HYPOTHETICAL CASE STUDY FOR RISK ASSESSMENT

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What is risk assessment?

"Risk assessment is the process of **estimating risks** to a given **target** organism, system, or (sub)population, following **exposure** to a particular **agent**, on the basis of what **adverse effects** may be caused, **how likely** the adverse effects are to occur, and the **consequences** should they occur".

Source: Adapted from WHO (2004) & UNEP (1995).

What is RISK?

"Combination of the magnitudes of the consequences of a hazard (if it occurs), and the likelihood that this consequences will occur."
Source: UNEP (1995).

Risk= "likelihood" (exposure) x "consequences" of hazard

What is Hazard?

The potential of an agent or stressor (GMO) to cause harm (**negative consequence**) to a biological system.

How we determine the likelihood of this consequences being realized?

We would have to estimate the **potential exposure** of target organism, system, or (sub)population to the agent (potential hazard).

Agent: *Genetically Modified Organism*

"Any living organism that possesses a **novel combination of genetic material** obtained through the use of **modern biotechnology**".
Source: Cartagena Protocol on Biosafety (2000)

"Organism in which **the genetic material (DNA/RNA) has been modified** by the use of any technique of **genetic engineering**."
Source: CTNBio (Brazil, 2005)

"Organisms in which the **genetic material (DNA) has been altered** in a way that does not occur naturally by mating and/or recombination."
Source: EFSA (EU, 2003).

Why is assessing risk important?

Risk assessment (RA) is focused on the **identification** and evaluation of any **novel genotypic and phenotypic characteristics** associated with the **GMO** that may have potential **adverse effects** on biological diversity in their receiving environment, taking into account their likelihood and consequences.

Risk Assessment Process.

"Risk assessment should be carried out in a scientifically sound and transparent manner, and on case-by-case basis".

Source: Adapted from Cartagena Protocol on Biosafety (2000).

- **Scientific soundness:** RA should be carried out in a systematic way on the basis of verifiable and reproducible data.
- **Transparency:** RA should be conducted in a manner that is as transparent as possible e.g., involving stakeholders at different levels and/or via public notification.
- **Case-by-case:** RA should be undertaken considering the GMO, its intended used and the likely potential receiving environment.

Risk Assessment Process.

"**Uncertainty** is an inherent component of any risk assessment, and should it **be consider** in a systematic manner at **each step of the RA**".

There are several possible sources of the inherent uncertainty:

- Lack of information,
- Incomplete knowledge,
- Biological or experimental variability.

Further information may be requested by risk assessors.

Risk Assessment Process.

The Risk assessment process is conducted in the context of a **National Biosafety Framework:**

"Combination policy, legal, administrative and technical **instruments** that are developed **for addressing safety** for the **environment and human health** in relation to modern biotechnology".

Source: Adapted from UNEP (2004).

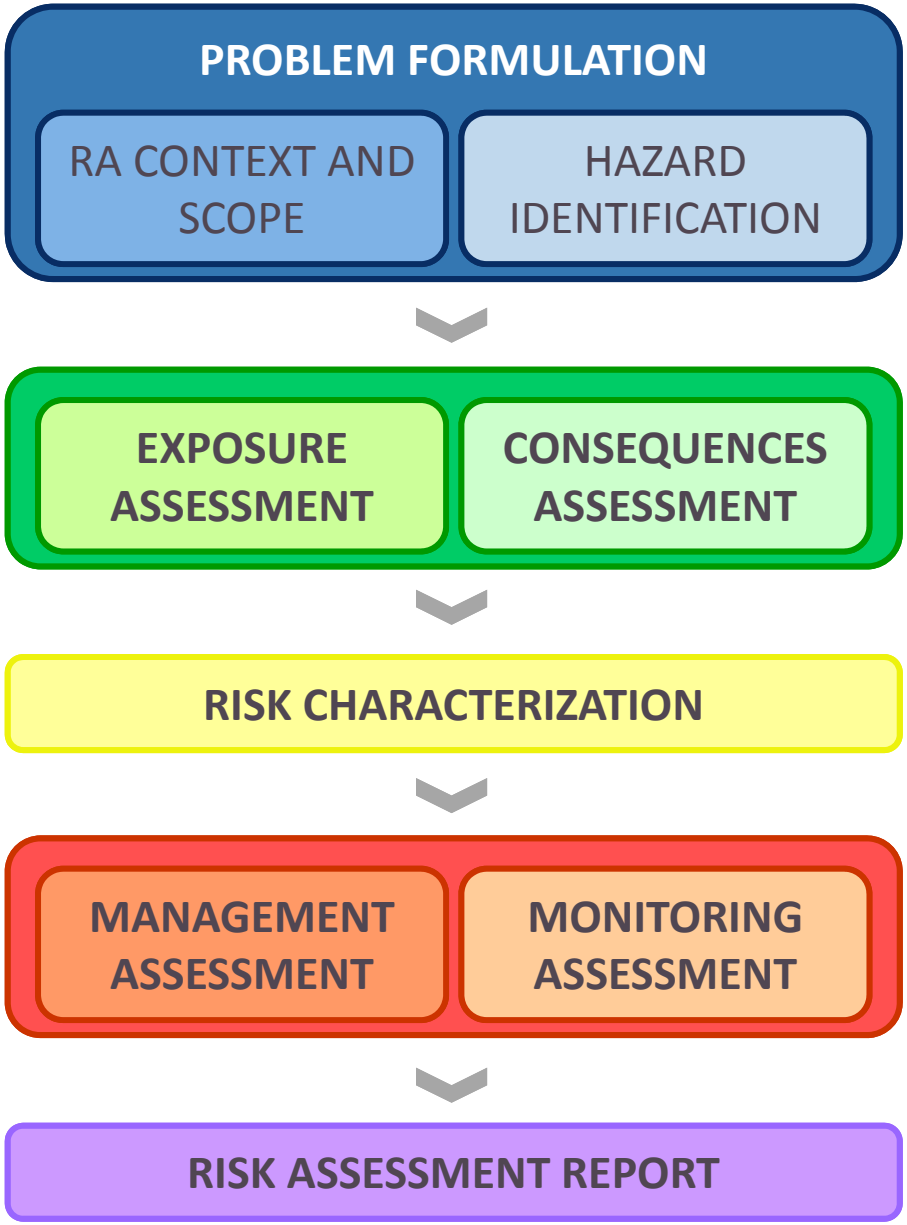
Examples of relevant elements of the National Biosafety Framework:

- National or International Guidelines, Regulations or Obligations adopted.
- Define Competent National Authorities.
- Agencies involved in biotechnology/health/environment related-issues.

Risk Assessment Methodology

MAIN PHASES

The main phases of Risk assessment methodology includes:



It combines:

a) stablishing the **RA context** and scope.

b) identification of any **novel characteristic** associated with the GMO that may **have adverse effects** on environment.

