

# Environmental risk assessment (ERA) in the food chain

A specific European approach - outcome of two training workshops

*IAIA Webinar presentation (11/22/2016)*

Jean-Roger Mercier and Ben Cave



International Association  
for Impact Assessment

[www.iaia.org](http://www.iaia.org)

*The leading global network on impact assessment*

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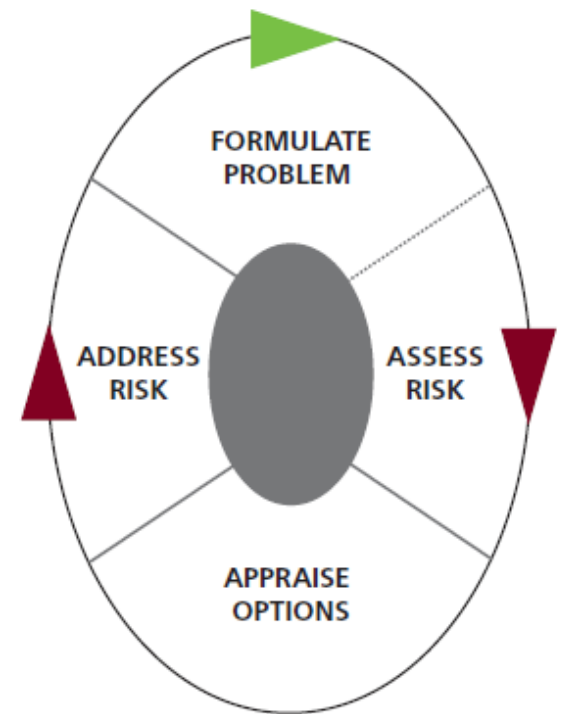
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# Content

- The ERA process of the European Food Safety Authority (EFSA)
- EFSA in short
- The Better Training for Safer Food (BTSF) program
- The two ERA workshops held
- Lessons learned from the workshops
- The way forward and the take away lessons for IA practitioners

# The ERA process

- One of eight risk assessments conducted to ensure that a product in the food chain is « safe » for the European consumer and its environment



## European Food Safety Authority

Source: <http://www.efsa.europa.eu/>

Created in the early 2,000's as per the recommendations of the White Paper on Food Safety in Europe.

Established in Parma (Italy) with a strong regulatory role on products in the food chain in Europe (« from field to fork »)

A key Risk Assessor providing independent advice to Risk Managers in the food chain (European Commission and Member States).

# Better training for safer food (BTSF)

- A huge tentacular programme combining conventional face-2-face with e-learning (35 categories of courses for EU Countries and 7 categories of courses for Third Countries, the 8 module course on Risk Assessment being just one of the 35....)
- Managed by the European Commission with input from EFSA
- Legal basis: Article 51 of [Regulation \(EC\) No 882/2004](#) on official controls on food and feed, animal health and animal welfare rules, and Article 2 of [Council Directive 2000/29](#) on protective measures on plants or plant products

# BTSF Objectives

- Ensuring and maintaining a high level of **consumer protection** and of animal **health, animal welfare and plant health**;
- To improve and harmonise **official controls** in EU countries;
- To ensure **safety of food imports** from non-EU countries on the EU market, and ultimately to reducing risks for EU consumers and providing EU businesses with easier access to safe goods from non-EU countries;
- To ensure a **harmonisation of control procedures** between EU and non-EU partners;
- To build confidence in the EU regulatory model with competent authorities of other international trade partners and pave the way for new food market opportunities and **increased competitiveness for EU operators**;
- Ensuring **fair trade with non-EU countries** and in particular developing countries.



# BTSF – The 8 Risk Assessment courses

Goal *“to train experts with a scientific background and an interest in food and/or feed safety risk assessment in order to expand their theoretical knowledge and practical skills on principles and methods of risk assessment.”*

- Microbiological risk assessment;
- Chemical risk assessment in food;
- Pest risk assessment;
- Risk assessment in nutrition;
- Risk assessment in Genetically Modified Organisms and other biotechnologies;
- Risk assessment applied to animal welfare;
- Risk assessment for animal health;
- **Environmental Risk Assessment.**

