GROUPE D'ETUDES ET D'OBSERVATION
SUR LES DRAGAGES ET L'ENVIRONNEMENT

Health risk assessment of dredging and disposal of dredged material at sea

Methodological guide

Part A — Principles and objectives of health risk assessment

August 2014




Steering committee members

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Acronyms and abbreviations

ADD	Average daily dose
ADI	Acceptable daily intake
AESN	Agence de l'Eau Seine-Normandie (Seine-Normandy Water Agency)
AFSSA	Agence Française de Sécurité Sanitaire de l'Alimentation (French Food Safety Agency)
ANSES	Agence Nationale de Sécurité Sanitaire (French Agency for Health Safety) (formerly AFSSA and AFSSET)
ASP	Amnesic shellfish poisoning
ATSDR	U.S. Agency for Toxic Substances and Disease Registry
AWI	Acceptable weekly intake
BCF	Bioconcentration factor
BMF	Biomagnification factor
CEREMA	Centre d'Études et d'Expertise sur les Risques, l'Environnement, la Mobilité et l'Aménagement (French Centre for Studies and Expertise on Risks, Environment, Mobility and Urban & Country Planning)
CETMEF	Centre d'Études Techniques Maritimes et Fluviales (French Centre for Technical Maritime and Waterway Studies) (became CEREMA in January 2014)
CFU	Colony-forming unit
CMR	Carcinogenic, mutagenic and reprotoxic
CRoral	Carcinogenic risk via intake
CSHPF	Conseil Supérieur d'Hygiène Publique de France (French Higher Council for Public Hygiene)
DED	Daily exposure dose
DSP	Diarrhoeic shellfish poisoning
EIR	Excess individual risk
ELR	Excess lifetime risk
ENSP	École Nationale de Santé Publique (French School of Public Health) (now EHESP)
EQS	Environmental Quality Standard (related to the WFD)
ER	Excess risk
GEODE	Groupement d'Étude et d'Observation sur les Dragages et l'Environnement (Study and Observation Group on Dredging and

	the Environment)
HAV	Hepatitis A Virus
HCB	Hexachlorobenzene
HEV	Hepatitis E Virus
HQ	Hazard quotient
HRA	Health risk assessment
IARC	International Agency for Research on Cancer
INERIS	Institut National de l'Environnement Industriel et des Risques (French Institute for Industrial Environment and Risks)
INRA	Institut National de Recherche Agronomique (French National Institute for Agricultural Research)
INSEE	Institut National de la Statistique et des Études Économiques (French Institute for Statistics and Economic Studies)
INVS	Institut National de Veille Sanitaire (French Institute for Public Health Surveillance)
LOAEL	Lowest observed adverse effect level
MID	Minimum infective dose
MIFCs	Microbial indicators of faecal contamination
MRL	Minimal risk level
NOAEL	No observed adverse effect level
NRC	National Research Council
OEHHA	Office of Environmental Health Hazard Assessment
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic ("OS" for Oslo and "PAR" for Paris)
PAHs	Polyaromatic hydrocarbons
PBT	Persistent, bioaccumulative and toxic
PCBs	Polychlorinated biphenyls. DL: Dioxin-like. NDL: Non-dioxine-like
PCR	Polymerase chain reaction
PHS	Priority hazardous substance (related to the WFD)
PNEC	Predicted no effect concentration
POP	Persistent organic pollutant (related to the Stockholm Convention)
PS	Priority substance (related to the WFD)
PSP	Paralytic shellfish poisoning
REMI	Réseau de Surveillance Microbiologique (French Microbiological Monitoring Network)

REPHY	Réseau de Surveillance du Phytoplancton et des Phycotoxines (French Phytoplankton and Phycotoxin Monitoring Network)
REPOM	Réseau de Surveillance de la Qualité des Eaux et des Sédiments des Ports Maritimes (French Seaport Water and Sediment Quality Monitoring Network)
RfD	Reference dose
RHO	Regional Health Observatory
RINBIO	Réseau Intégrateurs Biologiques (Biological Integrators Network)
RIVM	Dutch National Institute for Public Health and the Environment
ROCCH	Réseau d'Observation de la Contamination Chimique (French Chemical Contamination Monitoring Network) (formerly RNO)
SSs	Suspended solids
TBT	Tributyltin
TDI	Tolerable daily intake
TDI	Tolerable daily intake
TEF	Toxic equivalency factor
TGD	Technical guidance document
TOC	Total organic carbon
TRV	Toxicity reference value
US EPA	United States Environmental Protection Agency
WFD	Water Framework Directive
WHO	World Health Organization
WWTP	Wastewater treatment plant

Glossary

Acceptable daily intake (ADI)	Acceptable daily intake is the toxicity reference value used for toxic effects with a threshold when exposure occurs by the oral or dermal route. It is generally expressed in mg/kg/day (milligram of chemical substance per kilogram of body weight per day). ADI describes the maximum theoretical quantity of toxic agent that can be administered to an individual, who may or may not belong to a sensitive group, without causing adverse health effects.
Acute effects	Problems related to brief but high-dose exposure. In general, they are immediate or arise within a brief period of time (a few hours to a few days).
Average daily dose (ADD)	ADD is an estimate of daily intake by the oral or dermal route that takes into consideration the frequency and duration of subchronic or chronic exposure. It is expressed in the same units as the ADI*.
Bioaccumulation	Bioaccumulation refers to the capacity of certain organisms to absorb and concentrate certain chemical substances in part of or throughout their bodies.
Bioavailability	Bioavailability is the ability of a chemical substance to reach its organic target. This general concept includes all the phenomena set in motion from the time a hazardous agent enters a living organism to the time it is metabolised, eliminated or stored.
Bioconcentration	Bioconcentration refers to the phenomenon that causes concentrations of a given substance in living beings to become higher than its concentrations in the environment.
Biomagnification	Biomagnification, also called bioamplification, is a phenomenon in which concentrations of a pollutant within organisms increase from the bottom to the top of the food chain. It occurs with products that undergo no environmental degradation and very little to no degradation in the bodies of the organisms in which they are found.
Chronic effects	Problems related to prolonged low-level exposure. They generally arise following a latency period that may last several months or even decades.
Deterministic effects (effects with a threshold)	Refers to toxic effects with a severity level proportionate to the dose. Deterministic effects are considered to only occur if the dose threshold reached exceeds an organism's capacities for detoxification, repair and compensation.
Dose	Quantity of hazardous agent that comes into contact with a living organism. When referring to human or animal exposure to chemical substances, dose is generally expressed in milligrams per kilogram of body weight per day. In the absence of precise information, the dose is considered as external or administered.
Excess individual risk (IER)	Probability of a hazard arising that is related to exposure to a carcinogenic agent (without units).

Excess lifetime risk (ELR)	Estimate of IER from lifetime exposure equal to one dose unit of hazardous agent. This index is the toxicity reference value (TRV) for toxic effects without a threshold. It generally represents the slope of the upper limit of the confidence interval of the dose-response curve. For oral or dermal exposure, it is expressed in (mg/kg/day)-1.
Excess risk (ER)	Additional risk due to specific exposure compared to the risk in a reference population (generally not exposed).
Exposure	In the health field, exposure refers to contact between a hazardous situation or agent and a living organism. There are several vectors and routes of exposure: inhalation, skin contact, ingestion, etc.
Exposure scenario	Describes all the physiological and behavioural characteristics of human beings that are used to model exposure, including: age, weight, sex, tidal volume, skin surface area, space-time budget, activity performed on the site, food consumption, soil ingestion, etc.
Food chain	The food chain is the name given to a series of food relationships that exist between living beings, where each living being eats the one that precedes it.
Hazard	Undesirable health event such as illness, injury, disability or death. By extension, hazard refers to any toxic effect, i.e. any cell or body dysfunction related to interactions between a living organism and a chemical, physical or biological agent.
Hazard quotient (HQ)	Relationship between estimated exposure (expressed in terms of a single dose or concentration for a specified period of time) and the TRV of the hazardous agent for the corresponding route and duration of exposure. HQ (without units) is not a probability and only applies to effects with a threshold.
Hazardous substance	Molecule capable of producing a toxic effect in humans.
Lowest observed adverse effect level (LOAEL)	The lowest dose or concentration that has caused an observed adverse effect, compared to a control group, in an animal experiment or epidemiological study.
No observed adverse effect level (NOAEL)	The highest dose or concentration that has not caused an observed adverse effect compared to a control group in an animal experiment or epidemiological study.
Risk	Probability that a hazard will occur.
Stochastic effects (effects without a threshold)	Toxic effects without a threshold dose. This term refers to toxic xenobiotics capable of acting at any dose. Such effects may occur when, for example, a single molecule is enough to damage a cell in a way that is potentially harmful to the organism, e.g. a DNA mutation. This category includes CMR products, i.e. products that are carcinogenic, mutagenic (or genotoxic) and reprotoxic.
Toxicity reference value (TRV)	Generic expression comprising all toxicity index types that allow a relationship to be established between dose and effect (toxic with effect threshold) or dose and probability of effect (toxic without effect threshold).