Risk Assessment Methodology

MAIN PHASES

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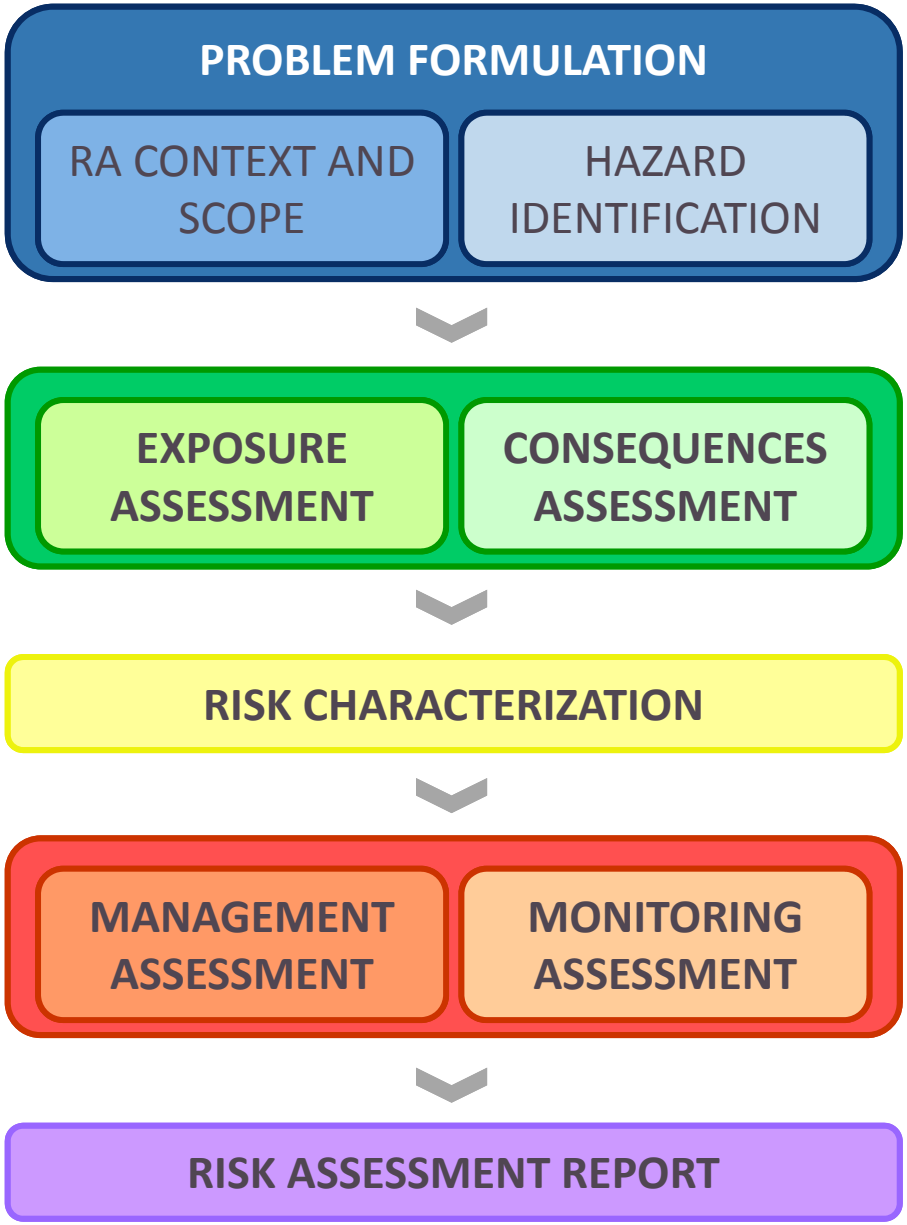

This is followed by an evaluation of the **likelihood of adverse effects** being realized and the **consequences** if this happens.

Risk Assessment Methodology

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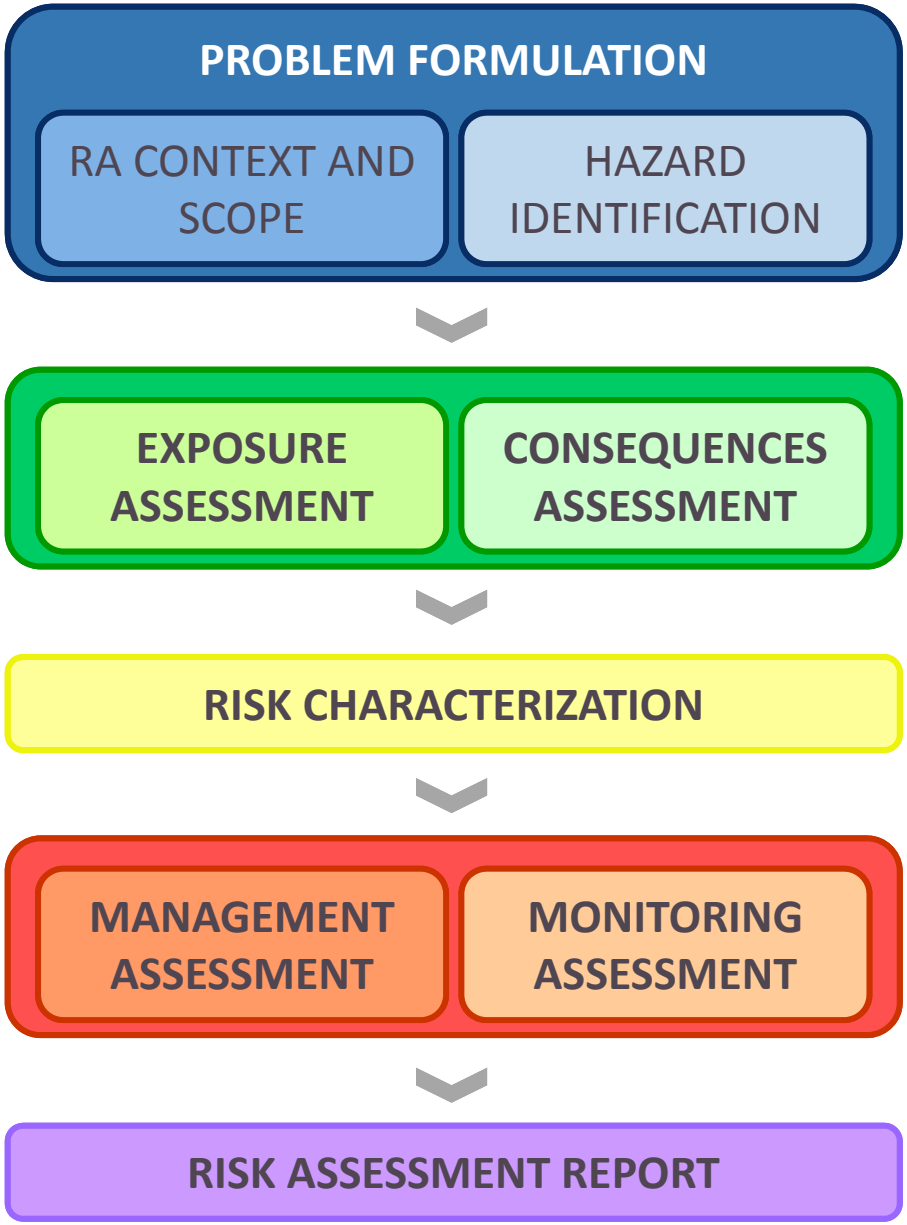

The information gathered is then used to make a qualitative and/or quantitative **estimation of the overall risk** posed by the GMO based on the **likelihood and consequences** of the identified adverse effects being realized.