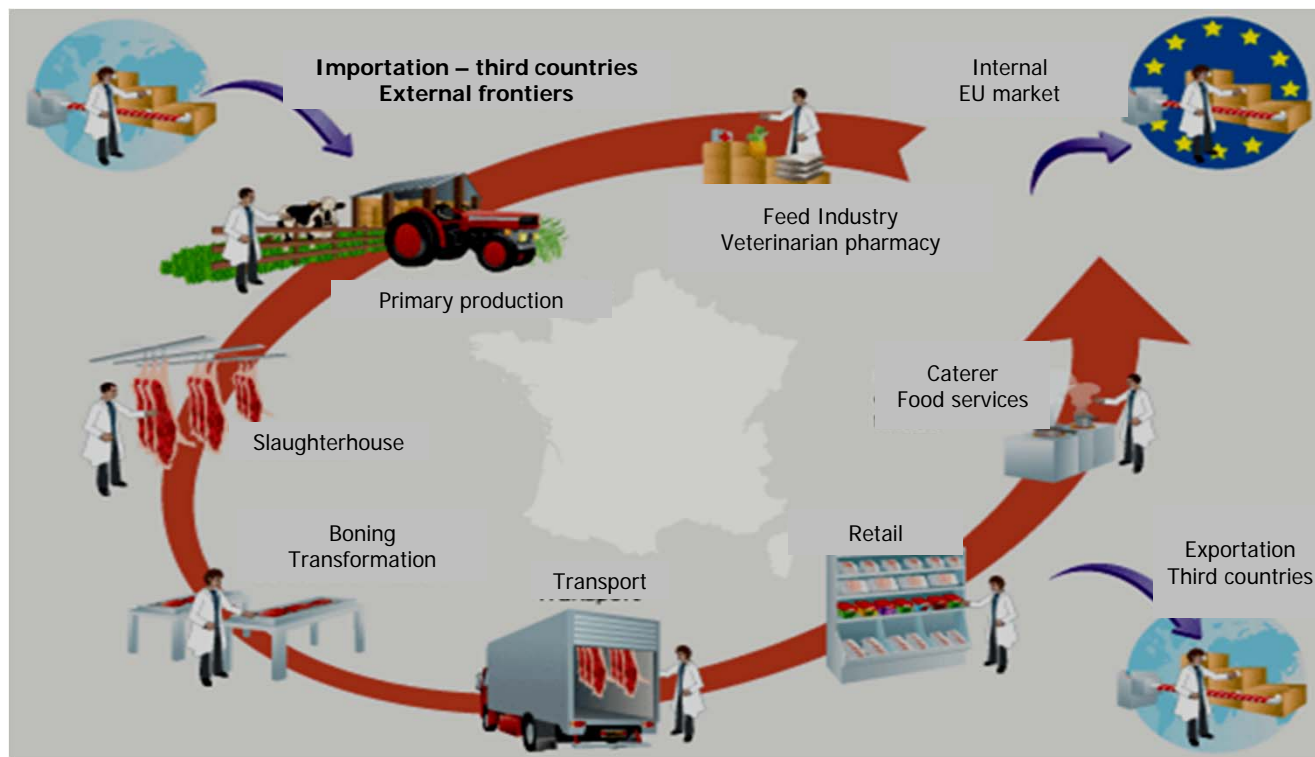
## ERA « in situation »

Typically, a private firm requests an European approval for a new product on the market or for importing an existing product. The request is processed at the national level and EFSA gives an independent advice to the European Commission.

That advice is based on the « passing » of a series of tests and risk assessments, of which ERA is one.

The key steps of ERA are presented next.

# “From the stable to the table”



# Workshop agenda

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Welcome and introduction ***Eugenia Chaideftou & Jean-Roger Mercier***

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Icebreaker ***Jean-Roger Mercier***

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Session 2: Environmental and social protection goals when dealing with environmental risk assessments related to products/species in the food/feed chain. ***Ben Cave***

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Session 3: Problem formulation steps of the ERA related to the food/feed chain. ***Jean-Roger Mercier***

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Session 4: Analysis phase of the ERA related to the food/feed chain (cont.)  
***Sophie Privat***

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# Workshop agenda (cont.)

Session 5: Application of ERA (breakout group exercise) ***All tutors***

Session 6a: Non-target organisms and risk assessment evaluation  
***Eugenia Chaideftou***

Session 6b: Non-target organisms and risk assessment evaluation (cont.)  
***Eugenia Chaideftou***

Session 7: Environmental exposure assessment for the food/feed chain  
***Agnès Baule***

## Workshop agenda (cont.)

Session 8: Environmental exposure assessment – Interpretation (break out groups and general session) **All tutors**

Session 9a: Life stage analysis **Jean Roger Mercier**

Session 9b: Life stage analysis (cont.) **Agnès Baule**

Session 10: Exchange of real-life experience with ERA by participants  
**All tutors**

Session 11: Review, prospects, questions & answers **Eugenia Chaideftou  
& Jean-Roger Mercier**