Preface

This guide has been produced by the **GEODE** group and prepared by the **CEREMA** in consultation with a monitoring committee comprised of port managers; representatives from the central administration and decentralised departments of the French Ministry of Ecology, Sustainable Development and Energy (MEDDE); representatives from the French Ministry of Health; and scientists from the Ifremer, INERIS and the Rouen University. It is intended to be a practical and operational reference for **health risk assessment of dredging operations and disposal operations of dredged materials into estuaries and seas.**

It constitutes a methodological tool to facilitate decision-making. It does not represent a set of regulations.

As the different sections of this work illustrate, health risk assessments are conducted according to a systematic process that should nevertheless not obscure the need to think critically and adapt the process to each individual project based on its particular characteristics. This guide therefore includes a compilation of questions to reflect on and should be considered as a "toolbox" to help stakeholders in assessing the project's health risks associated to dredging and sea disposal operations.

It is aimed at all stakeholders involved in the evaluation of the effects of dredging and sea disposal operations: contracting authorities, contractors, work supervisors, technical departments of public institutions, consulting firms, users, etc.

The guide comprises three sections and three technical appendixes:

- **Section A: introduction to principles and processes of health risk assessments**
  This section presents the principles of health risk assessment, its regulatory foundations and its relationship to the environmental impact assessment process. It also includes a plain-language summary of the assessment methods applied to chemical, bacterial and phytoplankton hazards. It finally includes approaches to processing and optimising the results of such an assessment in order to manage risks appropriately.
- **Section B: health risk assessment tools and methods**

  This section includes all the methodological work performed by the CEREMA and the GEODE group in preparing this guide. It presents the detailed methodologies that have been developed for each type of health risk to be considered and the associated calculation methods.
- **Section C: case studies**

  This section includes applications of the theoretical methods described in the first two sections of the guide on two case studies.

Only section A has been translated from French to English and is presented in this document

- **Three technical appendixes:**
    - The technical guidance document (TGD) method: this anppendix presents the calculation elements of this method that may be used to determine the concentrations of substances with health implications in the different compartments of the marine environment (sediment, water and biota).
    - The decision-making criteria for assessing the health sensitivity of dredging and sea disposal projects: this appendix presents the work carried out, when preparing this guide, to determine benchmark concentrations in sediments that allow rapid assessment of the project's sensitivity to health effects. These criteria also facilitate deciding on whether or not an in-depth assessment of health risks should be conducted.
    - The Ifremer's expertise in health risk assessment on the specific subject of microbiological contamination of sediments.

Introduction

Dredging and sea disposal operations, while necessary to sustain and develop maritime activities, impact marine and estuarine environments in various ways, which in turn may lead to certain human health risks.

Health risk assessments (HRA) are a part of the environmental impact assessment (EIA) of projects as stipulated in Article L122-1 of the French Environmental Code. Based on the environmental baseline assessment, the project's description and the assessment of effects on the other compartments of the environment (water, sediment and biota), the HRA is generally treated as a distinct part of the EIA.

HRA is an analytical and scientific process that qualifies and quantifies risks to allow better risk management through the application of certain measures and the implementation of strategic monitoring actions.

If the general principles of an HRA were laid down several years ago and codified in a standard process with four key stages, they must nevertheless be interpreted and adapted to the unique context of each dredging and sea-disposal operation.

The HRA for dredging and sea disposal operations aims at identifying potentially hazardous agents, represent the full spectrum of mechanisms by which individuals may be exposed to them, assess their severity and adapt the project as needed to achieve acceptable risk management.

The complexity of HRA related to dredging and sea disposal operations lies in the evaluation of how hazards are directly or indirectly transferred from sediments to users of the marine environment. The hazards to be considered are chemical substances with health implications, pathogenic microorganisms and toxic phytoplankton.[1]. The main risk associated to these hazards is harmful effects on the health of consumers of seafood in which these hazards may accumulate.

Finally, HRA must be conducted according to the key principles of an EIA: specificity, transparency and proportionality, among others.

[1] This document does not address the potential health effects of noise or radioactivity.

Part A — Principles and methods of health risk assessment

Chapitre 1 Foundations, principles and objectives of the HRA

1.1 Definitions

Risk is defined as the probability that exposure to a hazard will lead to a negative consequence, a hazard being any biological, chemical, mechanical, or physical agent that is reasonably likely to cause harm or damage to humans with sufficient exposure or dose.

In other words, risk results in the combination of a hazard, the severity of its potential effect on human health, and the probability of exposure.

The United States National Research Council (NRC, 1993) defines HRA as an analytical process based on the use of scientific facts to identify the health effects of the exposure of individuals and populations to hazardous materials and situations.

In a dredging and sea disposal project, this assessment focuses on the exposure of populations to potentially hazardous agents that may be released into the environment in the course of project operations. More specifically, it focuses on the chemical and biological contaminants that may be released into the various compartments of marine and estuarine environments when materials are mobilised.

1.2 Regulations

The assessment of a project's health risks is included in the scope of the impact assessment evaluation, introduced by Article L122-1 of the French Environmental Code, which stipulates that *"public and private works, construction and development projects that, by their nature, scope or location, may give rise to incidents with significant consequences on the environment and/or* ***human health*** *shall be preceded by an impact assessment".*

Article L122-3 of the French Environmental Code goes on to state that the impact assessment shall comprise, among other things, a study of the project's effects on human health; projected measures to prevent, reduce and/or offset substantial negative effects on human health; and arrangements for monitoring these measures. This content is described in Article R122-5 of the French Environmental Code.

Consideration of human health in impact assessments was brought about by Article 19 of Act No. 96-1236, of 30 December 1996, on air and the rational use of energy. Since then, it has been the subject of several fundamental memoranda. Three of these memoranda have a general methodological character that may be applied to impact assessments for dredging and sea disposal operations.

- Memorandum DGS/VS3/2000 No. 61, of 3 February 2000 (published in the French Health OB No. 9/2000)

  This document introduces the G*uide to reading and analysing the health component of impact assessments*, the conduct of which has been entrusted to the French Directorate of Health to INVS (Institute for Public Health Surveillance). The guide is intended to help local

authorities issue an opinion on projects requiring an assessment of health effects. It formalises what such assessments should ideally contain from a public health perspective. It also sets out the fundamentals of the process of quantitative risk assessment. This guide may be downloaded from the INVS website (http://www.invs.sante.fr/pmb/invs/(id)/PMB_5862).

- Memorandum DGS No. 2001/185, of 11 April 2001 (published in the French Health OB No. 18/2001)

  Following the memorandum DGS/VS3/2000 No. 61, of 3 February 2000, this document specifies the procedures for assessing and analysing health effects when conducting impact assessments. It includes a list of points that must necessarily figure in an impact assessment and suggests that all information relating to health effects should figure in a distinct part of the study. It also notes that the study of health risks should be proportionate to the hazardousness of the released substances and to the size and/or fragility of the population exposed to the works covered by the authorisation procedures.

- Memorandum DGS/SD. 7B No. 2006-234, of 30 May 2006

  This memorandum deals with procedures for selecting chemical substances and choosing toxicity reference values to conduct health risk assessments as part of impact assessments.

1.3 Principles of HRA

- **HRA is carried out *ex ante* under the responsibility of the contracting authority**

Like the impact assessment, the HRA is a technical and scientific analysis that is conducted prior to operations, and aimed at evaluating the operations' possible effects on human health. This process is incumbent on the contracting authority, which must fulfil this responsibility by qualifying and, if possible, quantifying the projected positive and negative health effects of its project.

- **HRA is a transparent evaluation process**

The principle of transparency holds that the scientific facts supporting recommendations and decisions are to be discussed and validated. The links between environmental factors and human health are the products of complex processes that are often poorly understood and indeed difficult to assess. In the face of the uncertainties that the impact assessment may raise in the marine or estuarine context of a dredging and sea disposal operation, health risk assessment constitutes a rigorous and transparent tool to facilitate the decision-making process for a better management of health risks. The limits of the analysis and the uncertainties associated to the results must clearly be established.

- **HRA results from a systematic four stage analysis**

In order to promote a systematic evaluation approach of health risks, the HRA unfolds in four standardised stages:

- Identification of hazards and their possible effects on human health,
- Identification of the relationship between exposure dose and organism response,
- Assessment of human exposure in the specific context of the project in question, and
- Characterisation of health risks.

This systematic approach is a basis for rigorous and explicit analysis, better management of uncertainties, and knowledge based decision-making.

Moreover, the assessment's relevance is ensured by duly taking into account the unique characteristics of the site, the physical and biological processes regulating the spread of hazards, and the potentially exposed populations.

- **HRA supports cautious decision making**

In dealing with the uncertainties surrounding the effects of hazards on human health on the one hand, and the models of population exposure to these hazards on the other hand, the health risk assessment process adopts a principle of caution. The quantitative assessment of the effects of exposure on human health is therefore often based on reasonably conservative hypotheses (or pessimistic scenarios) that are established on a case-by-case basis.

- **HRA must be carried out according to the principle of proportionate analysis**

Like impact assessments, the HRA consists of a balanced appraisal of health risks, and is underpinned by the principle of proportionate analysis, whereby the depth and scope of the analysis, and hence the resources allocated to it, are proportionate to the expected nature of the proposal and its likely impacts.

