, newsletter, website, etc.) By whom?
- Have the study's findings/conclusions been communicated? In what format? By whom?
- Have there been consequences or outcomes resulting from the study that was conducted (change(s) in industry process(es), redesign of facilities, renovation work, message(s) to local residents, etc.)? Do you know of them? How did you find out?

2. Your point of view:

- Do you think that this sort of study is useful? Understandable?
- If you were involved in the study, but you did not supply any information, how would you describe your participation (keeping informed, relaying information to others, etc.)?
- Does the methodology which is used to assess health risks seem relevant to you? If not, what problems do you think would be important to highlight?
- In your opinion, what are the important elements that need to be considered when defining an assessment zone?
- In your opinion, are local concerns taken into account in this type of study (yes, no, sufficiently, insufficiently, etc.)?
- What do you think of local authorities' ability to assess and manage risks? (Also, based on the people that were interviewed, which authorities are responsible for such assessments and for risk management?)
- If you have knowledge of any complainants, were they provided with support during the study or after it was conducted? What kind of support did they receive? (from associations, health professionals, governments (local, national, European)?)
- In your opinion, how and in which way can such studies/efforts be improved?

Interview grid for consulting firms and service providers

1. Your business and your experience

- What does your company do? How important are zone assessments within your business?
- How many zone assessments have you participated in, either in the past or currently?
- What was your role in the zone assessments in which you participated?
- In what other contexts do you perform health impact studies (industrial facility RAs, contaminated site assessments, etc.)?

2. How the assessment is conducted

- Was your participation/service well defined, especially in the required specifications: objectives, context, methodology, process, deliverables?
- Did you provide your opinion on the context and the progress of the study?
- What coordination efforts and methods of information exchange have been established with the study's other stakeholders (government, elected officials, industrial players, general public, associations)?
- Did you have any trouble identifying and gathering information that was useful for the study?
- How were the study's findings (interim and final) and conclusions communicated?
- Did you have any trouble interpreting the study's results and drawing conclusions?
- Were you subject to any pressure, of any kind or origin, which aimed to influence the conclusions of your study? How did you manage this pressure?

3. Your point of view

- In your opinion, what are the RA approach's strengths and weaknesses, especially in regards to zone assessments?
- In your opinion, in which way could RA methodology be improved in order to be more appropriate for zone assessments? Do you have any suggestions to improve it?
- How do you rate communication regarding zone RAs (during the briefings and outside of them)?
- In your opinion, were the findings well understood and accepted? Do you find that the recommendations that were made and the decisions that were made after the zone assessment were appropriate?

Interview grid for elected officials

1- Can you tell us about your experience with a RA that was conducted in your town or your county?

- Did the study involve several towns, counties or regions?
- Were several pollution emitters involved?
- Do you know why the study was conducted? What was the context?
- Do you know how the area was delimited for the RA to be conducted?
- Can you describe the involvement of elected officials? (for each territorial unit: city, town, county, or region if applicable)
 - What coordination was established between the various communities at the same level (ex: several municipalities)? Or between various overlapping communities (ex: towns and groups of towns, etc.)? Who took this initiative?
- What were the terms of your participation? And the terms of the other involved communities?
 - How was the joint effort with the other stakeholders organised (emitters, the general public, consulting firms, government, etc.)? What did it consist of?
- What were the findings of the study? What do you make of them?
 - Who coordinated the communication of these findings to the stakeholders (government agencies, elected officials, etc.)?
- What was the communication policy employed by elected officials?
- Did the study have operational consequences other than those relating to communication?
 - risk perception by elected officials, local citizens and emitters?
 - risk management?
 - other consequences? employment?

2- What is your point of view?

- In your opinion, what are the RA approach's strengths and weaknesses, and, in particular, what are those of the "zone" RA (several emitters)?
- Did you have a hard time interpreting the results, and if so, what were these difficulties?
- In your opinion, how could the approach be improved?
- Is the role of elected officials clear or should it be better defined for QRA assessments? Are they sufficiently involved and informed? (What role could or should these elected officials play?)
- In particular: What improvements are desirable in terms of communication towards and by elected officials (for the general public, emitters, the study's sponsors, etc.) prior to, during and after a health risk assessment in an area?
- What improvements could be made for other items (risk management)?
- How does one manage and communicate regarding diverging interests (ex: employment and economic development vs. health within an area)?

Interview grid for industry

1- The company's business and policy within the zone

- What is the company's business?
- Do you know what pollution is generated by this company? (types of waste, substances)
- Have health risk assessments been conducted by the industrial entity: impact studies, soil evaluations, hazards, environmental studies (how, by whom, internal corporate stakeholders)?
- Is there a general environment and health policy?
- Is there a local environment and health policy?
If so, what does this policy focus on?

2- Participation in a health risk assessment within a zone

- In what context?
- Do you know what deciding factor triggered the study?
- Do you know how the area was delimited?
- To what extent did the company get involved?
- What pollution caused by the company was taken into account in the zone assessment?
- What were the terms of participation?
- How was the collaboration between the other stakeholders (especially industrial entities) organised?
What did it consist of?
- What were the study's findings?
- What was the policy regarding the communication of findings?

3- The company's point of view

- In your opinion, what are the Z-RA approach's strengths and weaknesses?
- In your opinion, how can the approach be improved?
- What does the company communicate once the study has been completed (communication to the general public and the assessment zone's stakeholders)?
- What changes does the company make once the study has been completed: technical modifications, communications?
- In your opinion, what were the study's consequences in terms of:
 - risk perception by the local and national population and by the company (site manager, environmental manager, employees, etc.)
 - risk management
 - other consequences

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Health risk assessment in zone analyses

Utility, methodological issues and interpretation

On 21 May 2008, the Health Directorate General (DGS) made two requests to the High Council for Public Health (HCSP), one relating to "the development of an assessment methodology regarding health risks in the context of zone studies", the other one relating to "helping interpret the results of risk assessments conducted in the framework of impact studies".

The HCSP established a multidisciplinary working group made up of experts from various institutions.

The report is structured by the following topics: defining a zone as being a relevant area to assess health risks and devise risk management options; the utility of a zone analysis from a health risk management viewpoint; involvement of stakeholders and their roles in these situations; the main methodological principles of a Z-HRA (assessment of health risks in zones); interpretation of the results of an HRA (health risk assessment), notably on the same scale as the zone; and the benefit of regulations to guide zone assessments. Although this report questions the relevance of conducting a Z-HRA, it is not, however, intended to be a methodological guide to do so.

The HCSP then suggests a number of improvements, in terms of Z-RA, which aim to:

- restore to its rightful place the purely quantitative approach to RA,
- explain in detail the expected utility of a Z-RA with regards to an activity zone,
- establish dialogue between the various involved parties
- identify the contributory shares of the various past and present activities on the territory
- gradually move towards the systematisation of Z-RAs, which will replace the current single-site Z-RAs.

With these developments, the RA will fully satisfy its purpose, which is to provide the information required for informed discussion between the various stakeholders regarding risk management options.