Session 12: Evaluation and conclusions **All tutors**

Follow-up to the workshop **All tutors**

Official closing of the workshop and certificates **Eugenia Chaideftou**

## Key concepts : Hazard and Risk

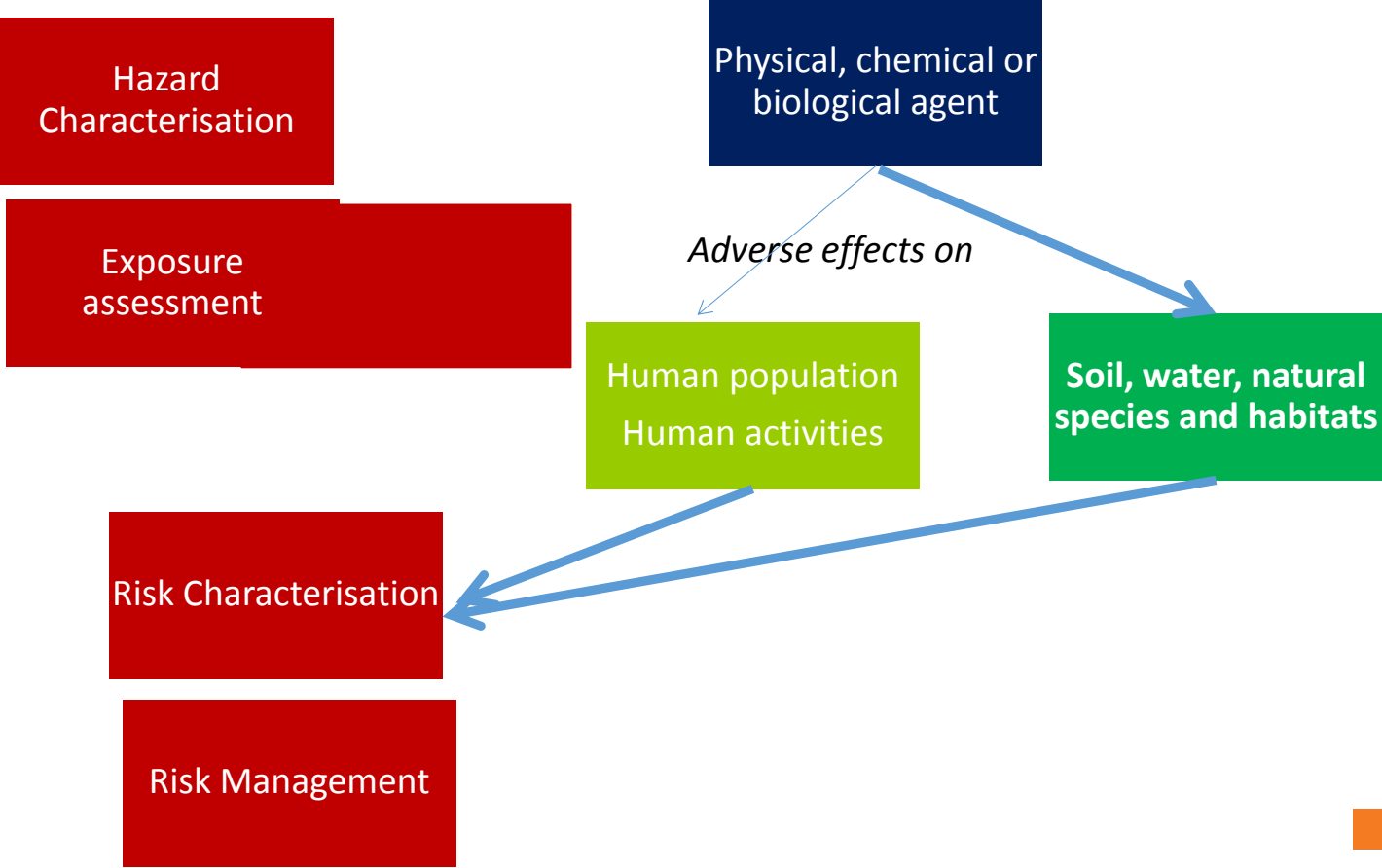
- **Hazard : potential to cause harm**
  - A situation
  - A biological, chemical or physical agent
  - that may lead to harm or cause adverse effects
- **Stressor**
  - any physical, chemical, or biological entity
  - that can adversely affect specific natural resources or entire ecosystems, including plants and animals, as well as the environment with which they interact
  - Ex: Air pollution, pollutants, pharmaceuticals, pesticides, radiation, water pollution, invasive species
- **Risk : chance of disaster**
  - The chance high or low, that somebody (human health) or ecological systems could be harmed by these and other hazards, or “stressors”
  - together with an indication of how serious the harm could be

# The 3 pillars of risk analysis

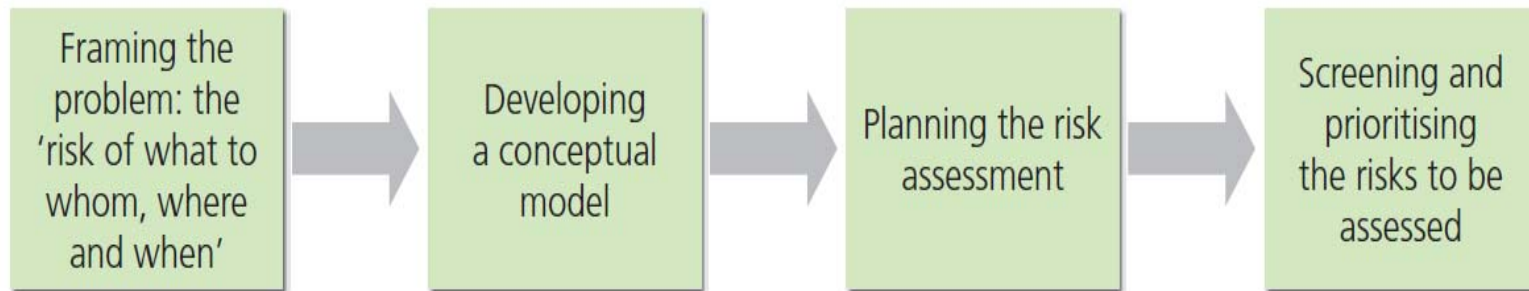
- Risk assessment = process of evaluation including
  - hazard identification and hazard characterisation
  - exposure assessment
  - risk characterisation.
- Risk management
  - process of weighing policy alternatives
  - in the light of the result of a risk assessment(s) and of other relevant evaluations,
  - and, if required, of selecting and implementing appropriate control options (including, where appropriate, monitoring/surveillance activities).
- Risk communication
  - the interactive exchange of information and opinions throughout the risk analysis process concerning risk.
  - Involving risk assessors and risk managers, but also consumers and a wide range of other actual or potential stakeholders