Risk Assessment Methodology

MAIN PHASES

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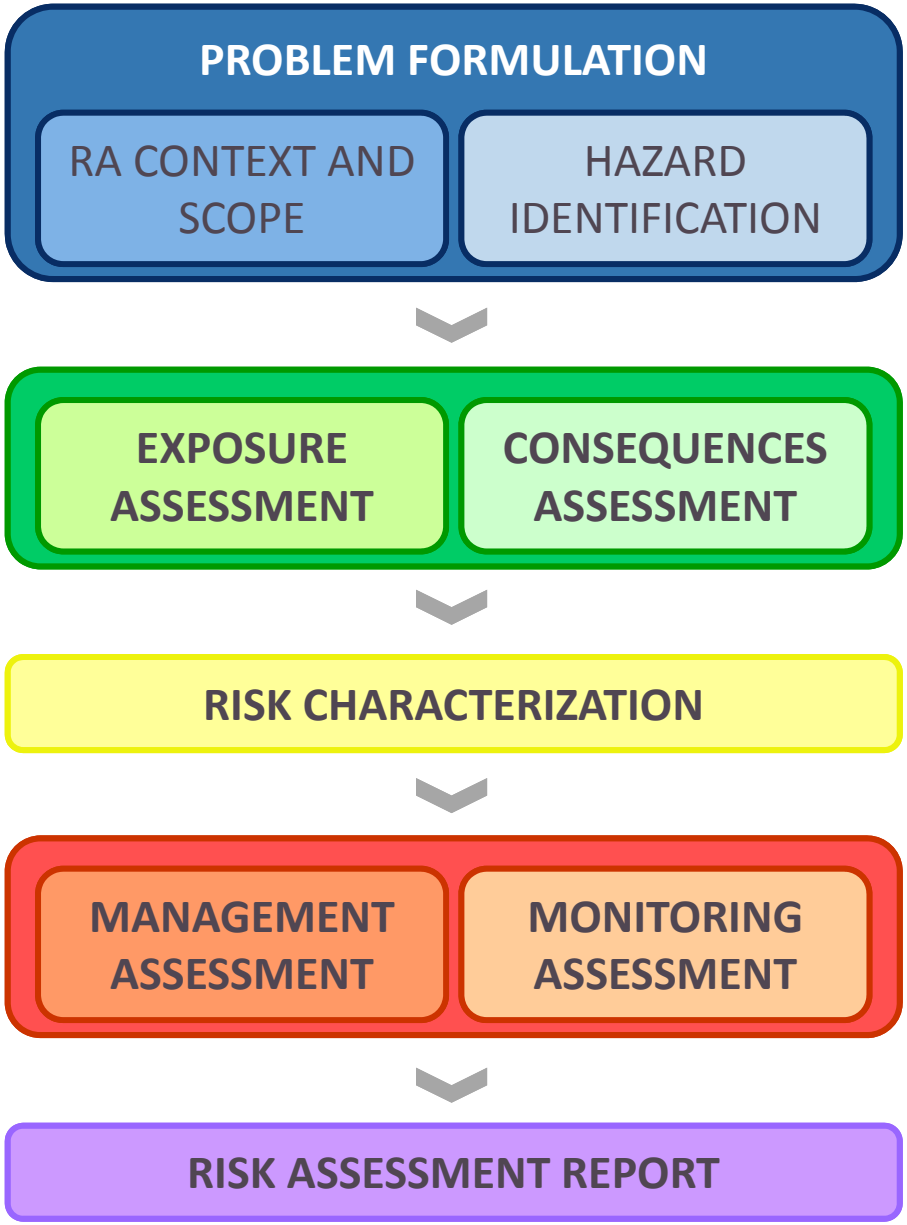

Finally, risk assessors conduct the **assessment of the risk management or monitoring strategies** that may be employed to reduce and/or keep under control the level of potential adverse effects posed by the GMO.

Risk Assessment Methodology

MAIN PHASES

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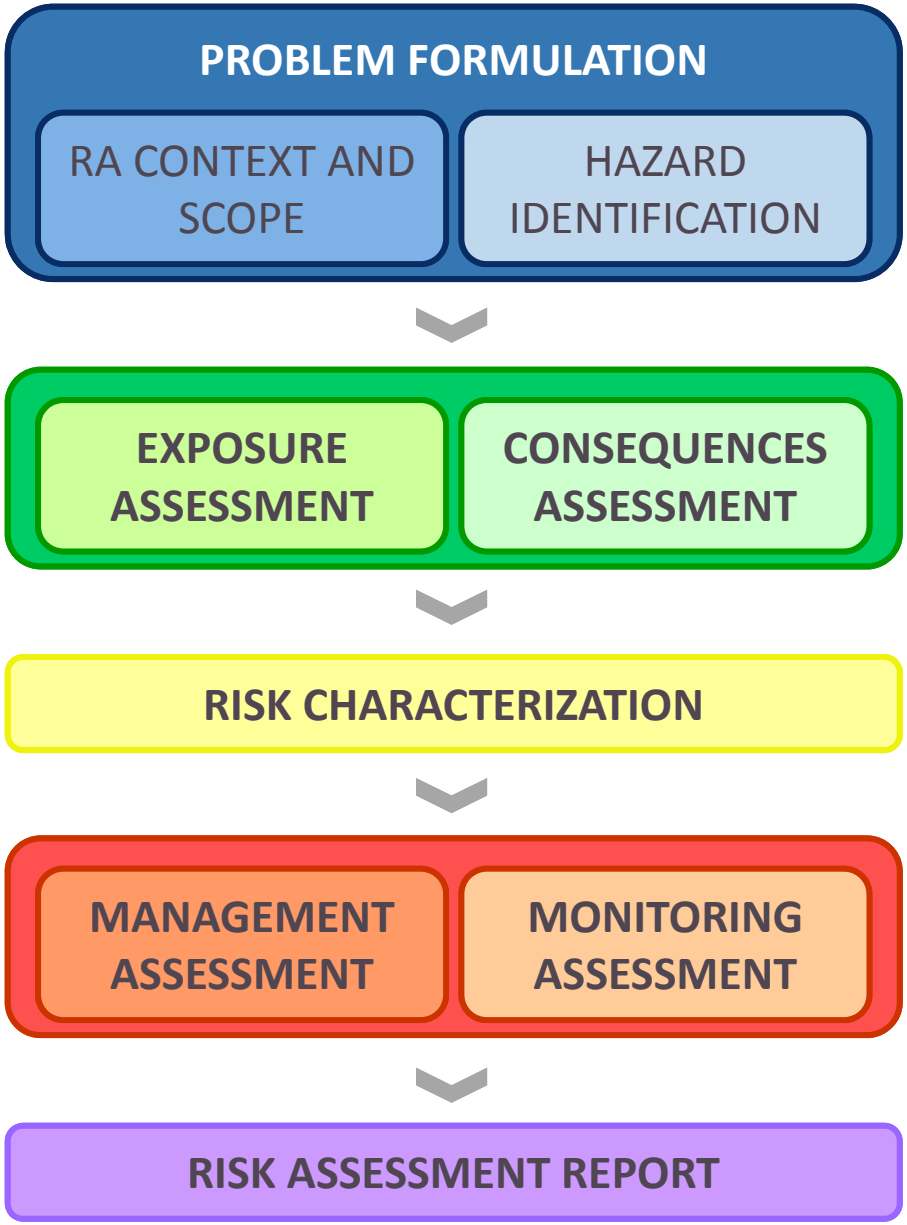


All the **information, conclusions and recommendations** that emerged from the RA process are included in a **RA report** that is intended to aid decision makers.

