Environmental Risk Assessment of GM and GE animals

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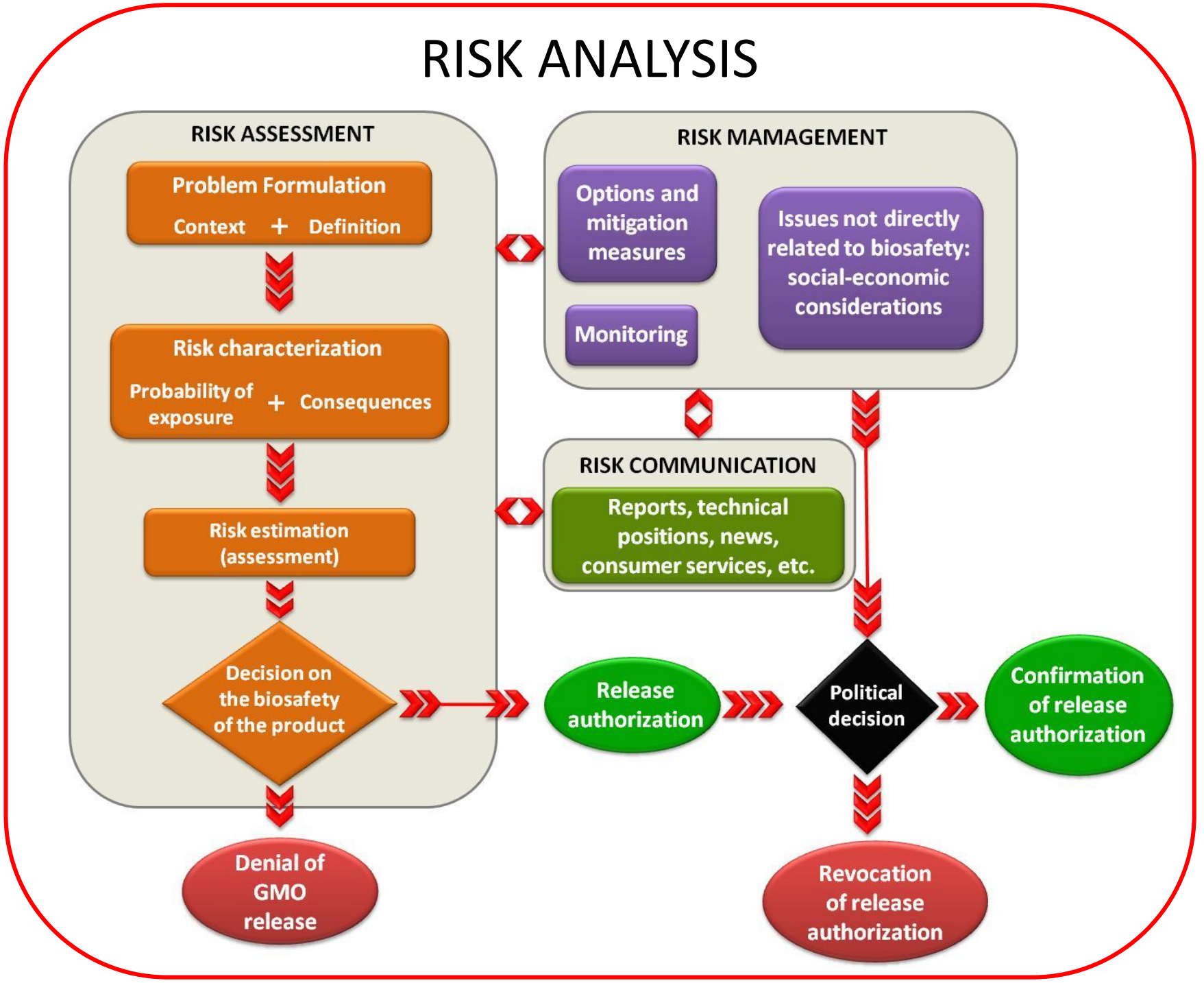