Each stage of the HRA should therefore be conducted in more or less depth depending on the available data and knowledge on the subject at the time that the study is conducted.

1.4 Objectives

A health risk assessment consists of studying a project's potential effects on human health in order to identify appropriate measures to allow these risks to be reduced to an acceptable level. It is a tool that facilitates making specific decisions with respect to health issues. Applied to dredging and sea disposal operations, the objectives of this process may be understood as follows:

- **Identifying hazards**

This includes identifying all of the processes that contribute to the potential occurrence of effects on one or several individuals or one or several populations making direct or indirect use of the project's area of influence. The main hazards to take into consideration for these operations are priority chemical substances, pathogenic microorganisms or phytoplankton toxins.

- **Mapping the sequence of exposure processes**

The mechanisms by which users of the sea are exposed to substances or organisms stored in the substrate are complex. The main risks in dredging and sea disposal operations are linked to ingestion of chemical substances, bacterial organisms and phytoplankton toxins, particularly by consuming seafood, wherein these agents may accumulate. The processes of dispersion and exposure that bring pathogens into contact with individuals are multiple and indirect. They fall within the space-time scales that depend on physical-chemical environmental conditions (e.g. currents and dispersion of materials), species and uses present (e.g. proximity to shellfish farms), the operation's technical characteristics (e.g. volumes and flows of materials brought into play) and the operation's technical and operational development (e.g. time of year and vulnerability of social systems and ecosystems).

It is therefore necessary to map exposure processes to have a clear vision of the operation's potential health risks. This map is hereinafter referred to as "conceptual exposure diagram".

Assessing severity of effects on health

The HRA aims to determine the potential severity of effects associated to each hazard to which humans could be exposed as a result of project operations. This is done by using methodologies adapted to the evaluation of deterministic effects (effects for which the degree of severity is proportionate to the exposure dose), and probabilistic effects (effects that have a probability of occurrence that is proportionate to the exposure dose). The probable severity of an effect is most often appreciated from available literature and data on the toxicity of the hazards considered in the analysis.

Determining acceptability

Determining risks and assessing their acceptability according to explicit and standard criteria allows for transparent decision-making in support of project authorisations.

In dredging and sea disposal operations, it is accepted that the available knowledge concerning the toxicity of hazards and their mechanisms of dispersion and accumulation in different compartments of the environments make it possible to:

- Qualify and quantify the risks associated to chemical substances with health implications, and
- Qualify, but not quantify, the risks associated to pathogenic microorganisms and phytoplankton toxins.

Neutralising or reducing risks

Neutralising risks is done by implementing as many preventive and protective measures as necessary in order to prevent undesired events from occurring and leading to harmful health effects.

During dredging and sea disposal operations, measures are most usually taken to limit exposure. They may be of a technical and operational nature (e.g. reducing the dispersion of suspended solids towards sensitive areas by changing the dredging technique), or based on monitoring key parameters of the environment for which thresholds can be set, and for which specific restrictions can be set regarding use of the environment (e.g. restricted access to bathing areas, temporary ban on seafood consumption, etc.).

These measures and their contribution to reducing risk must be detailed in terms of location and duration to ensure that they are relevant and sustainable.

Chapitre 2 HRA process and conduct

2.1 The four stages of the HRA

- **Stage 0: Identification of hazards**

This preliminary step of characterising sources involves identifying all the chemical, biological and physical hazards that may be released into the environment as a result of the project. It is based on the baseline analysis of the environment and allows hazardous substances and organisms likely to be found in the project environment to be identified.

- **Stage 1: Identification of possible effects of hazards on human health**

This is a stage in which harmful effects that may be caused by chemical, biological or physical hazards are identified according to the different ways in which individuals are exposed to these hazards.

- **Stage 2: Assessment of dose-response relationship**

In this stage, the relationship between the level of exposure to a hazard and its effects on health is estimated.

- **Stage 3: Assessment of exposure**

In this stage, dispersion and transmission routes, displacement, transformation or degradation dynamics are determined in order to assess the doses at which human populations and components of the environment are exposed or likely to be exposed to the previously identified hazardous substances or organisms.

- **Stage 4: Characterisation of risks**

This stage involves estimating the incidence and severity of the undesirable effects likely to be produced in a human population or in a component of the environment owing to the actual or projected exposure to a hazard.

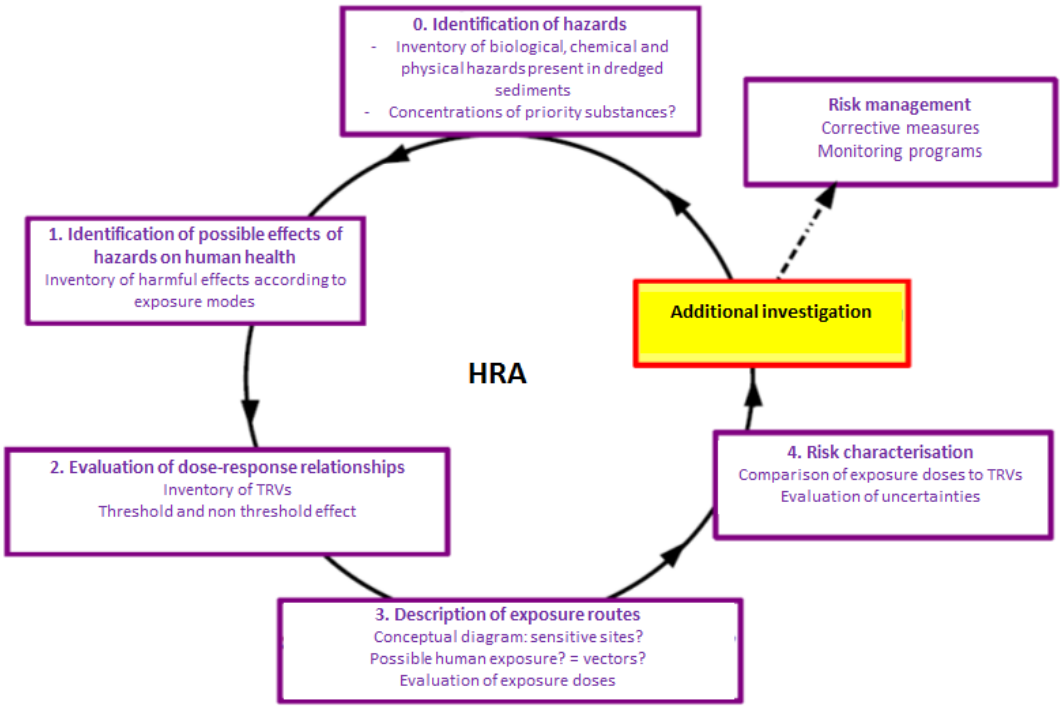


Figure1: Schematic representation of the risk-assessment process adapted to the specific issues of dredging and sea disposal

Stage 0

Identification of hazards

What are the chemical, physical and biological agents likely to be dispersed in the environment as a result of the project?

A hazard is any biological, chemical, or physical agent that is reasonably likely to cause harm or damage to humans in the absence of its control. The notions of harm or damage refer to any cell or body dysfunction related to interactions between a living organism and a chemical, physical or biological agent, and susceptible to lead to an illness, an injury, a disability or death.

This stage of the analysis therefore consists in identifying the chemical, physical and bacterial agents that may be dispersed in the environment as a result of the project.

This identification is based on:

- the techniques used for dredging and discharge, which influence the dispersal pattern of sediment in the water column,
- the hydrodynamic conditions of the project site(s), which also influence dispersal patterns, and
- the available environmental data that suggest or confirm the presence or risk of the presence of potentially hazardous chemical substances, microbial agents and phytoplankton in the project area.

Stage 1

Identification of possible effects of hazards on human health

What are harmful effects that could result from exposure to the physical, chemical and biological agents that are likely to be dispersed in the environment as a result of the project?

This stage consists in:

- Identifying the hazard potential of these agents and the routes of exposure associated to them, and
- Selecting the agents presenting a hazard potential that is likely to be significant. These agents will be studied in greater detail in subsequent stages.

While health risk assessment methodology has primarily been used to manage the toxic effects of chemical and biological substances, another pressure, namely noise, can be considered in the health part of impact studies of dredging and sea disposal operations when taking place in urban environments.

In the absence of hazards, the HRA stops at this stage, and it is concluded that there is an absence of risks. Otherwise, the HRA proceeds to the next stage, i.e. exposure assessment (the stage of identification of dose-response relationships, specific to chemical risks in dredging and sea disposal operations [see below], can be considered a concurrent stage, as it should be undertaken before the stage of characterisation of risks, but does not lie on the critical path of exposure assessment).

Stage 2

Identification of dose-response relationships

What are the theoretical doses above which the hazards identified in the previous stages are likely to induce harmful health effects?

This second stage consists in determining the **relationship(s) between exposure levels and occurrence of harmful effects for the hazards identified in the previous stages of the HRA.**

In dredging and sea disposal operations, health risk assessment focuses on the dispersion of physical, chemical and biological contaminants in the different compartments of the environment (seabed, water column, living organisms). The health effects that are taken into account are essentially the **effects of toxicity**.