Conducting Risk Assessment

Step 1- Problem Formulation

In this step risk assessors **combine** the process of:

- **Establishing the context and scope** of the risk assessment.
- **Hazard Identification.**

Risk Assessment Context and Scope.

The National Context.

Protection goals and assessment endpoints:

Risk Assessments must be carried out in the context of **national priorities and protection goals** defined by environmental and health policies and laws.

e.g., Conservation of biodiversity; Water protection; Protection of human health;

Risk Assessment Context and Scope.

The National Context.

Protection goals are expressed in terms that could be widely interpreted and too vague to be scientifically assessed (e.g., Biodiversity, Sustaintability)

In order to **scientifically evaluate** the occurrence of any potential adverse **effects on the protection goals** we have to identify and select appropriate "**assessment endpoints**" with **measurable** biological and/or ecological attributes.

Risk Assessment Context and Scope.

The National Context.

Assessment Endpoints are operationally defined by a **valued biological or ecological entity** and attributes of that entity that could potentially be impacted, in this case, by the GMA.

e.g., ***Honeybees*** *are a valued biological entity and* ***their abundance*** *is a very important attribute in agrosystems. Therefore,* ***"abundance of honeybees in a particular agroecosystem"*** *could be consider an* ***assessment endpoint*** *in the context of the conservation of biodiversity (protection goal).*

Risk Assessment Context and Scope.

The National Context.

Criteria for selecting assessment endpoints:

- **Relevant** to the protection goal.
- A **well-defined** biological/ecological entity.
- Accessibility to **measurement**.
- Level of **potential exposure** to the GMO.

Risk Assessment Context and Scope.

Example.- **Contained release of fertile Growth-enhanced transgenic Atlantic salmon** in Galicia Lakes.

EU protection goals:

Examples of protection goals			
Areas of protection		**Background**	**Scope**
Biodiversity conservation	Species of conservation or cultural value	Directive 2004/35/EC	Environmental liability
		Directive 92/43/EEC	Conservation of natural habitats and of wild fauna and flora
		Directive 2009/147/EC	Conservation of wild birds
		Regulation (EC) 338/1997	Protection of endangered wild fauna and flora
		Action plan for biodiversity	Conservation of biodiversity
	Protected habitats	Biodiversity strategy	Conservation of biodiversity
		Biodiversity action plan for the conservation of natural resources	Conservation of natural resources
		Biodiversity action plan for agriculture	Conservation of biodiversity
		Bern convention	Conservation of European wildlife and natural habitats
		Convention on biological diversity	Conservation of biological diversity
Ecological functions	Land	Directive 2004/35/EC	Environmental liability
		Thematic strategy for soil protection	Preservation of soil functions
	Water	Directive 2000/60/EC	Water protection
		Directive 2008/56/EC	Strategy for the marine environment
	Production systems	Regulation (EC) 708/2007	Use of alien and locally absent species in aquaculture
		Biodiversity strategy	Sustainable use of biodiversity
		Thematic strategy on the sustainable use of natural resources	Sustainable use of natural resources

Source: EFSA (EU, 2013)

Risk asssessors should take into account those **protection goals relevant** for the RA

Risk Assessment Context and Scope.

Example.- **Contained release of fertile Growth-enhanced transgenic Atlantic salmon** in Galicia Lakes.

Protection goal: **Conservation of biodiversity.**

ASSESSMENT ENDPOINTS

- Number/Diversity of fish species in Galicia Lakes.
- Abundance of wild salmon in Galicia Lakes.
- Abundance/Distribution of fishes that are natural prey of salmon in Galicia Lakes.
- Production of phytoplankton in Galicia Lakes.
- Abundance of microorganisms in Galicia Lakes, including salmon pathogens.

Risk Assessment Context and Scope.

The Biological Context.

Establishment a Baseline:

It is important **to analyzed the pre-existing environmental conditions** prior to the introduction of the GMA whose potential adverse effect is being assessed. It allows to identified both adverse and beneficial effects of the use of GMA.

Establishment the appropriate comparator:

Using a comparator **helps risk assessor identifying the novel characteristics of the GMA** and assessing weather it presents a greater risk than the non-modified organism used in a similar way and environment.
e.g. non-modified parental animal.

Hazard Identification.

What adverse effects could occur, why and how?

In this step, risk assessors aim to identify **scientifically plausible scenarios** to predict if the GMA could have an adverse effect on the assessment endpoints.

It is important to define a **causal link or pathway** between a **characteristic of the GMA** and a **possible adverse effect**, otherwise the risk assessment may generate information that will not be useful or accurate for decision-making.

Hazard Identification

RA case-by-case approach

Assessing three factors define the case-by-case approach:

- Genetically modified animal
- Likely potential receiving environment(s).
- Intended use.

Hazard Identification.

Genetically modified animal**.**

The genotypic and/or phenotypic characterization of an GMA allows to identify **differences between the GMA and the non-modified organism.**

Relevant characteristics of the non-GMA.

- **Origin** and Taxonomic status.
- **Biological characteristics**.
  Particularly those that, if altered could lead to changes that may cause adverse effects.
- **History of use** .
- Current **distribution areas & habitats.**

Hazard Identification.

Genetically modified animal**.**

Description of the genetic modification.

- **Donor** organism(s) and Vector.
  Identity, source or origin, potential horizontal gene transfer.

- **Modified genetics elements** or inserts.
  Relevant characteristics of the genes and of other functional sequences, that have been inserted (e.g., functions of the gene and product in the donor organism).

- **Transformation method.**
  e.g., Information on whether it results in the presence of (parts of) the vector in the OGM, including any marker genes.

Hazard Identification.

Genetically modified animal**.**

Description of the genetic modification.

- **Characterization** of the modification.

  e.g., Insertion site(s) and copy number of the inserts; levels of gene expression and intended and unintended gene products; genetic stability over generations.

- **Genotypic and phenotypic changes.**

  Comparing with the non-modified recipient. e.g., changes in endogenous gene expression and regulation, changes in foraging or reproductive characteristics and behaviour, alterations in metabolism or in susceptibility to pest and diseases.

Hazard Identification.

Potential receiving environment**.**

The Potential receiving environment includes the **area** where the **GMA will be intentionally introduced** as well as any **other environment potentially exposed** to the GMA or its products.