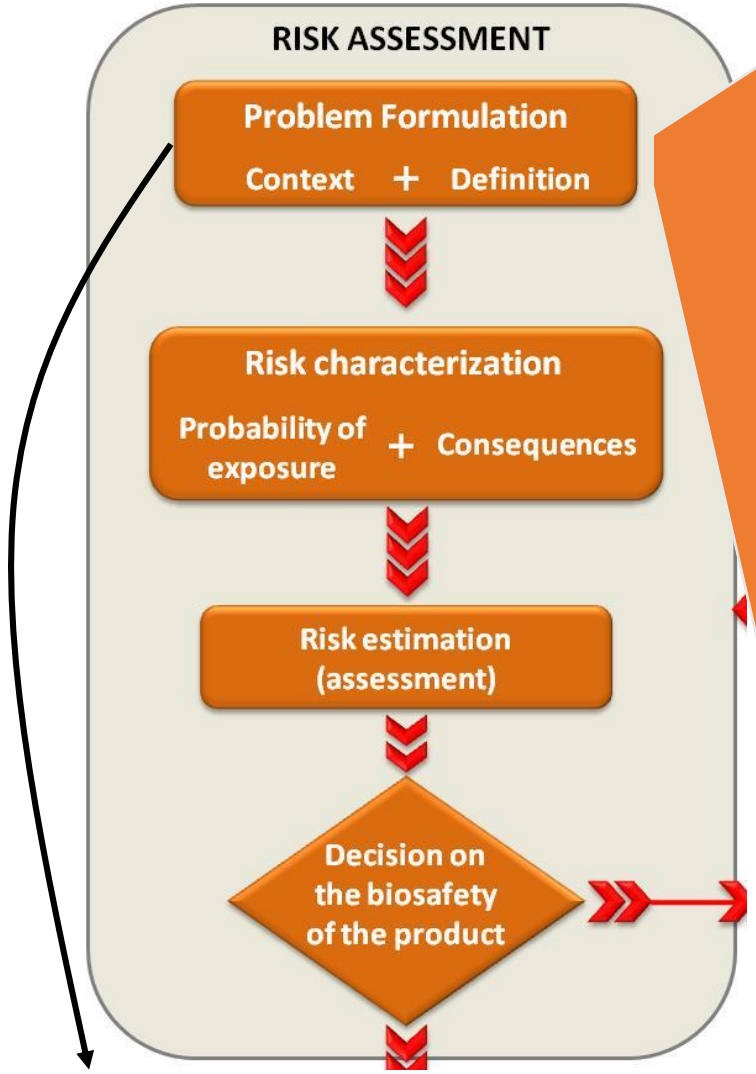
The Environmental Risk Assessment (**ERA**) is part of a broader process called **Risk Analysis**