ERA, Environmental Risk Assessment



# In graphic terms

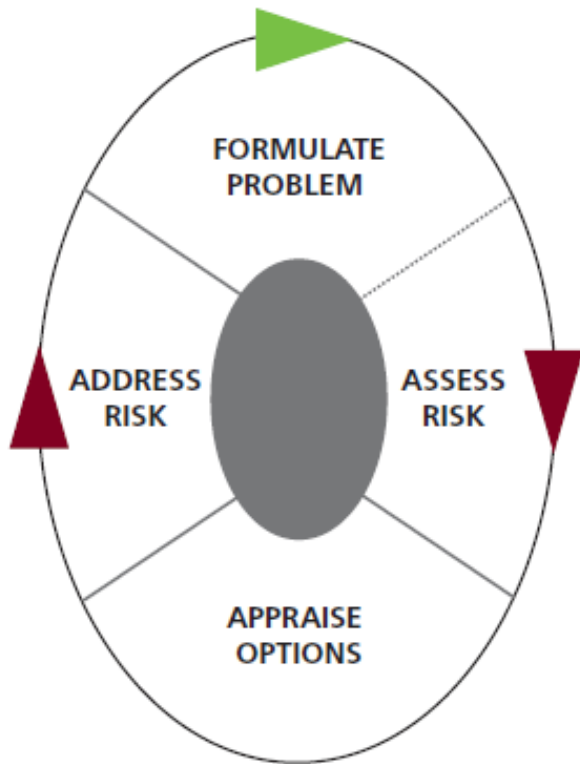


*Consider a discharge to a surface water body. Key elements of the risk assessment include which discharge point is to be considered, over what period in time, to which receiving water body, affecting which receptors or outcome measures.*



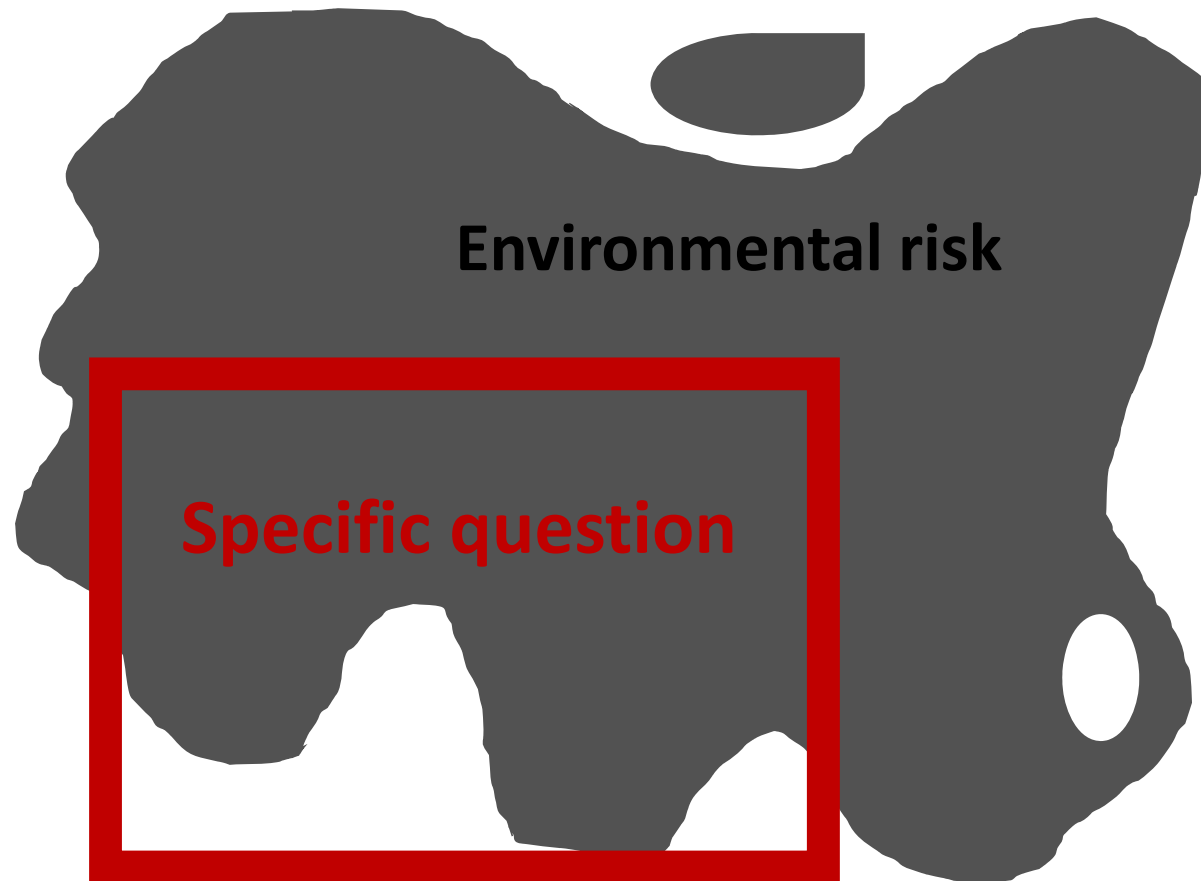
## Vignettes from the presentations at the workshops