RA requires evaluating both the **physical and biological characteristics** of the likely potential receiving environment in order to determine **relevant assessment endpoints as well as to gather sufficient data to establish a meaningful *baseline.***

Hazard Identification.

Potential receiving environment**.**

- **Physical characteristics**

  Extension *of dimension;* ***Climatic and Geographic conditions****;* ***Soil, water and sediment*** *properties;* ***previous use/history*** *(e.g. use for aquaculture or agronomic purposes).*

- **Biological characteristics**

  Ecosystem type *(e.g., agroecosystem, aquatic ecosystems, urban or rural environments);* ***Organisms*** *present in the environment and* ***interaction among them*** *including information on GMA sexually compatible wild or feral species;* ***biodiversity status*** *(e.g. status as center of origin and diversity of the non-modified organism and the occurrence of rare, endangered, protected species).*

Hazard Identification.

Potential receiving environment**.**

Points to consider regarding the potential adverse effects resulting from GMA- environment interaction:

- **Characteristics** of the GMA in relation to the **receiving environment** .
  e.g., Phenotypic traits relevant for developing a fitness advantage (increasing the survival or sexual component of fitness)

- Potential for **inbreeding or interbreeding** (**gene flow**) that could lead to **introgression** of the genetic modification into the genetic pool of wild/native populations.

Hazard Identification.

Potential receiving environment**.**

Points to consider regarding the potential adverse effects resulting from GMA- environment interaction:

- Potential **adverse effects on wild or feral animals** such as **toxicity, allergenicity and multi-trophic effects**.
  e.g. *disease- resistant GMA acting as pathogen carriers.*

- Potential adverse **effects of the incidental exposure of humans** to the GMA, such as **toxic or allergenic effects**.
  e.g., exposure to modified gene products in human biting insects, food poisoning.

Hazard Identification.

The intended use.

Knowing the **intended use** of the GMA allows the risk assessor to:

- Make considerations for factors such as **exposure or potential for breeding** within the environment where the GMA will be deliberately introduced,

- Considering the possibility of **dispersal or transfer** of the GMA **in** and/or outside the potential **receiving environment,** becoming **persistent or invasive**.

Hazard Identification.

The intended use**.**

Relevant information on the intended use:

- Regular **user practices** and habits.
- **New or changed use or practices** in comparison to the non-GMA.
- **Previous experiences** with similar organism, their management and exposure to the environment.
- Scale, duration, level of **confinement and type of the introduction** into the environment.

  e.g., whether it is for import only, (strict) confined release, field testing or for commercial use.

Hazard Identification.

Risk scenario**: *How could adverse effects occur?***

Once risk assessors **finish assessing the *novel characteristics and intended use*** *of the GMA* and identified their potential adverse effects, **proceed to the development of scientifically plausible risk scenarios**.

Risk scenarios are useful **tools to help in the estimation of likelihood and consequences of GMA** potential adverse effects on the assessment endpoints.

Hazard Identification.

Example.-

Contained release of fertile Growth-enhanced transgenic Atlantic salmon in Galicia Lakes.
Protection goal: **Conservation of biodiversity.**
ASSESSMENT ENDPOINT: Number/Diversity of fish species.
HAZARD: Growth-enhanced transgenic Salmon.

GMS POTENTIAL ADVERSE EFECTS-RISK SCENARIOS

- Reduction in wild salmons population in Galicia Lakes.
- Extinction/Displacement of the wild salmon specie in Galicia Lakes.
- Reduction in wild fishes population.
- Reduction in the diversity of native species of fish.
- Extinction/Displacement of native species of fish.

Step 2- Evaluation of the likelihood

How likely is an individual/population to be exposed to the GMA?

The second step of a RA involves **assessing the likelihood** that the adverse effect identified in step 1 will occur, taking into account the **level and kind of exposure** of the potential receiving environment to the GMA.

e.g., frequency of exposure, the expression level, dose and environmental fate of transgene products, number of animal frequently released/escaped.

Experimental studies and models may be used for an **assessment of the potential level and type of exposure.**

Step 2- Evaluation of the likelihood

How likely is an individual/population to be exposed to the GMO?

The likelihood reflects **the probability that one or more series of circumstances actually occurring**.

Route of exposure: "**Scientifically supportable chain of causal events** (risk hypothesis) through which GMA might have an **adverse consequences on the assessment endpoints** and/or protection goals".

The risk scenarios that **could not be explained by an exposure route** should **be dissmissed**.

Step 2- Evaluation of the likelihood

Points to consider:

- Valuable information coming from **past experience** with similar situations.

  e.g., same GMA, trait, receiving environment, intended use in the context of previous approvals or prohibitions of the same GMA.

- Information on the **confinement conditions**, **location of the release** and/or the potential receiving environment

  e.g., geographic and biogeographic information, climatic conditions.

- Factors that may affect the **spreading of the GMA** or its **ability to disperse** by anthropogenic mechanisms.

  e.g., ecological range and ability to move; its reproductive ability (e.g., numbers of offspring); transport, rearing practices, intentional releases.

Step 2- Evaluation of the likelihood

Points to consider:

- Factors or events related to **likelihood of intra- or inter- breeding**.

  e.g., Presence of sexually compatible individuals; probability of encounter; probability of survival and reproduction of the hybrid offspring; probability of introgression of the genetic modification.

- Expected **type and level of exposure** in the environment where the GMA is released and mechanisms by which **incidental exposure could occur**.