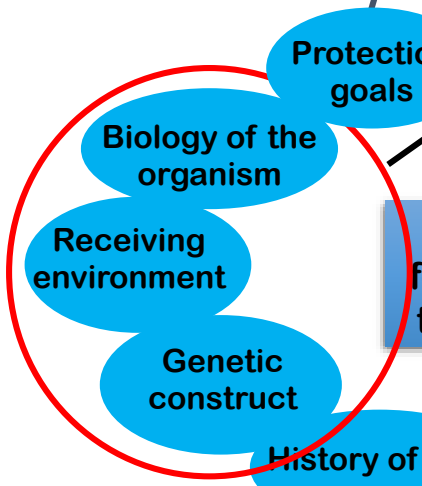




Problem formulation is the hard core of risk assessment

General aims defined by national and international law. It will be necessary to choose representative assessment endpoints for each broad aim.

These three elements allow an adequate definition of the assessment endpoints suggested by the protection goals



Problem formulation: the context

Problem formulation: list of hazards

Following steps

Allows the choice of assessment endpoints

Transmits the global experience with the GMO

Allows the inclusion of all risks perceived both by experts and by the general public

Hazards (or concerns) from "the lists"

Some may be relevant, but many may be irrelevant to assess risks of GM animals and many may be missing!

Why do we produce and keep these lists active? What questions are mandatory and why?

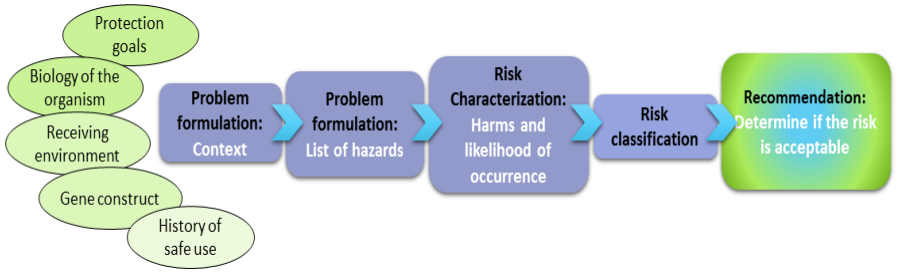
Hazards derived from the risk assessment

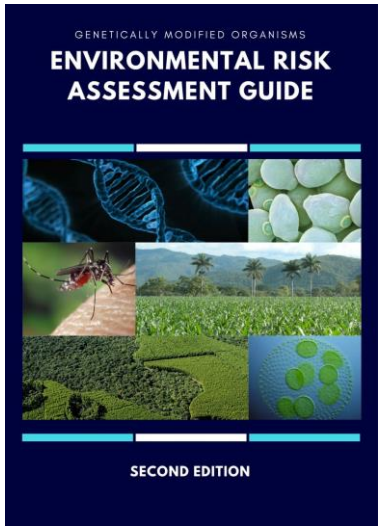
They should come **from ALL stakeholders**.
After risk characterization, most remaining hazard may be relevant, some may be useless to assess risks

Hazards (or concerns) from different stakeholders are considered, but most do not trigger new experiments

All questions derived from hazards must be be (primarily) answered by the developer/applicant, but risk assessors should be highly trained to do it

Our postulate: all relevant issues (or questions) will be derived from the environmental risk assessment (ERA) step by step procedure as accepted today – it can be applied to many, possibly all, GMOs inclusive animals (even gene drives)





Environmental risk assessment of GMOs

http://2015.igem.org/wiki/images/9/98/Tec_Guadalajara_ERA_Guide.pdf

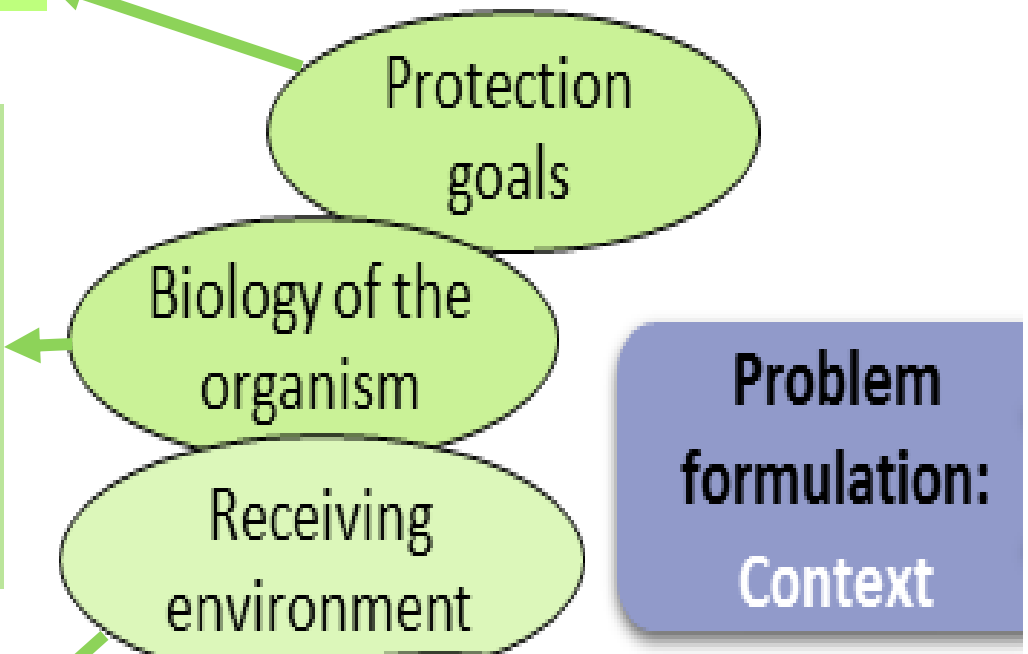
How to derive some relevant questions from ERA for:

A gene-edited hornless cow in Brazil

Problem formulation: the context

Biodiversity: **no** obvious protection goal

- Non-native
- No sexually compatible species
- Dispersion under control
  Moderately invasive
- Not relevant for wildlife food chain



Ag environments

Gene construct

CRISPR/CAS9 leading to gene silencing

History of safe use

To some extent, yes

How to derive some relevant questions from ERA for:

A transgenic fast-growing tilapia

Problem formulation: the context

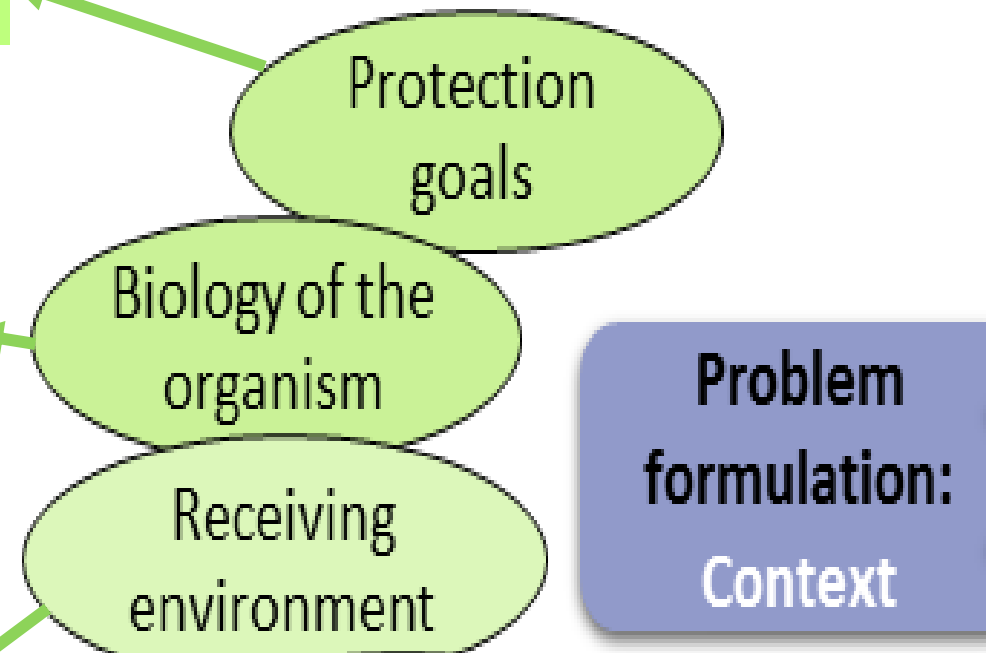
Biodiversity: **competing native river species**

- Non-native
- No sexually compatible species
- Dispersion under poor control
- Very invasive
- relevant for wildlife food chain

Ponds, rivers and lakes

Transgene constitutively expressing a growth hormone

None



How to derive some relevant questions from ERA for:

A gene-drive invasive snail (male-only) for population suppression

Problem formulation: the context

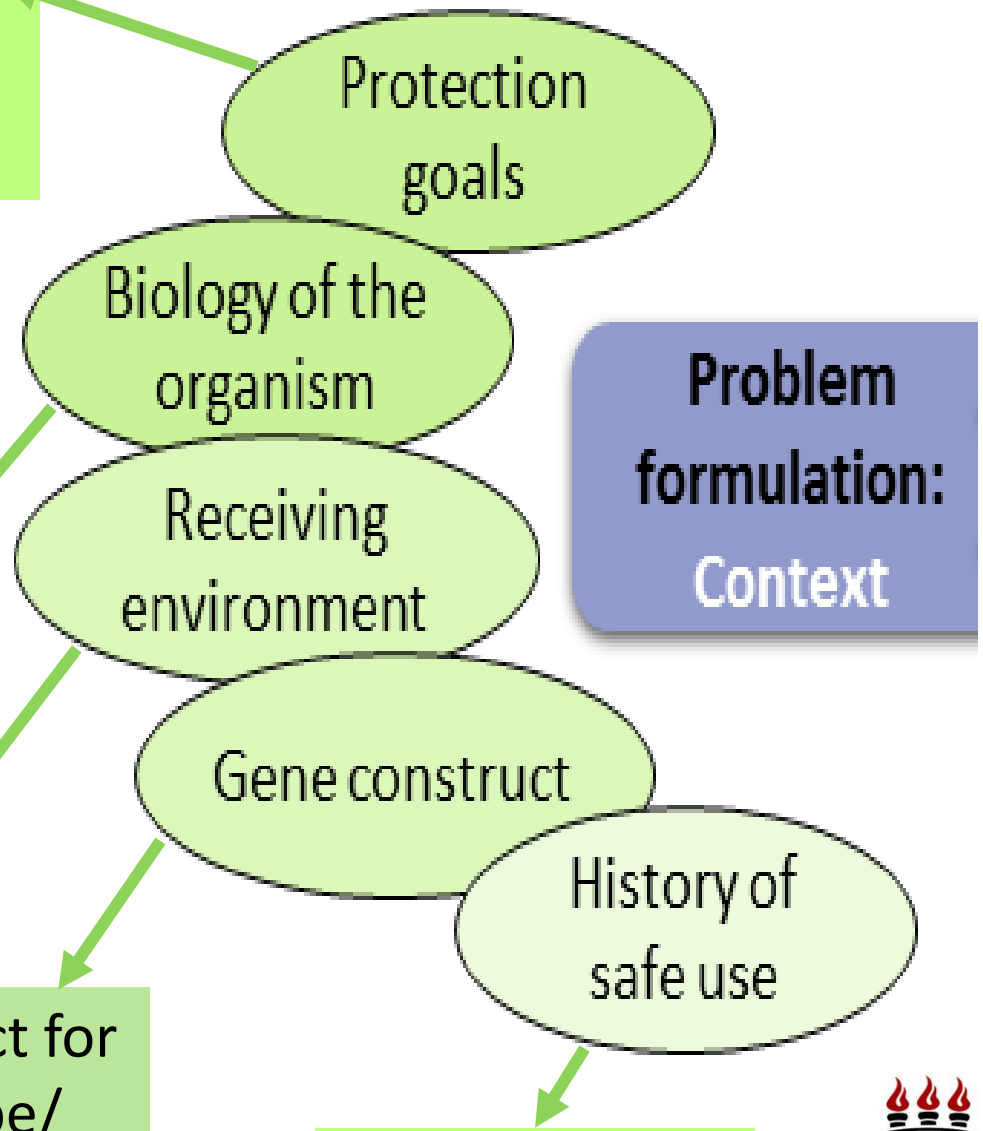
Biodiversity: no obvious protection objectives, except if it doesn't function as expected: then **competing native river species**

- Non-native
- No sexually compatible species
- Uncontrolled dispersion/ Very invasive
- Not relevant for wildlife food chain

Agricultural areas

Gene-drive construct for male-only phenotype/ fluorescence

None for snails



What are the relevant questions if we have/don´t have a protection goal that could be plausibly affected?