For chemical substances, the relationship between dose and response can be described with a **toxicity reference value (TRV)**. This stage of the analysis therefore consists in taking inventory of the TRVs associated to the previously selected hazards, provided that such TRVs have been determined. The absence of a TRV for a given hazard does not impede the assessment process (see below).

It should be remembered that memorandum DGS/SD. 7B No. 2006-234, of 30 May 2006, describes the procedures for selecting chemical substances and choosing toxicity reference values to conduct health risk assessments as part of impact assessments.

Minimum infective doses (MIDs) of pathogenic microorganisms are proposed in the literature to determine pathogenic microorganisms' dose-response relationships. However, these values vary widely among studies, and the unique characteristics of marine routes of exposure complicate the use of these indices. Therefore, this stage is not applied in HRAs relating to bacteriology.

Dose-response relationships for phytoplankton toxins are determined using threshold limit values of toxin concentrations in seafood products above which the products are not fit for consumption. These concentration values are determined by European and State regulations. As with pathogenic bacteria, optimal use of these indices in dredging and sea disposal projects is overly complex. This stage is not applied in HRAs relating to phytoplankton.

Stage 3

Assessment of human exposure

Who is exposed, by which means (contact, ingestion, inhalation, rate, level) and to which agent(s)?

This third stage of assessment consists in **determining the routes through which humans may be exposed to a hazard.** It is done by examining the mechanisms by which environments are contaminated on the one hand, and the populations making use of these environments on the other hand.

Hence, this stage involves:

- Describing the ways in which hazards are dispersed and propagated in the different compartments of the environment,
- Assessing the induced rates of contamination,
- Describing the relationship to the environment of the populations making direct or indirect use of it, and
- Establishing an exposure model.

In the event that the absence of exposure is determined in this stage, it becomes the final stage of the HRA.

It should be noted that stages 2 and 3 may be conducted concurrently, and that exposure assessment can be conducted immediately after identification of hazards.

Stage 4

Characterisation of risks

Does a risk exist and can it be quantified?

This last stage of the HRA consists in synthesising the results of the preceding stages in order to estimate the probability that individuals will experience harmful health effects as a result of the project.

For chemical substances, this stage involves calculations that yield an estimated risk score reflecting this probability.

For biological agents, this is a qualitative stage in which it is determined whether or not a risk exists.

2.2 HRA conduct: relationship to the impact assessment

Although a specific methodology is applied (see previous chapter) the health risk assessment forms part of the broader environmental impact assessment (EIA) process of the project. It therefore guides the project at different key points in its development, starting with project design.

The following diagram illustrates the links between HRA and EIA.

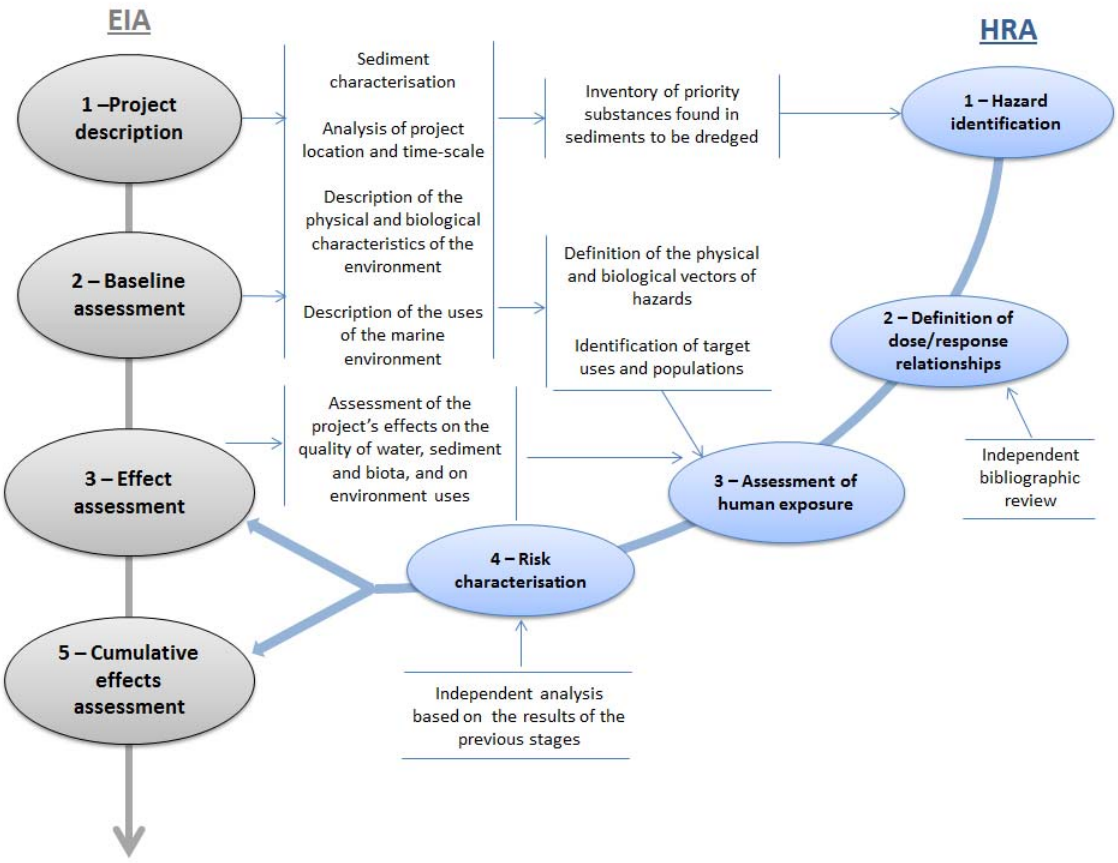


Figure2: Illustration of the links between the impact assessment and the part specific to health risk assessment

The HRA thus rests on the project's description and the baseline analysis of the project site(s). It can include results of the assessment of the effects of the project on other compartments of the environment that are vectors for hazards to human beings: water quality, sediment quality, living matter quality, and wild-caught and farm-raised fishery resources.

Identification of dose-response relationships and characterisation of risks can be considered as independent stages. The risk characterisation stage differs from other stages of the analysis in the way that it includes conducting an analytical synthesis of the results of the three stages that precede it.

2.2.1 Relationship to the project description

To conduct an HRA, the project's spatial organisation and time-scale must be described precisely. This information will enable the description of exposure routes and the identification of sensitive populations to be taken into account.

- **Time-scale:** the extent of health risks can be highly dependent on the time of the year during which operations are taking place. For example, it is important to determine whether the project will unfold during specific fishing or bathing seasons. Physiological processes in certain organisms in which substances accumulate, such as shellfish, can also depend on the time of the year under consideration.
- **Spatial organisation:** the location of the operation(s) and the extent of its effects on the environment directly condition the project's interaction with the environment and its users. A precise description of the work site and its surroundings is necessary from the preliminary impact assessment phase on.

2.2.2 Relationship to the baseline environmental assessment

The baseline environmental assessment feeds two of the four fundamental stages of the HRA: identification of hazards and identification of routes of exposure.

Identification of hazards

Identification of hazards involves identifying the chemical, physical and bacterial agents associated to the project and likely to cause harmful effects to the environment. Thus, characterisation of the materials to be dredged drives the first stage of the HRA. It is a mandatory part of the project impact assessment and is described baseline environmental assessment.

Sediment analyses are stipulated in the French decree of 9 August 2006, complemented by the French decrees of 23 December 2009 and 8 February 2013. The list of substances to be analysed nearly covers the entire list of priority substances to be considered in HRAs. Studying other data sources such as that of the REPOM (French Seaport Water and Sediment Quality Monitoring Network) facilitates determining whether or not analysis of additional substances is necessary or not.

Identification of routes of exposure

To identify the routes of exposure to hazardous material, it is necessary to be familiar with the local physical dynamics of the environment (hydrodynamic conditions, sediment transportation, etc.). A precise description of local uses of the environment and their organisation is also necessary.

This stage involves describing the processes by which agents are transmitted from source areas (work sites and, more specifically, sites from which materials are released in the water column) to target areas (e.g. areas of seafood consumers) to reach the population that becomes exposed. It also involves describing means of exposure such as ingestion, skin contact or inhalation.

- **Physical processes**: dispersion of materials and associated substances in the water column is determined by currentology, bathymetry and particle size. Characterisation of these baseline conditions is therefore necessary to construct more or less complex

dispersion models. These data are exploited in the HRA to identify the risks of damage to sensitive intermediary targets (e.g. shellfish farms).

- **Uses of the environment:** understanding human use of maritime and estuarine territories is essential to understand how exposure to hazards generated by the project may occur. The baseline environmental assessment must describe professional and recreational fishing areas, mariculture sites, organisation of supply chains, etc. Its comprehensive approach to the project environment allows specific elements of impact assessment used in the HRA to be reinforced. It particularly seeks to specify all possible direct and indirect links to individuals in the project's area of influence.

2.2.3 Relationship to the effect assessment

In most cases, health risks from projects stem from indirect exposure processes. Characterisation of exposure should therefore include assessment of the dispersion of agents in the compartments of the environment that bring the source (in this case, sediment) into contact with the target (the exposed individual or population).

