Environmental release of animals developed via biotechnology

Regulation and risk assessment

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Regulation and risk assessment

Questions to be answered (primarily) by the developer/applicant

Questions from "the lists"

Some may be relevant, many may be useless to assess risks of GM animals

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

Questions derived from the risk assessment

After characterization, most remaining questions may be relevant, some may be useless

Questions from different stakeholders are considered, but most do not trigger new experiments

What is the answer to the Ultimate Question of Life, The Universe, and Everything?

From the Hitchhiker's Guide to the Galaxy

A relevant answer must comes from a relevant question!

How do we produce relevant questions concerning the environmental release of GM animals?

As shown before, most regulatory frameworks have:

- List of questions
- Case-by-case risk assessment

Useless mandatory questions frequently imply new experiments/field releases and imply costs. Setting too high standards, disproportionate to risks, and disregarding previous experience also increase costs

High regulatory costs will preclude the release of GM animals

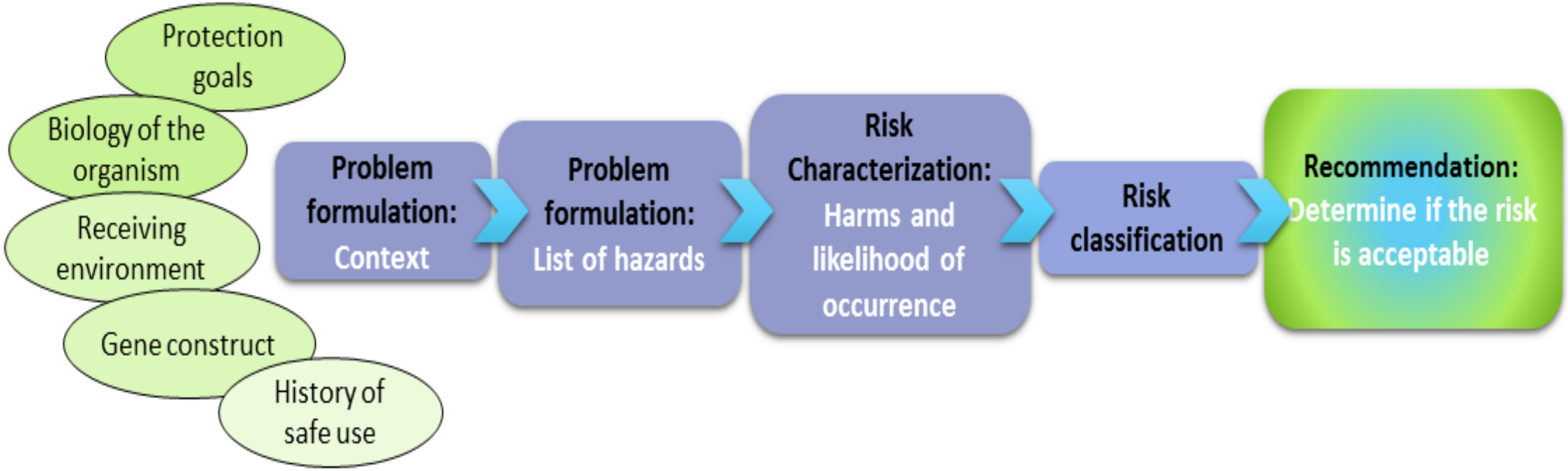
The logical approach would be:

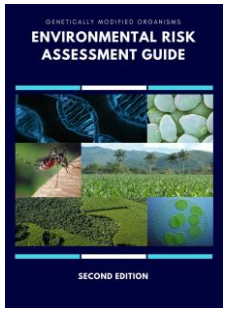
- Case-by-case risk assessment

Only relevant questions will trigger new experiments

Lower regulatory costs will allow the release of GM animals

Our postulate: 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





Environmental risk assessment of GMOs (Draft - June 2017)

https://goo.gl/T4Uxnl

How to derive relevant questions for:

a) a gene-edited hornless cow

b) a transgenic virus resistant goat

c) A transgenic fast growing tilapia

d) A gene-drive invasive snail

In Brazil????