Animal	Trait	Protection goal	Questions (hazards or concerns)
Cow	Hornless	None	None
Tilapia	Fast growth	Other river dwelling organisms	Some (in case of escapes)
Snail	Male-only	None	Transboundary movements regulated by the Cartagena Protocol

What if no relevant questions can be found?

Impasse…?

How to proceed with the regulatory process if we do not have questions?
How to fulfill public´s expectation on rigor and precaution?

Obvious approach: take into account the concerns of all stakeholders. This will bring a list of concerns (hazards or questions) which must be anyway assessed, and their risks characterized and classified. If all of them are clearly irrelevant, the conclusion will be for the safety of the product.

Avoid discarding hazards without a proper risk assessment, proportional to its plausibility.

If questions do exist, how should the developer/applicant produce the answers?

Literature

It makes no sense to repeat experiments, either in the lab or in the fields, ***if the needed information is available*** and can be transported

Lab experiments

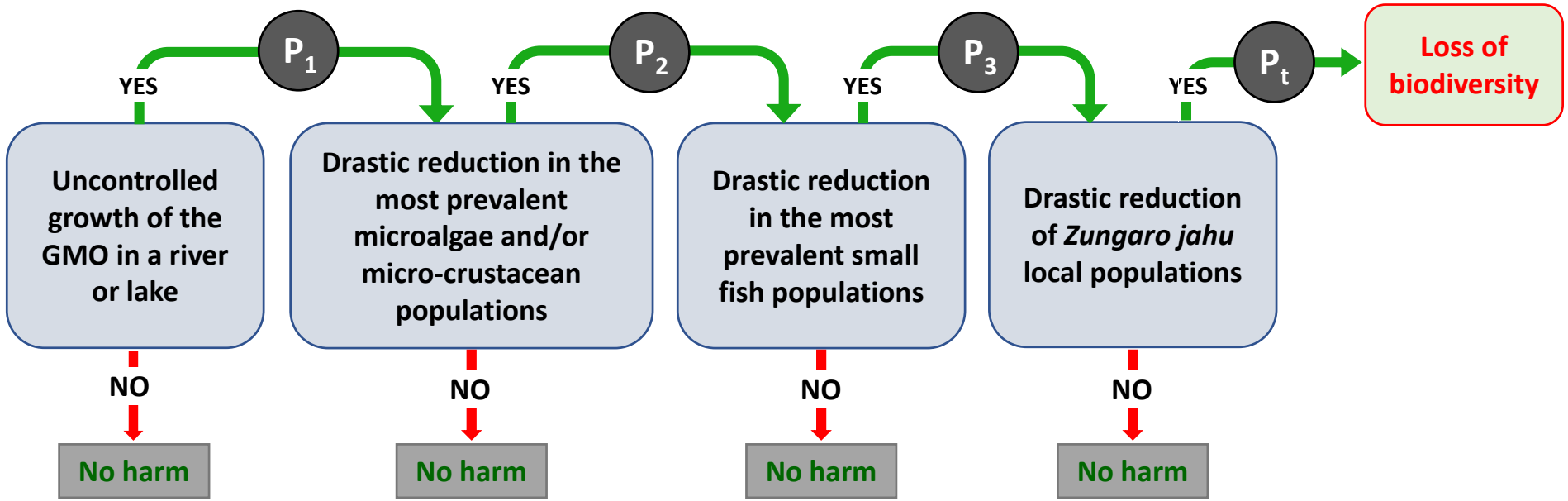
It makes no sense to do expensive, ill controlled field labs, ***if you can get the right answer in the lab***

Field releases

Although much used for GM plants, they seldom produce relevant answers for the environmental risk assessment. They will possibly be **of very limited use for the risk assessment for GM animals.** Methodologies are also very different for containment of plants and animals (sometimes plainly impossible)