# The overall framework

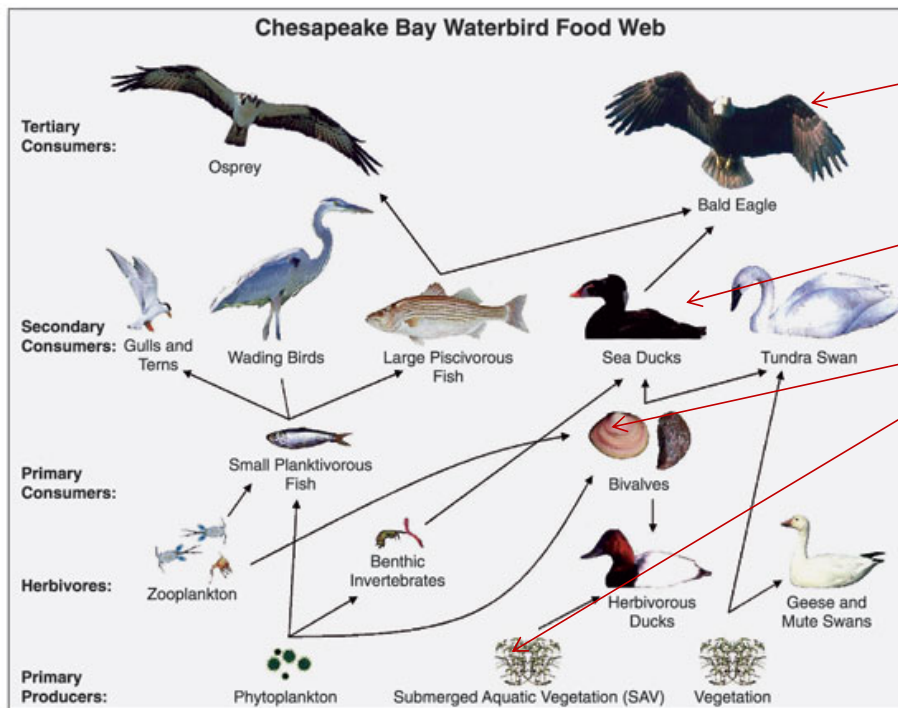


A useful reference: “Green Leaves III”, Guidelines for Environmental Risk Assessment and Management (2011)

# A workshop participant's rendition



# Which species?



Umbrella species

Keystone species

Indicator species

... Other...



**Tetrao  
urogallus**

Black grouse dietary habits depend on the life stages (in the French Mountains)

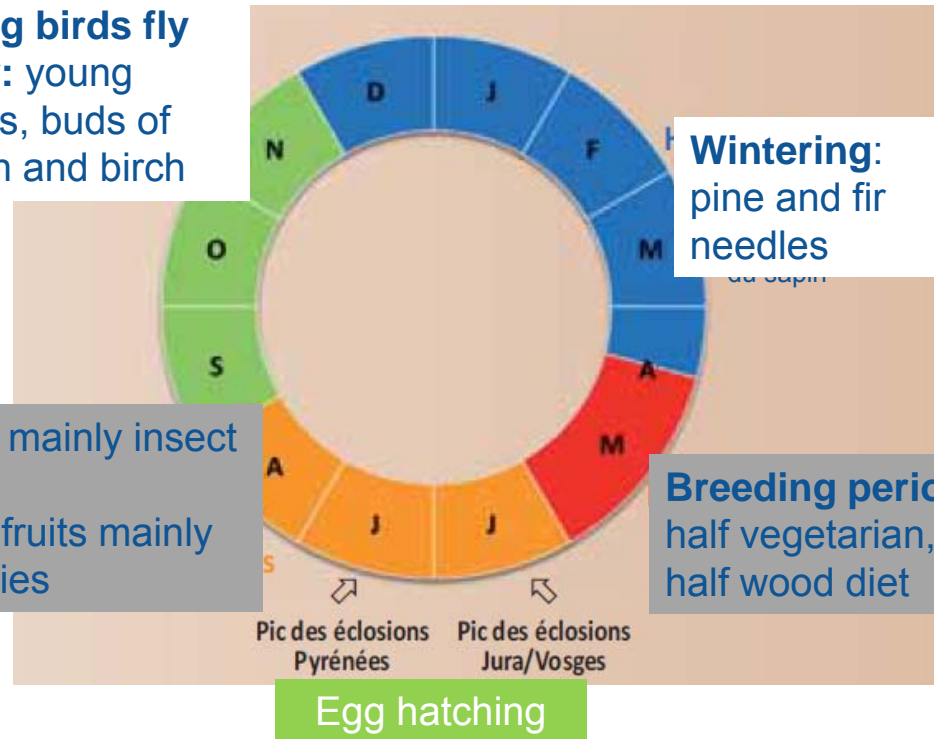
## At What Life Stage?