Health risk assessment thus hinges on:

- Assessment of effects on water quality: extent of the turbid plume and of concentrations of SSs and other substances or microorganisms;
- Assessment of effects on substrate quality: the extent of sediment disruption due to the project and the variation in chemical substances and microorganism concentrations;
- Assessment of effects on living matter: exposure of living matter to project materials and accumulation of potentially hazardous substances and microorganisms; and
- Assessment of effects on uses: relationship between living matter and exploited resources, relocation of activities, etc.

2.3 Governance

In addition to the modes of governance common to all impact assessments, some specific features may be noted for HRA.

2.3.1 Specific stakeholders of HRA

The French Regional Health Agencies (ARSs) are the local reference institutions for health risk assessments of projects requiring an environmental impact assessment. They are involved in the evaluation process of environmental impact assessments, during which they may be asked by environmental authorities to provide an opinion on the health risk part of the assessment.

Their opinion is based on the quality of the hazard census (an exhaustive, detailed inventory of emissions); the quality of the agent selection process; the quality of population exposure assessment; the results of the characterisation of health risks that may be attributed to the project and those that are already present in the project's impact area; the critical discussion of the main conclusions, effective measures for reducing toxic pollutants and site monitoring (emissions, environments and populations) proposed by the applicant; and the health risks presented to local stakeholders and the general public..

2.3.2 Mode of governance

HRA governance falls under the governance of environmental impact assessment and does not have any major specific features.

It should be noted, however, that in view of the project's sensitivity regarding hazard dispersion, it may prove necessary to associate specific health experts to the study of the project's effects and to consult public reference bodies on the subject (e.g. INERIS, INVS, ARSs, etc.)

It should also be noted that the concern for the project’s health risks is substantial during the consultation of affected stakeholders and the general public. The clarity and the rigour with which the HRA has been conducted are therefore essential to the project’s acceptability.

2.4 Application to dredging and sea disposal operations

2.4.1 Assessment of chemical risks

Potential for hazard

1 - Potential effect(s) of the project on environmental chemistry

Dredging and sea disposal operations can affect the chemical quality of the environment by disrupting the seabed and dispersing solids and chemical substances that accumulate in sediments, in the water column.

2 - Routes of exposure to risk

The main route of exposure to be considered, owing to the health risk linked to chemical contaminants, is ingestion of seafood. The concentration of priority substances in shellfish, and their accumulation along the food chain by bioconcentration and biomagnification, must be considered.

3 - Chemical contaminations to be considered in an HRA

The chemical substances with health implications to be considered in marine sediments are the priority substances according to the WFD and the OSPAR that are likely to be found in sediments and biota. These substances can be divided into four categories:

- Contaminants with regulated levels in seafood: *arsenic, benzo(a)pyrene, cadmium, lead, mercury, DL-PCBs, dioxins, furans and hexachlorobenzene.*
- Contaminants with recommended levels in seafood: *indicator PCBs (CB 28, 52, 101, 118, 138, 153 and 180), anthracene, fluoranthene, naphthalene, benzo(b)fluoranthene, benzo(ghi)perylene, benzo(k)fluoranthene, benzo(a)anthracene, indeno(1,2,3-cd)pyrene and chrysene.*
- Priority contaminants that are found in marine environments and possess a TRV: *pyrene, phenanthrene, nickel, lindane and tributyltin (TBT).*
- Contaminants from agricultural river basins that may be found in marine environments and possess a TRV: *dieldrin.*

4 - Site sensitivity

Site sensitivity is assessed based on the identification and dosage of contaminants in sediments. The French decree of 9 August 2009, complemented by the French decrees of 23 December 2009 and 8 February 2013, lists the substances to be analysed in sediments prior to dredging. All of the substances mentioned above appear on the list, except hexachlorobenzene, dieldrin, $_{DL}$-PCBs, dioxins and furans. If contamination by these substances is suspected, specific additional analyses may be performed.

Section B of this guide gives methods by which environmental contamination by these substances may be assessed.

Dose-response relationship

Dose-response relationships for chemical substances are expressed in toxicity reference values (TRVs). TRVs are toxicity indices that allow a relationship to be established between dose and effect (toxic with effect threshold) or between dose and probability of effect (toxic without effect threshold).

A distinction is made between TRVs with a dose threshold, which are estimates of the quantity of substance to which an individual can theoretically be exposed without experiencing harmful health effects, and TRVs without a dose threshold, which are defined as an increase in the probability that an individual exposed throughout the course of his or her entire lifetime to a dose unit of the substance develops a disease compared to a non-exposed subject.

It should be noted that these TRVs are specific to duration of exposure (acute, subchronic or chronic), route of exposure (oral, respiratory, etc.), type of effect (reprotoxic, carcinogenic, etc.) and population category (child, pregnant woman, etc.).

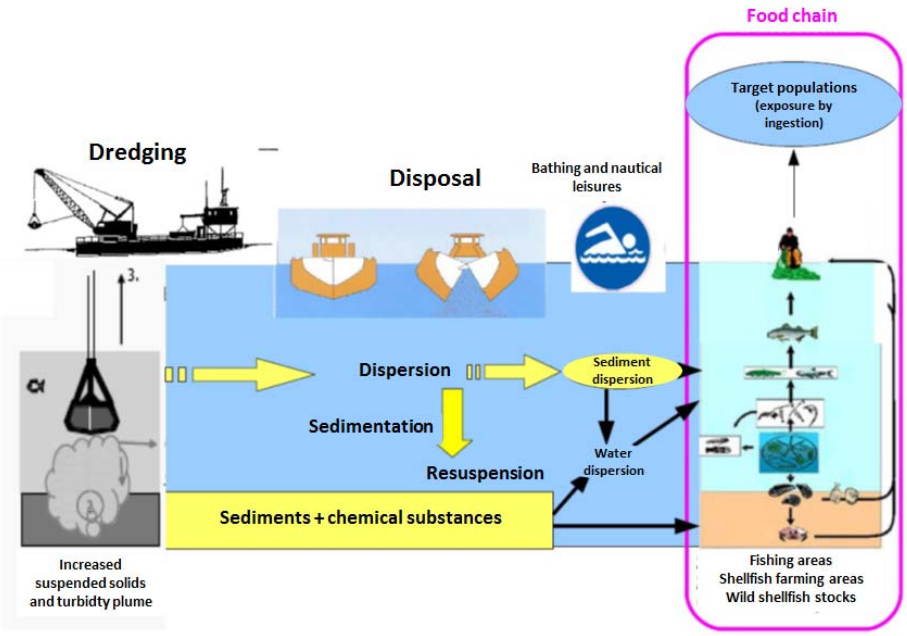
In HRAs relating to sea disposal of dredged sediments, TRVs relating to subchronic to chronic exposure by ingestion are considered.

Section B of this guide presents the different types of existing TRVs for subchronic to chronic exposure by ingestion and lists the existing values for the priority substances listed above.

These TRVs are defined by various health risk assessment research organisations such as the IRIS (Integrated Risk Information System) of the US EPA (Environmental Protection Agency), the ATSDR (Agency for Toxic Substances and Disease Registry), the WHO (World Health Organization), Health Canada and the OEHHA (Office of Environmental Health Hazard Assessment).

Routes of exposure

The only route of exposure to chemical substances that may lead to health problems during dredging and sea disposal operations is the accumulation in the food chain and the transmission to human beings by ingestion of seafood. The conceptual diagram below shows the different routes to be taken into account in determining the level of human exposure to substances initially present in the sediment.



Exposure is calculated as follows:

- Identification of the project's area of physical and chemical influence: influence of dredging and sea disposal areas + influence of the turbidity plume;
- Identification of fished species and their capacity to take in the substances present in the water column, sediment or biota. It should be noted that only the fish, crustaceans and molluscs feeding exclusively in the area of physical-chemical influence of sediment dredging and/or sea disposal sites should be considered;
- Identification of populations that consume species from the project's area of influence and assessment of the frequency and duration of consumption habits.

Section B of this guide includes calculation methods for each of these analytical stages.

Characterisation of risks

Risk is characterised quantitatively for chemical substances. The method used to calculate the risk that an individual or population develops a disease by ingesting seafood varies and depends on whether the effect that is considered in the evaluation is threshold effect or not[2]. Section B of this guide includes the calculation methods used for these two categories of substance.

[2] Effects with a threshold: effects that have a threshold under which no effect exists and above which effect severity is proportionate to exposure

Effects without a threshold: effects that a have a probability of arising that is proportionate to exposure dose, however small, but not to severity

2.4.2 Assessment of microbial risks

Potential for hazard

1 - Potential effect(s) of the project on bacteriology

Dredging and sea disposal operations are likely to affect the microbial quality of environments owing to remobilisation of pathogenic bacteria, viruses and even protozoa. Certain species are likely to be present in sediments when these sediments are exposed to various anthropogenic discharges.

2 - Routes of exposure to risk

There are multiple routes of exposure to these hazards: ingestion, inhalation and skin contact.