Once the **potentially relevant questions** (concerns or hazards) are defined (by preliminarily excluding the obviously irrelevant ones), the next step is to create a **Pathway to harm** for every one of them (may be like the one below or just plain text, but both based on science and evidence)

Pathway to harm for a transgenic salmon. **Protection goal**: a native species. **Expected harm**: loss of a native species
Assessment endpoint: the jaú fish (Zun*garo jahu*)



$P_t = P_1 + P_2 + P_3$ → **The pathway generates the probability the hazard will materialize in harm**

Now, for every hazard, you must classify the risk. The previous Path to harm defines the probability class (likelihood of exposure) and science defines the class of the harm (the magnitude of the consequence of a GM release for that assessment endpoint). You enter both info the table below AND FIND the risk

		CLASS OF RISK			
LIKELIHOOD OF EXPOSURE	Very high	Low	Moderate	High	High
	High	Low	Low	Moderate	High
	Low	**Negligible**	Low	Moderate	Moderate
	Very low	**Negligible**	**Negligible**	Low	Moderate
		Marginal	Minor	Intermediate	Major
		CONSEQUENCE			

Usually only the negligible risks are acceptable

You did your job!

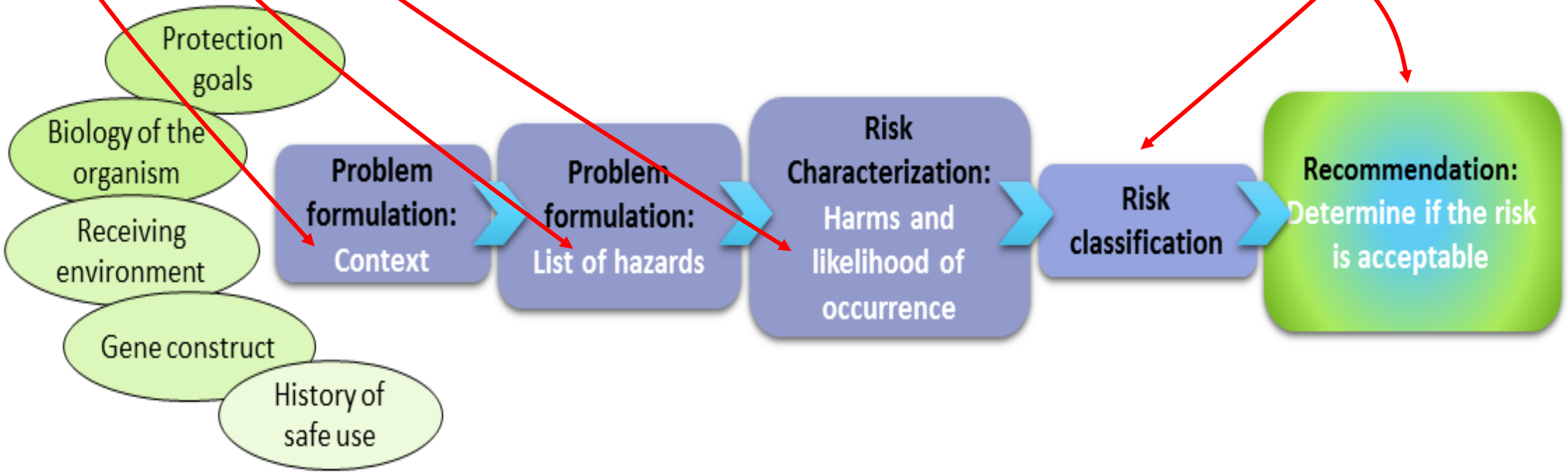
You were able to define the context and found the protection objectives

you listed hazards,

you discarded the obviously irrelevant ones (based on good science) and made paths to harm for the remaining ones,

you classified the remaining hazards according to their risk classes

and **now you can decide, based on a full risk assessment**.




THANKS!
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