**Young birds fly away:** young leaves, buds of beech and birch

**Chicks:** mainly insect eaters  
**Adults:** fruits mainly blueberries

**Wintering:** pine and fir needles

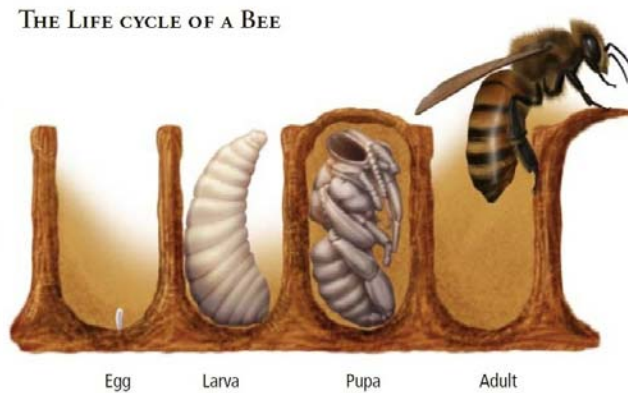
**Breeding period:** half vegetarian, half wood diet



*Black grouse is an umbrella species because of its wide home range that covers multiple habitat types.*

# Life Stage Analysis (LSA) methods for population structure forecast

- Perturbation analyses, which explore the effects on population growth of changes in the vital rates, have become a standard part of demographic practice.





# Databases that can be consulted to find the relevant traits for LSA

For animals

<http://www.scales-project.net/>

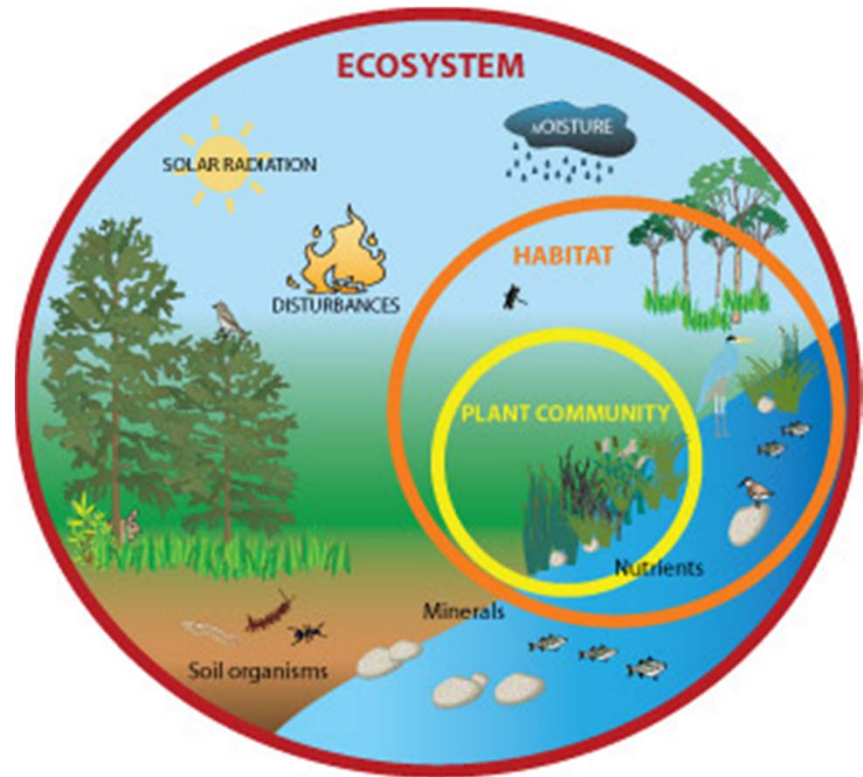
<http://marinebio.org/oceans/marine-life-cycles/>

For plants:

<https://www.try-db.org/TryWeb/Home.php>

# Methods

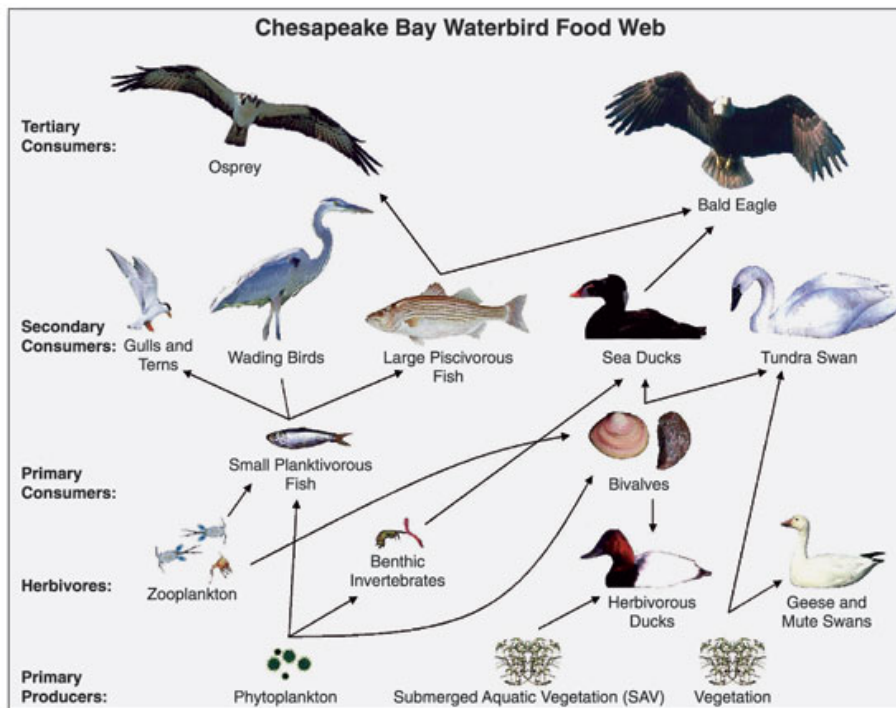
Source Pathways  
Receptors



Ecosystem diagram, source: nps.gov

# Receptors

*Trophic network : A set of interconnected food chains within an ecosystem*



How to choose a species ?

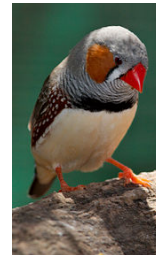
**An umbrella species :** have large home ranges that cover multiple habitat types

**A keystone species:** whose presence contributes to ecosystem function and whose elimination would lead to the disappearance of other species in the ecosystem.

**An indicator species :** whose presence, absence or abundance reflects a specific environmental condition

## Table of contents on Methods

1. Selection of non-target organisms for risk assessment evaluation studies
2. Gathering relevant evidence
3. Role of extrapolation factors to cover different types of uncertainty
4. The application and use of statistics to the measurable endpoint results &
5. Appropriate interpretation of the biological relevance of statistically significant results



How?



### *Session 6b*

#### *Non-target organisms & risk assessment evaluations*

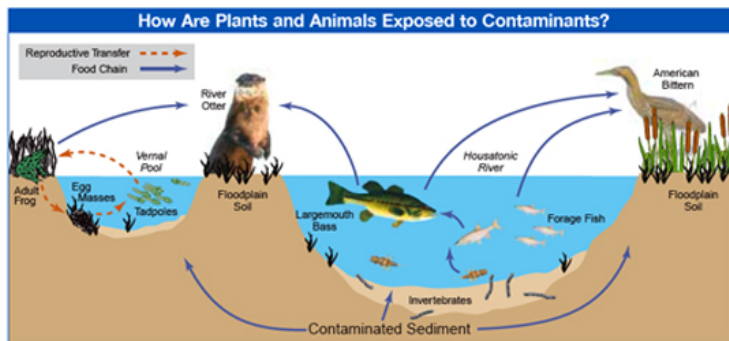
- ✓ Case study arthropods:
- field conditions,
- higher tiers & analysis

## Goals & purpose



## Data requirements *Legal background*

Non-target organisms  
& risk assessment evaluation



<http://www.efsa.europa.eu/en/pesticidesapplicationshelpdesk/guidancedocumentspesticides.htm>

- **Regulation (EC) No 1107/2009** of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. Official Journal of the European Union, L 309/1-50, EN, 24.11.2009
- **Commission Regulation EU 283/2013** setting out the data requirements for active substances, in accordance with Regulation EC 1107/2009.
- **Commission Regulation EU No 284/2013** setting out the data requirements for plant protection products, in accordance with Regulation EC No 1107/2009.

## The Rome workshop

A real-life « dry run » of the training programme and of trainers' team (never before worked together);

25 participants from EU member states and non-EU (e.g. Macedonia) states

Combination of Risk analysts and risk managers

Diverse academic background (veterinarians, chemists and more)

A programme comprising of both lectures and group case studies. A bit of fun on the last case study simulating a real life permit request processing.

## The Tallin workshop

Second delivery with a team that had functioned well the first time

Disappointment on the limited number of participants (10)

Very few changes in the curriculum and in presenters' material

EFSA officer present and extremely cooperative

Success calling for the repeat of two additional ERA training sessions (Rome and Lisboa) scheduled for during the winter of 2016-2017.