3 - Species to consider in an HRA

The microorganisms to consider in an HRA are the following:

- **Enteric bacteria:** C. jejuni Campylobacter, pathogenic strains of *E. coli* (STEC, EHEC, VTEC, etc.), *Salmonella* (*S. enteriditis, S. typhi and S. paratyphi*), *Shigella* (*S. sonnei, S. flexneri*), *Yersinia spp., Clostridium* (*C. perfringens*) and *Listeria* (*L. monocytogenes*).
- **Non-enteric bacteria:** *Aeromonas (A. hydrophila, A. caviae, A. sobria, A. veronii, A. jandaei, A. trota and A. schubertii), Pseudomonas (P. aeruginosa), Staphylococcus (S. aureus), Vibrio (V. alginolyticus, V. carchariae, V. cholerae, V. cincinnatiensis, V. damsela, V. fluvialis, V. furnissii, V. hollisae, V. metschnikovii, V. mimicus, V. parahaemolyticus and V. vulnificus)*.
- **Enteric viruses:** Enterovirus (poliovirus, coxsackievirus, echovirus and unclassified enterovirus), norovirus (Norwalk, a member of the calicivirus group), rotavirus, adenovirus, hepatic viruses (hepatitis A virus [HAV] and hepatitis E virus [HEV]), astrovirus, sapovirus (a member of the calicivirus group), orthoreovirus and coronavirus.
- **Enteric protozoa:** *Giardia (G. lamblia), Cryptosporidium (C. parvum*), intestinal amoebae (*Entamoeba histolytica*) and *Toxoplasma gondii*.

These species' characteristics are summed up in section B of this guide.

4 - Site sensitivity

A first approximation to assessment of site sensitivity can be done based on sediment granulometry and organic matter content as these parameters condition the sediments' potential for microbial colonisation.

In the presence of a favourable physical environment, analysis of MIFCs (microbial indicators of faecal contamination) allows assessment of sediment microbial contamination. E. coli and enterococci are recommended here as indicators.

Comparison of analyses results to sensitivity thresholds (or decision-making criteria) provided in section B of this guide, determine whether or not to proceed or not to the next stages of the HRA.

Dose-response relationship

Dose-response relationships depend on the pathogenic agent, host sensitivity (immune status, age, etc.) and exposure conditions.

Minimum infective doses (MIDs) have been proposed for certain microorganisms in some specific studies. Nevertheless, these relationships vary widely from one study to another.

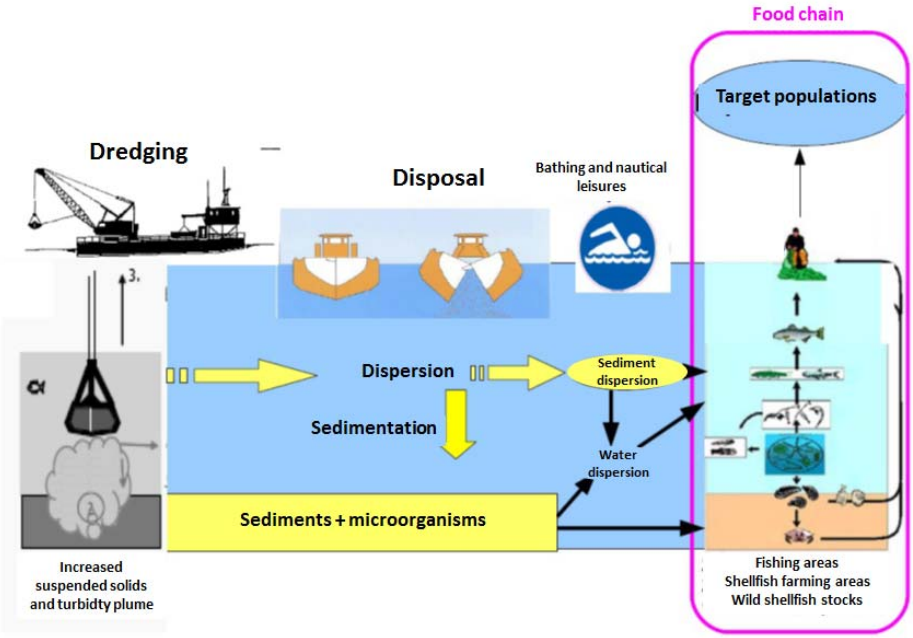
Moreover, in dredging and sea disposal operations, there is an indirect relationship between dose in sediment and user response. The relationship depends on numerous environmental factors (dispersion in the water column + efflorescence + accumulation in living matter) that complicate modelling the passage from the sediment to the user and thus establishing a direct dose-response relationship.

For these two reasons, the dose-response criterion is not taken into account in HRAs relating to microbiology. Such HRA will therefore conclude qualitatively and not quantitatively as for risks related to chemical substances.

Routes of exposure

The routes of exposure to consider for biological risk are ingestion, inhalation and skin contact.

These three routes of exposure are based on a series of complex biological and physical mechanisms represented in the following conceptual diagram:



The area of influence of dredging and sea disposal operations can be appreciated in part by modelling the dispersion of re-suspended particles (which adsorb microorganisms) and the survival time of the various microorganisms in the environment.

In the absence of a model or local data on physical conditions, a maximum radius of influence of 5 km can be considered.

Characterisation of risks

The assessment of health risks relating to pathogenic microorganisms results in a qualitative approach. It is concluded on whether a risk does or does not exist; and no conclusions are drawn with respect to level of risk.

The existence or non-existence of a risk is to be determined based on whether or not the concentration limits for microbial indicators of faecal contamination (E. coli and enterococci) are exceeded and, if so, on whether or not pathogenic germs are detected in sediment.

2.4.3 Assessment of phytoplankton risks

Potential for hazard

1 - Potential effect(s) of the project on phytoplankton

Dredging and sea disposal operations are likely to affect the phytoplankton in the water column owing to remobilisation of cysts buried in sediments. Some species belonging to the class Dinophyceae are able to form cysts likely to remain hidden in sediments over a relatively long period of time. By remobilising cysts in the water column during a period favourable to their germination, dredging and sea disposal operations create a risk of efflorescence for these species.

2 - Routes of exposure to risk

The main route of exposure to be considered for health risks related to toxic phytoplankton is ingestion of contaminated shellfish (and of fish for a limited number of plankton species).

3 - Species to consider in an HRA

The marine species that produce phycotoxins likely to be found in seafood and fish consumed by human beings belong to two classes of eukaryotic microalgae: Dinophyceae (dinoflagellates) and Diatomophyceae (diatoms).

As the species belonging to the class **Dinophyceae** are the only ones likely to form cysts in sediments, these are the only species that are considered in HRAs: *Alexandrium minutum, Alexandrium spp. (andersonii, catenella and tamarense), Dinophysis spp., Prorocentrum spp., Pyrodinium bahamense var. compressa, Ostreopsis spp., Karenia brevis and Gambierdiscus sp.*

4 - Site sensitivity

Site sensitivity for these species is appreciated qualitatively by consulting the results of the French national monitoring network REPHY (see Section 3). The risk of the presence of cysts of a given species in sediments is assessed by analysing past detections of the species in the water column, at the network checkpoint nearest to the site. Detection of the species in a reference period indicates a risk of its presence.

Dose-response relationship

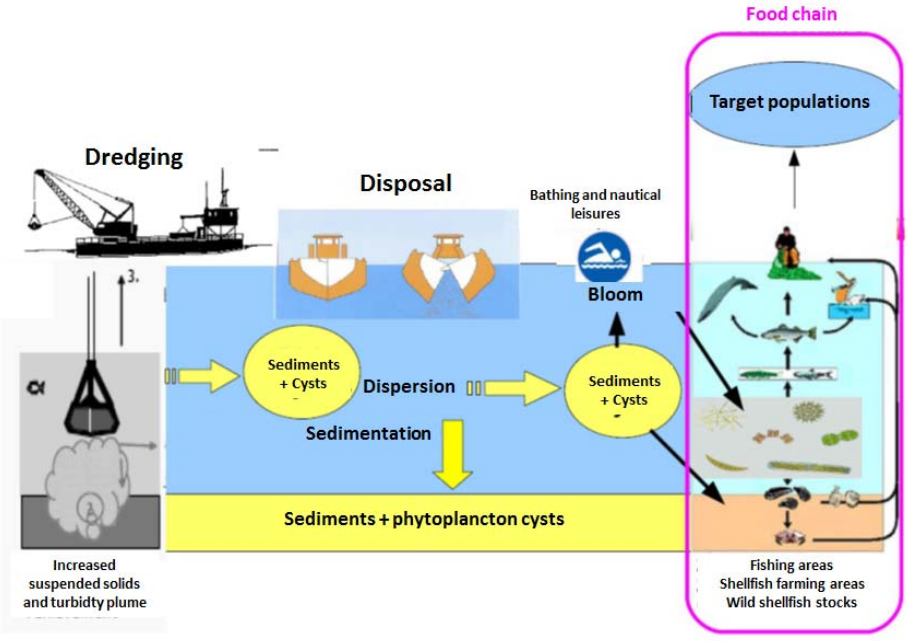
As the health risks of phycotoxins are related to ingestion of contaminated seafood, the existing dose-response relationships are defined by the regulatory thresholds that establish the concentration limits of toxins in these products, and for which they are fit or not for consumption.

In dredging and sea disposal operations, the relationship between dose in the sediment and consumer response is of course indirect. It depends on numerous environmental factors (dispersion in the water column + efflorescence + accumulation in living matter) that complicate modelling the passage from the sediment to the consumer and thus establishing a direct dose-response relationship.