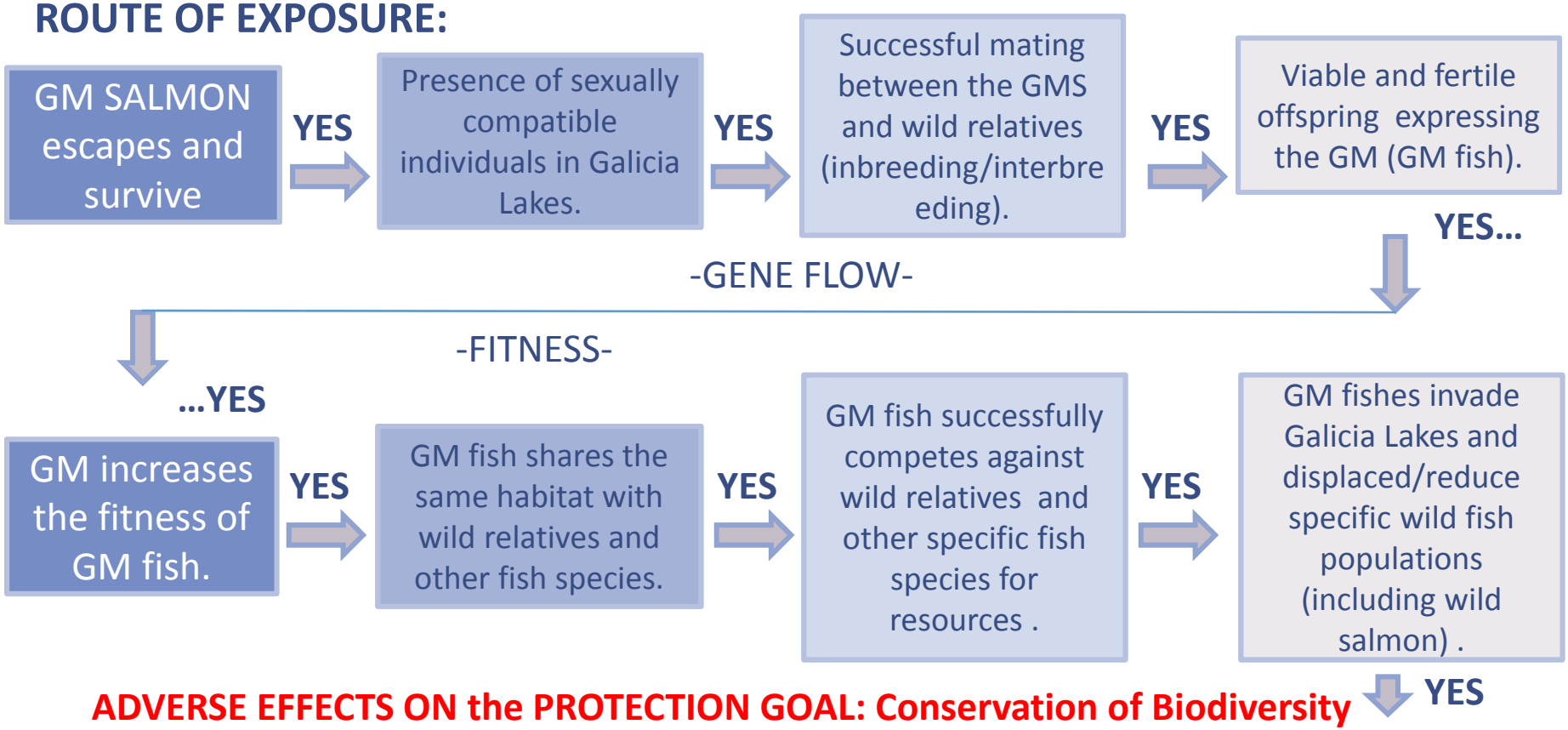
  e.g., incidental exposure due to losses during transport and handling, intentional or unintentional dispersed by animals, people or climatic events, frequency of escape events and number of escapees.

Evaluation of the likelihood

EXPOSURE ASSESSMENT

Example.- **Fertile Growth-enhanced transgenic Atlantic salmon** rear in Galicia Lakes
RISK SCENARIO: Reduction of Number/Diversity of fish species in Galicia Lakes.

ROUTE OF EXPOSURE:



ADVERSE EFFECTS ON the PROTECTION GOAL: Conservation of Biodiversity

Risk assessors should scientifically assess the probability of occurrence of each step. The risk scenarios that could not be explained by an exposure route should be dissmissed.

Step 3- Evaluation of the consequences

Would it be a problem if the risk escenario is actualized?

The third step of a risk assessment involves analyzing the **magnitude of consequences** of the possible adverse effect if it occurs.

In this step, risk assessors pay **special attention to** possible negative consequences on **protected areas** and **centers** of origin and genetic diversity, and take into account **protection goals and endpoints** of the country where the environmental release may take place.

Step 3- Evaluation of the consequences

Points to consider:

- Relevant knowledge and previous **experience with the non-GMA** or GMA **in similar receiving environments**. This may include the effects of:

  - ***Breeding and Rearing practices****; dispersal rate and range; change in abundance of pathogens and beneficial organisms.*

  - *The **behavior of populations of other species**, including interactions between predators and prey, their role in food webs, disease transmission, and interaction with humans.*

Step 3- Evaluation of the consequences

Points to consider:

- Important information on the **duration** of the potential adverse effect *(i.e., short or long term),* the **scale** *(i.e., are implications local, national or regional)*, the **reversibility** of effects, and the expected **ecological scale** (*i.e., individual organisms or populations*).

- Possible consequences of **genetic modification introgression** resulting from inbreeding/ interbreeding.

Step 3- Evaluation of the consequences

Points to consider:

- Results from **laboratory experiments** examining, as appropriate, different **levels** of e.g., *metabolites, gene products, toxins, allergens, hormones, or other potential toxic substances.*

- Results from **field trials evaluating**, for instance, potential **invasiveness**.

Step 3- Evaluation of the consequences

Example.- **Fertile Growth-enhanced transgenic Atlantic salmon rear** in Galicia Lakes
RISK SCENARIO: Reduction of Number/Diversity of fish species in Galicia Lakes.
LIKELY ADVERSE EFFECTS ON the PROTECTION GOAL: Conservation of Biodiversity.

CONSEQUENCES

- Loss or reduction in wild fishes populations, including wild salmon.
- If the affected wild population is native, there will be loss/reduction in the frequency of unique alleles/genes.
- The alteration in the frequency of allele/genes could reduce the population´s ability to adapt to changing conditions, affecting extinction risk.
- Alterations in the trophic structures. e.g., increases in number of top predator (salmon) could result in decreasing numbers of intermediate level predator, which then allows herbivores to increase, ultimately decreasing plant and phytoplakton.

Conducting Risk Assessment

Step 4- Estimation of the overall risk.

Overall Risk= ∑ Individual Risks ("likelihood x consequences").

This step consists in the **integration of the likelihood and consequences** of each **of the individual risks** identified through the preceding steps. Any **relevant uncertainty** detected is also considered.

Conducting Risk Assessment

Step 4- Estimation of the overall risk.

Risk assessor should consider:

- The identified **potential adverse effects** (step 1) and their **likelihood of occurrence** (step 2).
- The evaluation of the **consequences** should the adverse effects be realized (step 3).
- **Individual risks** and any interaction among them, such as *synergism* or *antagonism*.
- Any risk **management strategies** (see step 5) or relevant **uncertainty** that affect the estimation of the overall risk of the GMA.

Step 4- Estimation of the overall risk.

Example.- **Fertile Growth-enhanced transgenic Atlantic salmon rear** in Galicia Lakes

LIKELIHOOD of CAUSE HARM: UNLIKELY ✖ **POTENTIAL CONSEQUENCE: MAJOR** = The contained realese of fertile growth-enhanced transgenic Atlantic salmon in Galicia Lakes poses a **MEDIUM** level of risk.

		POTENTIAL CONSEQUENCE				
		NEGLIGIBLE	MINOR	MODERATE	MAJOR	EXTREME
LIKELYHOOD	ALMOST CERTAIN	MEDIUM	HIGH	HIGH	VERY HIGH	VERY HIGH
	LIKELY	MEDIUM	MEDIUM	HIGH	HIGH	VERY HIGH
	POSSIBLE	LOW	MEDIUM	MEDIUM	HIGH	HIGH
	UNLIKELY	LOW	MEDIUM	MEDIUM	MEDIUM	HIGH
	RARE	LOW	LOW	LOW	MEDIUM	MEDIUM

Conducting Risk Assessment

Step 5- Identification of risk management and monitoring strategies.

Step 5 involves making recommendations as to whether or not the **risks are acceptable or manageable**, including identification of strategies to **manage** these **risks**.