## Lessons learned from the workshops

ERA is a complex and very formatted approach

Performing a good and useful ERA requires a strong scientific background and a vast array of knowledge on various topics

Data requirements for the preparation and conduct of a good ERA are huge and diverse

The sophisticated approach used and promoted by EFSA transcends national-level methods and techniques, especially in the less advanced member states and in non-member states

ERA is a necessary, but not sufficient, approach for good risk management and communication. The very prescribed and formatted approach of ERA requires lots of communication efforts to transfer its usefulness into the real world.



## Interest/relevance for IAIA members

Many of the data requirements for ERA have a lot in common with what IA experts require for a good EIA

The social factors are out of the scope of ERA, but present in other risk assessment techniques used and « blended » into the risk management and communication performed by the European Commission in the food chain

Impact assessment focuses on projects and activities; ERA focuses on products and their potential toxicity, especially on non-target organisms

IA works at various geographical and temporal scales, ERA focuses on micro-level, but also on various temporal scales

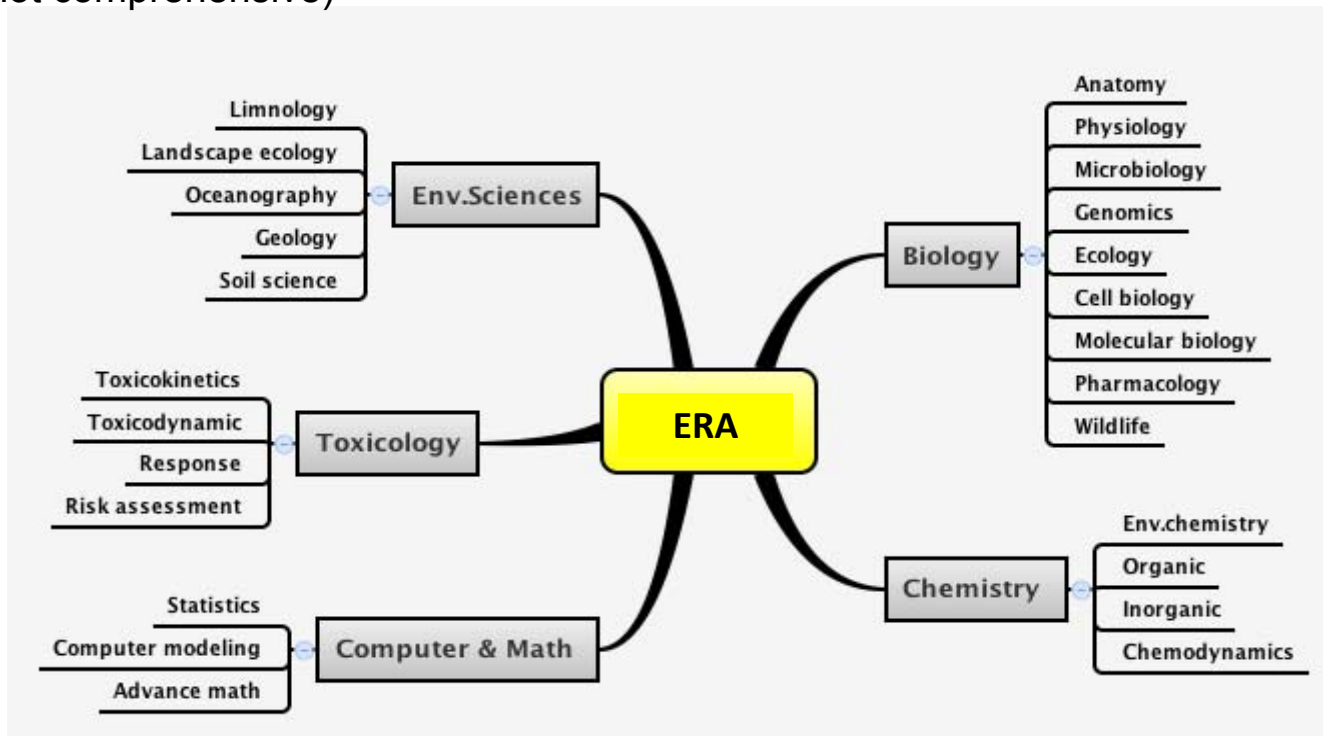
IA experts are often faced with the same issues of communication and enforcement as ERA experts are.

The same logics of searching for causal relationships applies to IA and ERA alike

When IA deals with projects touching on the agrobusiness in general, the outcome of ERA of products having gone through that process should be used in the impact/risk analysis sections of IA

# ERA interdisciplinary core

(not comprehensive)



Author: Agnès Baule (Aliséa)

# Coming up on Pre-VEB Channel...

## **Accountability in Europe**

- EIB delivering on the mechanisms that European institutions (Ombudsman, EIB Complaints) have built and maintain to allow simple citizens to protect their rights.

## **IAIA's got talents**

- Anyone else ready to take up the challenge and use the IAIA Webinar facilities to spread the word, among smart people, about their research? Who's the next Susan Boyle of IA in Europe?