For this reason, this criterion is not taken into account in the HRA. Such HRA will therefore conclude qualitatively and not quantitatively as for risks related to chemical substances.

Routes of exposure

The main route of exposure to be considered for health risks related to toxic phytoplankton is ingestion of seafood or fish (it should be noted that poisoning by fish is only a matter of concern with *Ostreopsis* and *Gambierdiscus*). As mentioned above, exposure occurs by a series of complex biological and physical mechanisms that preclude quantifying consumer exposure to toxins. Nevertheless, a conceptual diagram can be established:



Characterisation of risks

Assessment of health risks related to toxic dinoflagellate cysts in sediments is based on a qualitative presence/absence approach. Risks are thus determined by the classification or non-classification of the study area as a risk area.

Chapitre 3 Interpretation of results and risk management

The health risk assessment process described by risk type in the previous chapter aims to provide conclusions on whether a risk exists or not, and when possible, to quantify its probability of occurrence. This process however does not provide methods to conclude on these risks' acceptability, nor on ways to manage these risks. Interpreting the results of the assessment process and including them in the larger environmental impact assessment process enables decision-making regarding project operations.

3.1 Understanding the results and their significance

3.1.1 HRAs relating to chemical substances

HRAs relating to chemical substances are based on a quantitative approach involving calculations.

In the case **of effects without a threshold** (substances with carcinogenic effects), the results are expressed as **individual excess risks**, i.e. increases in an individual's probability of developing health effects following exposure to a risk factor (or substance). Collective risk (or health impact) is calculated by multiplying the probability that effects will appear by the total number of individuals in the population that are exposed. Hence, the result of the evaluation takes the form of a number of individual cases.

In the case **of effects with a threshold**, risk is expressed in terms of a **hazard ratio**. This ratio is calculated by dividing the dose of hazard to which an individual or a population is exposed by the reference dose below which the appearance of health effects is not detected. This result allows conclusions to be drawn on the potential appearance of effects, but not on their severity.

3.1.2 HRAs relating to pathogenic microorganisms

HRAs relating to pathogenic microorganisms are based on a qualitative approach in which the presence or absence of pathogenic germs is determined. Consequently, the results are not quantitative and may be summed up in a statement on the presence or absence of risk.

3.1.3 HRAs relating to phytoplankton

HRAs relating to phytoplankton toxins are based on a qualitative approach in which the presence or absence of toxic phytoplankton species is determined. Consequently, the results are not quantitative and may be summed up in a statement on the presence or absence of risk.

3.2 Considering and managing uncertainties

The health risk assessment method described in the previous chapter is based on a set of data, the acquisition and modelling of which may be complex and sensitive to different variability factors.

In order to respect the transparency of the process, uncertainties must be identified and reported. Identification of uncertainties regards characterisation of sources, assessment of individual exposure, assessment of substance toxicity and determination of risks. Reporting includes information of the different stakeholders, the justification of the consistency of the assessment, and evaluation of the suitability and effectiveness of measures taken to keep risks at an acceptable level.

Sensitivity analyses are therefore a useful tool for weighing uncertainties in the final stages of an HRA. They are calculation processes that consist of modifying one or several calculation values and observing the effect on the final result. It should be noted that, among the methodologies proposed in this guide, these sensitivity analyses can only be applied to quantitative health risk assessment processes relating to chemical substances (see above).

Moreover, classification of uncertainties allows determination of whether or not a parameter's degree of confidence may be improved by increasing assessment efforts, and if so, by which means (additional analyses of sediments, strengthening dispersion models, etc.). It should be noted that by applying the principle of proportionality to the assessment, the relevance of increasing assessment efforts should always be assessed by considering the availability of measures for managing risk *a posteriori* (e.g. improved modelling of dispersion vs implementation of preventive monitoring of product quality).

Finally, it must be kept in mind that depending on existing uncertainties, it may be impossible to draw conclusions on the existence or non-existence of a health risk and its significance. In this case, decision-making is based on the analysis of uncertainties and identifies appropriate means of risk management.

3.2.1 Uncertainties relating to hazards

3.2.1.1 Characterisation of sources

Chemical contaminants

Uncertainties relating to chemical characterisation of dredged materials may be linked to:

- The sampling plan,
- The sampling methods (coring, sampling by bucket, etc.), and
- Laboratory analytical quantification.

This uncertainty may be managed in part by following the memorandum of 14 June 2000 regulating the protocol for characterising materials in dredging and sea disposal operations, particularly with respect to sampling point selection, sampling equipment and selection of laboratories officially registered for these analyses. The guide to environmental monitoring in dredging and sea disposal operations includes methodological elements regarding these analyses and reflections on their representativeness.

Pathogenic microorganisms

Uncertainties relating to microorganism characterisation of the dredged materials may be linked to:

- Sampling strategy and spatial-temporal variability of the presence of these microorganisms in the materials, and
- Laboratory analytical quantification.

As with chemical substances, this uncertainty can be managed by following the indications for analysis described in the memorandum of 14 June 2000. If site sensitivity requires it, temporal variability can be reduced by increasing analyses over time. Nevertheless, precisely identifying bacterial contamination values of sediments at the time of dredging operations is hardly feasible, given, for example, the dynamics of germ decay, the time needed to analyse germs and the time gap between analyses and operations. It should be noted that the main goal is to determine the presence or absence of pathogenic germs rather than to obtain a reliable and representative concentration, which cannot be appreciated in the HRA process (qualitative process).

Toxic phytoplankton

Uncertainties relating to phytoplankton characterisation of the dredged materials may be linked to:

- Sampling plan and spatial-temporal variability of phytoplankton efflorescence, and
- Laboratory detection and analytical quantification of specific cysts[3].

Uncertainty about spatial-temporal variability is generally controlled by combining observations of efflorescence over a period of several years. This can be done by consulting results of the French national monitoring network REPHY.

3.2.1.2 Evolution of substances and organisms over time and space

The evolution over time of substances and microorganisms once they have been dispersed in the water column and/or living matter, results from processes that are complex and difficult to model. Sources of uncertainty in this evaluation may concern:

- Interactions between contaminants,
- Degradation products of chemical substances, and
- Dynamics of dispersion/accumulation in the environment and projected individual exposure doses.

[3] This is only done at Ifremer's research laboratories and cannot be performed routinely.

3.2.2 Uncertainties relating to the toxicity of chemical contaminants

Uncertainties relating to toxicity assessment include:

- Choice and relevance of the TRV:
    - Has this value been defined based on human or animal data?
    - Can the observations made during mean dose experiments be extrapolated to lower doses of population exposure?
    - Can the observations made on one population be transposed to another population?
- Possibility of interaction relating to concomitant exposure to several pollutants producing synergistic or antagonistic effects,
- Risk relating to substances not taken into account during the assessment owing to a lack of data on them, and
- Similarities among the effects of several different risk factors.

3.2.3 Uncertainties relating to exposure

Levels of uncertainty regarding exposure assessment are particularly high in the maritime and estuarine context of dredging and sea disposal operations. They may include:

- Assessment of the behaviour of sediments in the dredging and sea disposal area: these uncertainties are related to the material dispersion model and also affect ecosystem risk assessments. Reducing uncertainties generally involves substantial modelling work that itself requires complex physical data, the acquisition of which is generally difficult and costly.
- Assessment of the substances' behaviour over time in the dredging area and in the discharge area: uncertainty is related to a lack of scientific knowledge, to the variability of controlling factors (KPs, Pmes-water, etc.) and to a lack of data on sediment behaviour. These uncertainties are difficult to overcome in the scope of the project's environmental impact assessment study.
- TGD methodology and associated hypotheses:
    - Hypothesis of a state of equilibrium between the solid phase and the liquid phase in an aquatic environment,
    - Hypothesis on the distribution of contaminants in sediment compartments and between water, sediment and organic carbon,
    - Hypothesis of similar sensitivity to contaminants among benthic organisms and pelagic organisms, and
    - Hypothesis of contamination of benthic organisms by the intermediary of interstitial water (and not by way of ingestion of solid sediment particles).
- Failure to take chemical substance degradation into account;
- The method of conversion between biota and water entails significant uncertainty factors: it does not allow to take into account potential processes by which substances are metabolised within organisms (processes that does not seem to occur in molluscs). Most of the time, there are uncertainties regarding the bioconcentration factor (BCF);

therefore, the strongest factor is used in calculations resulting in the description of the most pessimistic scenario.

- Consumers: it is mainly consumers of seafood who are susceptible to being contaminated by project materials. Usually, consumers are a diffuse population that may be distributed very widely over the territory. Assessing data on consumer identity and consumption is therefore complex.

3.3 Management of risk

3.3.1 Support to decision-making

As for the environmental impact assessment, the primary goal of the HRA is to support decision-making regarding project authorization. The results of the HRA must contribute to answer the following essential questions: Should the project be authorized? Should the project not be authorized? Should the project be authorized in a different form?

Therefore, at this stage, the expected risks may be considered:

- Acceptable given the current state of definition of the project,
- Unacceptable no matter what form the project may take, or
- Acceptable on the condition that the project be adapted.

For this last point, adaptations may take the form of measures or specific monitoring to prevent or reduce effects, and thus risks.