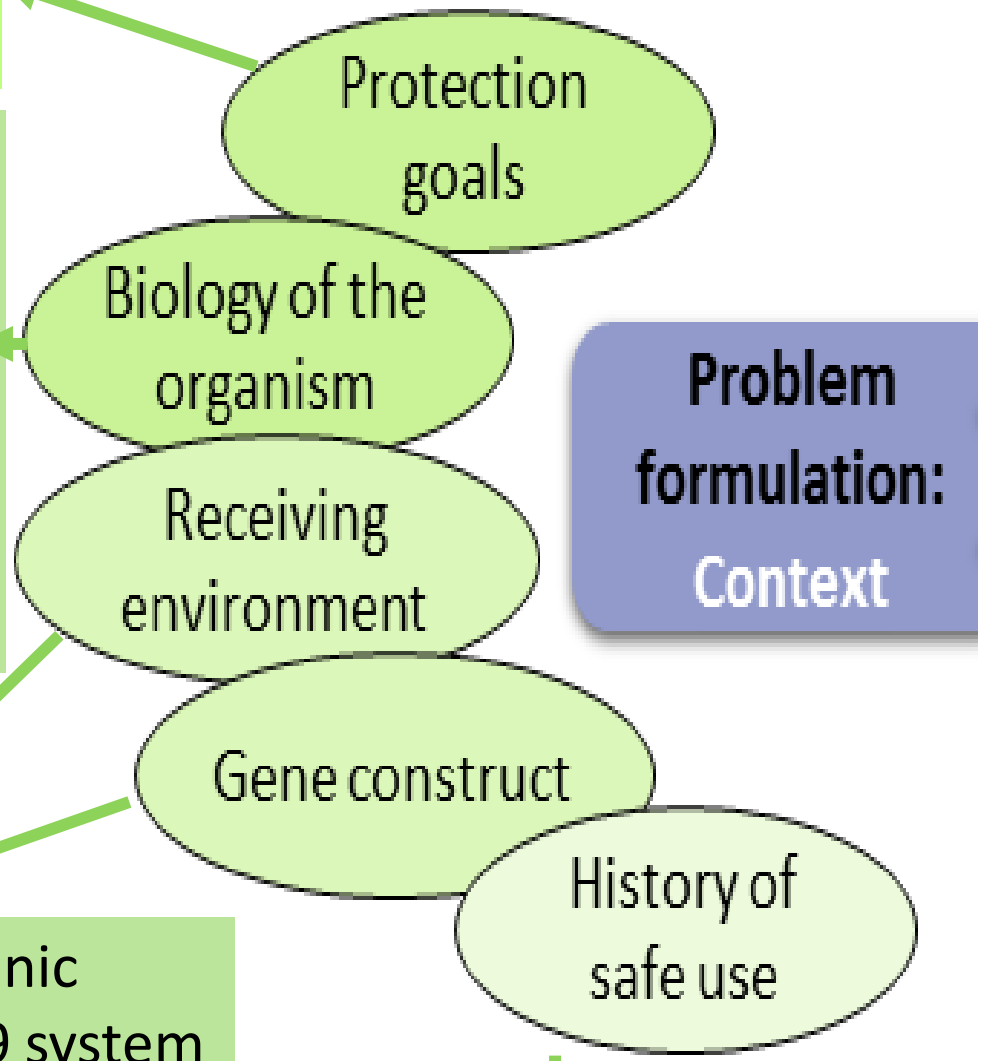
Problem formulation: the context

Biodiversity: **none**, **none**, **competing river species**, **none**

Non native
No sexually compatible species
Dispersion under control (a/b)
Moderate/high invasive potential (c/d)
Not important in for wild life food chain

Agri-environments/ rivers

CRISPR/CAS9 or transgenic animals or CRISPR/CAS9 system to drive a gene that confers a female sterile phenotype



For some, yes

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

Animal	Trait	Protection goal	Question
Cow	Hornless	None	None
Goat	Virus-resistant	None	None
Tilapia	Fast growth	Other river dwelling organisms	Some (in case of escapes)
Snail	Female sterility	None	Transboundary movement Regulated by the Cartagena Protocol

What are the relevant questions if we don´t have a protection goal that could be plausibly affected? None

Impasse…

How to proceed with the regulatory process if we do not have questions?

How to fulfill public´s expectation on rigor and precaution?

The worst solution: Create an imaginary risk assessment by adding irrelevant questions only to suppress or reduce public outrage

Some of the irrelevant questions can be social-economical issues, including coexistence

The best solution: find relevant protection goals and work on them or otherwise be transparent to all stakeholders, but don’t create imaginary risk assessments

If there are relevant questions, 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 GM animals risk assessment. Methodologies are also very different for containment of plants and animals (sometimes plainly impossible)

Approaches to do an environmental release of animals developed via biotech

1) Scrutinize your regulatory framework and see if you can get rid of it or at least circumvent the pitfalls…

- Lack of clear guidelines for animals
- List of useless questions
- Obligatory use of certain data
- Obligatory use of field releases prior to a commercial release
- Etc

2) Start doing your hypothetical risk assessments much before having your product and discuss the results with the regulators

3) Once a consensus is achieved, start your broad benefit/risk communication, engaging a skilled staff to help you coming to a happy end

4) Then proceed with your experiments, and good luck


THANKS!