- **Recommendations** are made in the context of criteria for the **acceptability of risk**, taking into account:
  - Established **protection goals, assessment endpoints and risk thresholds**,
  - **Risks** posed by the **non- GMA** and its use.

Conducting Risk Assessment

Step 5- Identification of risk management and monitoring strategies.

- While making recommendations, risk assessors should:
  - **take into account potential benefits** for the environment, biodiversity, and animal/human health and welfare.
  - consider the **ability to identify, manage and confine adverse effects** in case that the GMA is released into the environment.

Conducting Risk Assessment

Step 5- Identification of risk management and monitoring strategies.

- Where there is **uncertainty** regarding the level of risk, it may be addressed by **requesting further information.**

- **Uncertainties could also be addressed**, by implementing appropriate risk **management strategies and/or monitoring** the GMA in the receiving environment.

Conducting Risk Assessment

Step 5- Identification of risk management and monitoring strategies.

What is Risk Management?

Strategies aiming to **reduce** the **risks** identified during the assessment to a level that **may be considered as acceptable**.

It is recommended to combine different risk management strategies including:

- "**Preventive measures**" aim at **reducing the likelihood**;
- **"Mitigation measures"** aim at **reducing consequences**.

  e.g., physical, geographic and biological confinement.

Conducting Risk Assessment

Step 5- Identification of risk management and monitoring strategies.

Monitoring strategies.

This concept aims at **detecting changes** (e.g. in the receiving environment(s) or in the GMA) that could **affect the likelihood or consequences** of one or more potential adverse effects.

A number of **monitoring strategies** can be applied at this step including the use of:

- **"general surveillance"** to predict and/or identify unexpected long-term effect of the GMA.
- **"case-specific"** monitoring to investigate potential adverse effects identified during the risk assessment.

Step 5- Identification of risk management and monitoring strategies.

Example.- **Confined release of Fertile Growth-enhanced transgenic Atlantic salmon** in Galicia Lakes.

MANAGEMENT

Application of integrated confinement measures designed to minimize the likelihood of the GM fish causing harm to the environment.

- Improvement of **physical confinement** farming fish in close (strict confined), **land-based facilities (instead of net-pen).**
- Application of **biological confinement** limiting or eliminating the reproductive potential of GM fish (strategies of single-sex population; triploidy).

MONITORING

- Monitor the presence of GM escapees.
- Monitor changes in the number of local fish species and their relative abundance.

Preparing a RA Report.

Finally, risk assessors prepare a **report summarizing** the risk assessment process:

The **RA report** provides **valuable scientifically-based information** used by competent authorities to **make informed decisions** regarding the **use of GMOs**.

Sources & References

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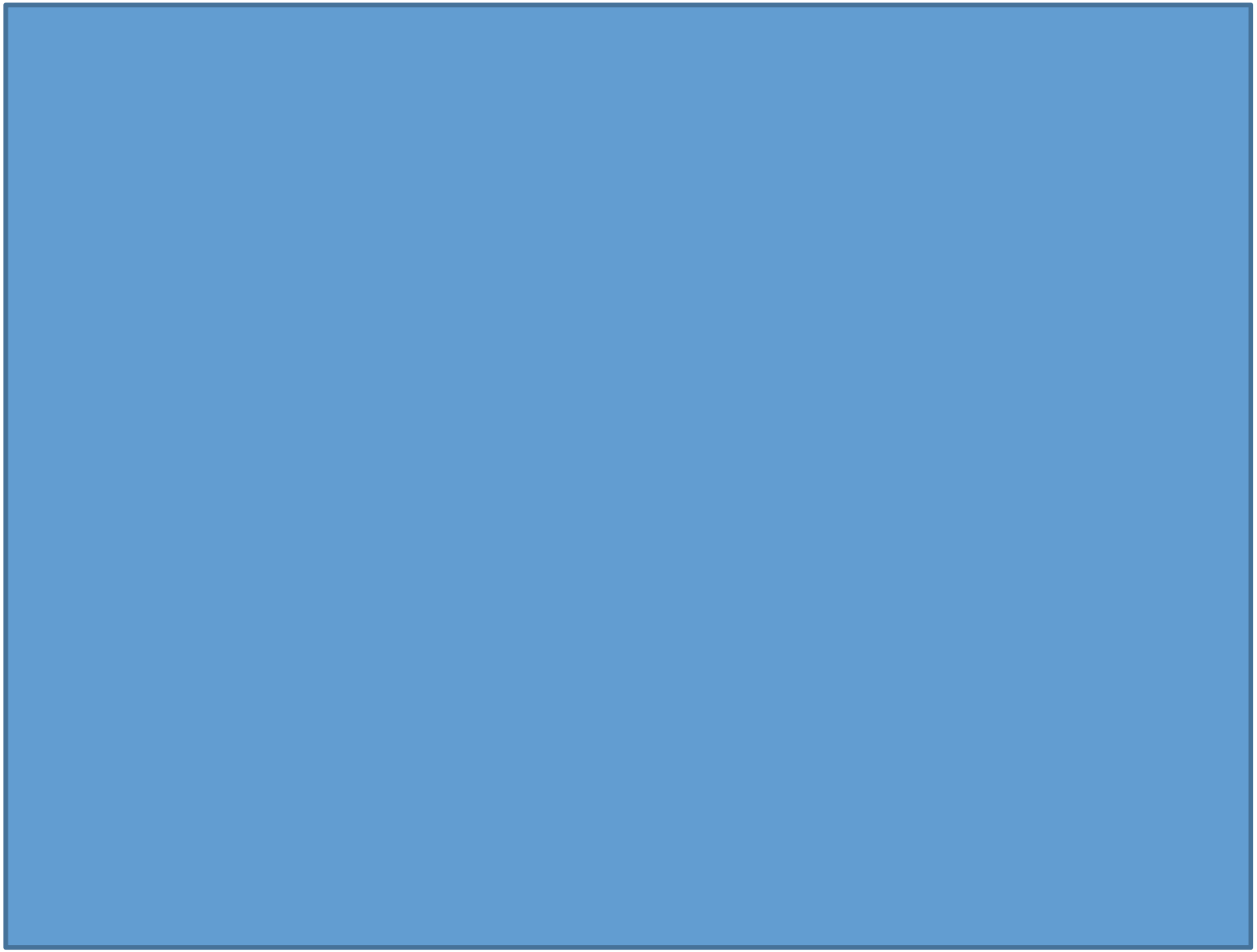


HYPOTHETICAL CASE STUDY FOR RISK ASSESSMENT

Confined release of Atlantic salmon resistant to furunculosis in Perú.

HOST ORGANISM: Atlantic Salmon.

Figure 1. Atlantic salmon. Source: Timothy Knepp, U.S. Fish and Wildlife Service, Wikimedia commons. http://commons.wikimedia.org/wiki/File:Atlantic_salmon_fish.jpg

RECEIVING ENVIRONMENT:

"Laguna Carpa" in the Mid- Northern mountains of Perú.

BIOTIC INTERACTIONS (in Peru):

Animals that prey upon Salmon (bigger fish, birds, mammals) in Peru, Salmon´s prey (macro-invertebrates, small fish) and sexually compatible species: Trout.