3.3.2 Implementation of an adapted monitoring strategy

The main objective of environmental monitoring is to protect the environment; either through real-time monitoring that allows immediate adaptation of operations and implementation of corrective actions, or through medium- and long-term monitoring aimed at improving projects by using feedback of past experiences. Monitoring health effects serves preventing risks through two types of monitoring strategies:

- implementation of specific project monitoring, which can be custom designed to the project's characteristics, and
- use of existing monitoring networks, which can contribute to monitor project effects at a larger and non-specific scale.

3.3.2.1 Identification of monitoring strategies specific to health risks

The methodological guide to environmental monitoring of dredging and sea disposal operations (GEODE, 2012) supports project operators in the design of strategic monitoring plans. Chapter 4 of that guide discusses the relevance of implementing environmental monitoring for the different compartments of the environment that may be impacted by dredging and sea disposal operations (water column, seabed, fish populations, marine mammals, phytoplncton, etc.). The technical appendix of that guide presents detailed monitoring methods for each of these compartiments.

The following monitoring strategies can support better management of health risks health risks during or after dredging and sea disposal operations.

- **Monitoring of water quality for control of spatial extent of effects**

Water is the main vector for dispersion of materials and the contaminants associated to them. Given the usual uncertainties regarding this dispersion, monitoring of water quality generally is the number-one means of controlling dispersion and managing health risks in sites that are sensitive to increased hazard concentration. Such monitoring of water quality may be coupled with:

- Operational project requirements resulting in reducing or postponing dispersion (e.g. suspending dredging operations or temporarily moving them to another site);
- Initiation of additional monitoring (e.g. monitoring of seafood quality if the monitoring of water quality has shown a significant increase in turbidity in a shellfish farm area due to the project).

- **Monitoring of water quality for precise effect description**

Given the uncertainties associated to the estimation of contamination phenomena on the water column (salting-out of contaminants, potential phytoplankton efflorescence, etc.) during EIA, monitoring of water quality enables on-site verification of the project's effects on the environment. By refining the description of these intermediate effects, monitoring contributes to reducing HRA uncertainties *a posteriori*. They also facilitate launching corrective measures for better risk management.

- **Monitoring of living matter quality to eliminate risk**

In the event that a fishing or farming resource is affected by the operation, reinforced monitoring of animal quality allows for appropriate restriction measures regarding product distribution to be applied if necessary.

3.3.2.2 Integration of existing monitoring networks

There are several coastal sea observation and monitoring networks along the French coast. These networks watch over environmental quality in order to protect users of the marine environment from health risks caused by various phenomena: accidental contamination of human origin, efflorescence of toxic phytoplankton, etc. The networks also make it possible to satisfy general needs in terms of:

- Respect for health regulations relating to shellfish safety in fishing areas and on shellfish farms, and
- Respect for health regulations relating to bathing water quality.

The information provided by these networks can be used to support monitoring activities relating to health risks induced by dredging and sea disposal operations, provided that the nature of this information is consistent with predicted effects of the project on the environment:

- Location of network sampling points relative to the location of project effects,
- Frequency and seasonality of checks relative to the seasonality (occurrence and duration) of project effects, and
- Contaminants that are monitored.

The French national networks that could support health risk assessment of dredging and sea disposal operations are described here-after.

3.3.2.3 The REMI network: microbial monitoring

REMI is **a network for microbial monitoring of shellfish production areas**. It rests on a health surveillance system of shellfish-farming areas and grades them according to standards defined by regulation.

It includes a routine monitoring system and an alert system.

The routine monitoring system verifies that the level of microbial contamination in each production area continues to fall within the threshold values established by local authorities and detects unusual contamination episodes.

The alert system is triggered by monitoring results that exceed or threaten to exceed the quality threshold values, or by specific causes of pollutant discharge such as storms or oil spills, or by known or suspected outbreaks of shellfish poisoning.

Geographical coverage	Monitoring of 299 of the 468 areas classified as A, B or C by the French public administration (2009). The monitoring point(s) are located in one or several areas that may be affected by contamination sources, so that the alert system can be triggered when necessary.
Frequency and duration of analyses	In routine monitoring, shellfish sampling is done once a month, or once every two months if the contamination level in the area is stable. In the event of an alert, a new sample is taken within 48 hours and then once a week until the alert is deactivated.
Contaminants analysed	The indicators of faecal contamination measured in shellfish samples are the bacteria Escherichia coli.
Further reading	http://envlit.ifremer.fr/surveillance/microbiologie_sanitaire/presentation (in French)

3.3.2.4 REPHY: phytoplankton and phycotoxin monitoring

The REPHY is the French national network for monitoring phytoplankton and phycotoxins in coastal areas. It's objectives are:

- To observe all phytoplankton species in coastal waters and monitor events such as water discolouration, unusual efflorescence and proliferation of species that are toxic or harmful to marine life, and
- More specifically, to monitor the species that produce toxins that are hazardous to shellfish consumers.

These objectives complement one another, as routine monitoring of all phytoplankton species allows to detect known toxic and harmful species, as well as potentially toxic species. The presence of these toxic species in water triggers monitoring of toxins in shellfish (in wild stocks and farming areas).

The REPHY monitors shellfish in their natural environment, i.e. in production areas or in professional fishing areas (subject to French regulations on wild offshore stocks).

Geographical coverage	Water sampling is done at roughly 60 checkpoints distributed along the coastline. When toxic species are detected, monitoring is reinforced: additional checkpoints are activated (up to 200 checkpoints) and shellfish in the areas of concern are included in analyses.
Frequency and duration of analyses	Water sampling is done throughout the year to detect toxic phytoplankton species. When species that do not contaminate shellfish unless present in high concentrations in the water exceed the alert threshold in a water sample, shellfish sampling is conducted once a week. For phytoplankton species, shellfish species and areas subject to systematic toxin research, shellfish sampling and analysis schedules depend on risk areas and periods[4]: • Lipophilic toxins: weekly sampling during a risk period and in a risk area; • Offshore stocks and very deep stocks: sampling every two weeks during the fishing season and weekly in times of high alert; and • Mediterranean sea urchins: monthly sampling before and during the fishing season.
Contaminants analysed	Shellfish: phycotoxins
Further reading	http://envlit.ifremer.fr/surveillance/phytoplancton_phycotoxines/presentation (in French)

3.3.2.5

[4] According to the REPHY, risk areas are marine areas in which results exceeding the health threshold have been observed at least one year out of a reference period established as the last three years of observation.

Risk periods include all the risk months in each of the risk areas. If a result exceeds the health threshold in one month in one of the last three years, the month in question is labelled a risk month.

It should be noted that these areas and periods are specific to geographical features, the physiology of shellfish species and the physical-chemical characteristics of the toxins concerned.

3.3.2.6 ROCCH: chemical contaminant monitoring

The ROCCH network monitors chemical contamination in coastal areas, and aims to meet national, European and international obligations with respect to chemical monitoring[5].

Chemical contaminant monitoring is done in the three marine matrices: water, biota and sediment. Moreover, by demand of the DGAL (French General Directorate of Food), the ROCCH carries out chemical monitoring in shellfish production areas.

Geographical coverage	Health monitoring by the ROCCH covers the shellfish areas classified as A, B or C in order to assess the chemical contamination levels of shellfish in the classified areas and monitor their evolution, and covers certain areas classified as D in order to follow their improvement or decline. It should be noted that the ROCCH also monitors areas that do not directly represent production areas but may affect the condition of adjacent areas (e.g. estuaries).
Frequency and duration of analyses	Health monitoring is conducted on shellfish in February in all areas with a "health monitoring" classification as well as on species during specific fishing or farming periods. It is thought that chemical changes occur slowly and that contamination levels do not vary substantially from one year to another. This ensures optimal consumer protection, since contaminant levels effectively approach their yearly maximum at the end of the winter.
Contaminants analysed	Health monitoring covers the three regulated metals (cadmium, lead and mercury); PAHs (polyaromatic hydrocarbons), represented by benzo(a)pyrene; and dioxins and DL-PCBs (dioxin-like polychlorinated biphenyls). However, it must be specified that only metals and hydrophobic organic contaminants (e.g. PAHs, PCBs and organochlorine insecticides) are concerned in this monitoring strategy. Hydrophilic organic contaminants (numerous pesticides) cannot be monitored using this type of monitoring.
Further reading	http://envlit.ifremer.fr/surveillance/contaminants_chimiques/presentation (in French)

[5] Application of the WFD (Water Framework Directive), the OSPAR Convention and the Barcelona Convention.

3.3.2.7 Bathing water monitoring network

Routine monitoring of bathing water is conducted by the ARSs at an approximate rate of one analysis every 10 days, as part of their efforts to monitor bathing water quality.

It takes 48 hours to conduct one of these analyses and obtain the results, which, being *a posteriori*, do not allow immediate prevention of exposure to occasional pollution risks.

To fulfil their obligations under the new bathing directive, in addition to regulatory monitoring of bathing water by the ARSs, municipalities must conduct their own bathing water monitoring activities, thus supporting a process of proactive management (analysis every morning before beaches open) and crisis management (analysis at any time of day at the express request of the municipalities). The analytical methods applied in these monitoring activities provide nearly instantaneous results.

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