HYPOTHETICAL CASE STUDY FOR RISK ASSESSMENT

Confined release of Atlantic salmon resistant to furunculosis in Perú.

GENETIC MODIFICATION:

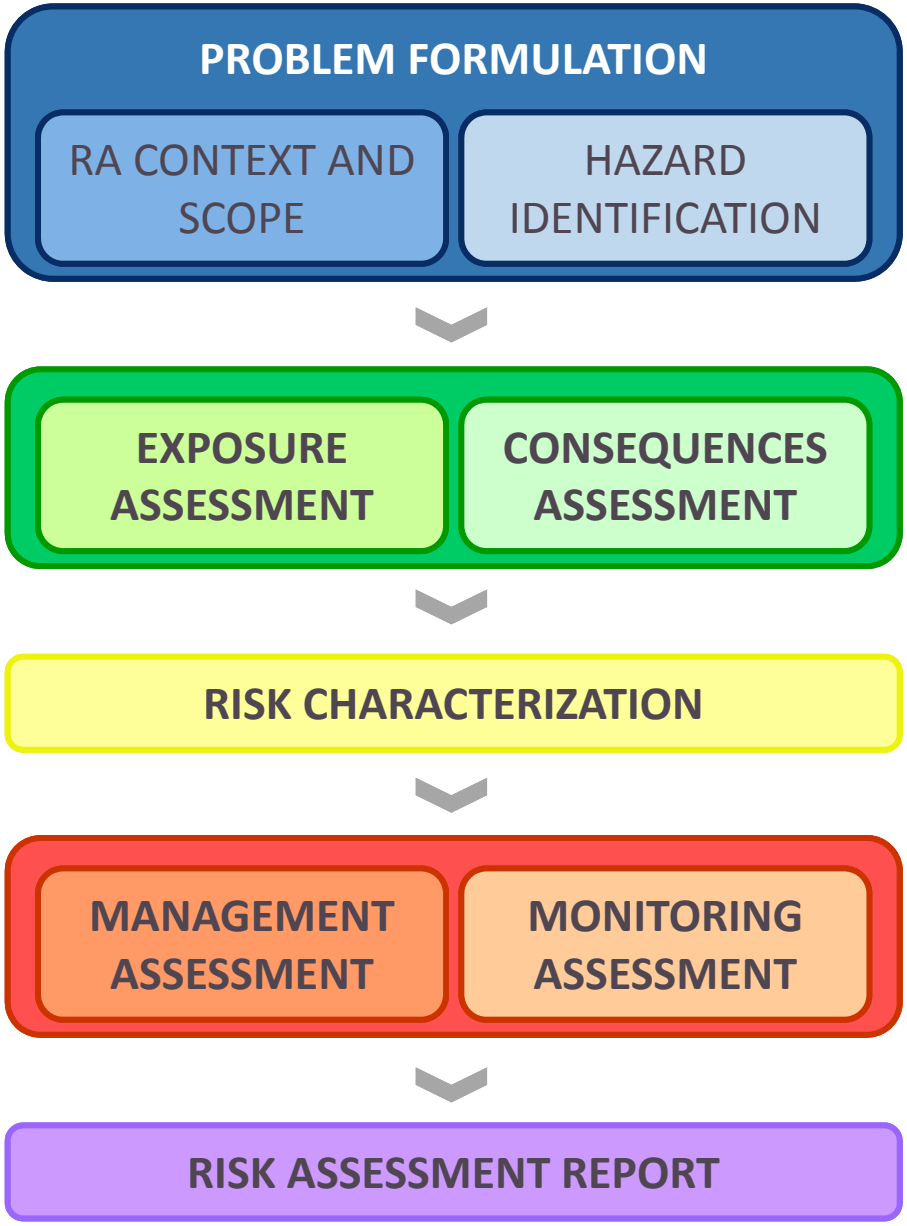
GM Salmon express two specific alleles of the major histocompatibility complex (one for MHC I and other for MHC II) identified in a population of Chinook Salmon (Pacific).

METHODS OF INTRODUCTION: Micro-injecting linear DNA.

TRAIT: Increased resistance to furunculosis (*Aeromona salmonicida*).

INTENDED USE: Salmon would be reared to market size in cages in the lake and harvest for processing.

Risk Assessment Methodology



It combines:

a) stablishing the **RA context** and scope (**protection goals and endpoints**).

b) identification of any **novel characteristic** associated with the GMO that may **have adverse effects** on environment.

Evaluation of the **likelihood of adverse effects** being realized and the **consequences** if this happens.

Make a qualitative and/or quantitative **estimation of the overall risk** posed by the GMO based on the **likelihood and consequences** of the identified adverse effects being realized.

Assessment of the risk management or monitoring strategies that may be employed to reduce and/or keep under control the level of potential adverse effects posed by the GMO.

Fugitive Salmon: Assessing the Risks of Escaped Fish from Net-Pen Aquaculture

Box 1. Relevant questions for assessing risks associated with aquaculture escapes.

Ecology and genetics

- What are the chances that escaped farm fish will establish feral populations?
- To what extent will escaped farm fish compete with wild fish for prey, space, and mates?
- What is the likelihood that escaped farm fish will interbreed with and alter the genetic characteristics of wild fish?
- Will escaped farm fish transmit pathogens to wild fish?

Socioeconomics

- What are the potential long-term consequences to the fishing industry from the establishment of escaped farm fish?
- Will the presence of escaped farm fish mask any decline in native wild fish, causing unwarranted relaxation of fishery management?
- What is the potential loss to the aquaculture industry from escapes in the short and long run?
- What are the ethical aspects of permitting the potential establishment of feral farm species and any consequent decline in wild populations?
- What are the most cost-effective means to minimize the occurrence of escapes?

Technology

- What is the likelihood of escapes from the aquaculture technology proposed or in use?
- Are effective sterilization techniques available?
- Can farm fish be marked or tagged for identification in the wild?

Box 2. Furunculosis in salmon farms.

Furunculosis, caused by the bacterium *Aeromonas salmonicida*, was first described in brown trout culture in Germany in 1894, and in North America in 1902. Opinions differ on its geographical origin, but not on the potential of its spread through translocated and cultured fish. Outbreaks can occur several hundred kilometers from the last known outbreak, often associated with known translocation of fish. In 1985, the disease was introduced to Norwegian fish farms by transport of smolts from Scotland. The disease spread rapidly from the first few infected farms to reach 550 fish farms (70% of the total) by the end of 1992. In 1988–1989, more than 250,000 escaped farm salmon were from farms infected with furunculosis. These fish were then found among spawning salmon (both farm escapees and wild fish) the following autumn. By 1992, furunculosis had been registered in 74 Norwegian rivers. In four rivers, the disease reached epidemic proportions. The rapid spread of furunculosis after the development of Norwegian marine aquaculture contrasts with the limited spread from a natural population that was infected in the late 1960s without showing evidence of further transmission. Vaccination programs and better husbandry in the aquaculture industry seem to have eliminated the furunculosis problem in recent years.