Swiss legacy applied to our project

Introduction: basic questions

- Pratical case of our project
  - Arsenic sensor → humanitarian goal
  - Use of a GMO bacteria
  - Desire to measure in the field
- Questions looking for legacy able to be applied
  - What are we allowed to do?
  - What do we have to pay attention to?
  - Will our research be legally usable?

Introduction: domains and general questions

- Environment
  - To be protected
  - Theme of water
  - Analyze of water
    - Lead to another domain

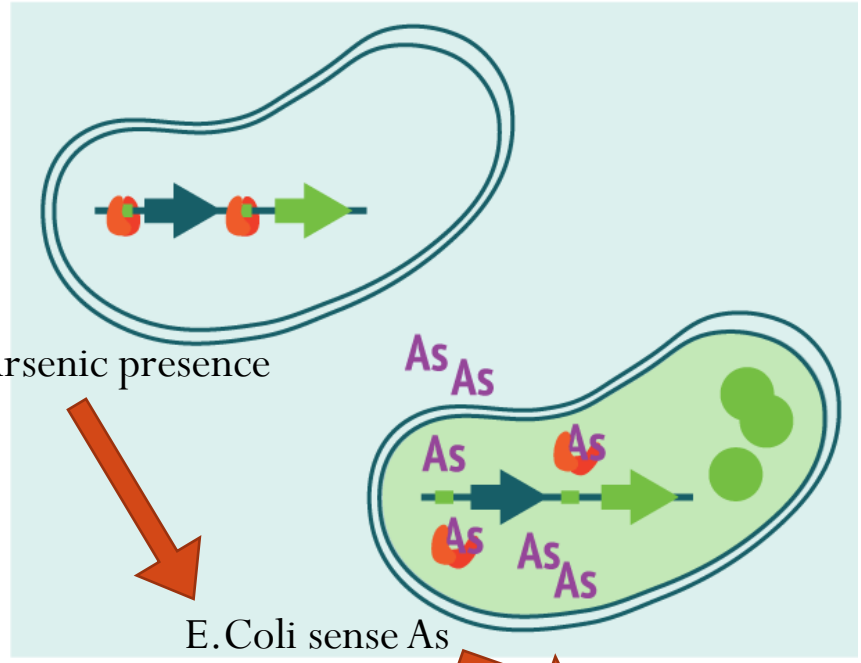
- Public health
  - Raise awareness
    - About water quality
    - And its implication on health
  - To be protected (also)

Weighing interests

Questions:

- What are we allowed to take in the environment?
- To what extent goes the protection?
- Which domain do we have to give the priority to?

Arsenic sensor



Production of green fluorescence: measurable, proportional to Arsenic concentration

Problems:

- It is a GMO
- Gene inducing a resistance to an antibiotic (kanamycin) → dangerous if the gene is transmitted to other pathogenic bacterias because kanamycin is use in human medicine.
- Can we legally, ethically make a measure in the field with this bacteria?
- What to do with the waste?

Legal reference framework (plan)

- Laws are more about GMO food but we use an organism.
- Basic principles about GMO:
  - Precaution principle (used more in European Union)
  - Substantial equivalence principle (used more in the United States)
- Other means for protection
- Authorization procedures
- Swiss legal framework

Legal reference framework: precaution principle

Rio declaration: If there is any risk of serious or irreversible damage, the absence of absolute scientific certainty must not serve as pretext to postpone adoption of effective measures to prevent environment degradation.

The idea is that we need to proove absence of potential risks and not their presence. Any project must proove scientifically that there are no risks due to their product. A quite difficult work with GMOs.

Legal reference framework: Substantial equivalence principle

This principle is used to regulate production and commercialization of new food products as those derived from biotechnologies (GMOs). It statuates that if an alimentary coumpound is essentially similar to an existing coumpound, it can be treated the same manner concerning security.

This principle applied to a GMOs signify that if the GMO is substantially equivalent to its conventionnal equivalent, it will be declared as healthy as the conventionnal product.

This concept is used among others by the american Food and Drug Administration to appreciate and declare innocuousness of GMOs.

Legal reference framework

- An authorization procedure involve:
  - Security: The product must be securized and not cause damage to human, environment or animals. Tests must be done with the most recent knowledge and technology.

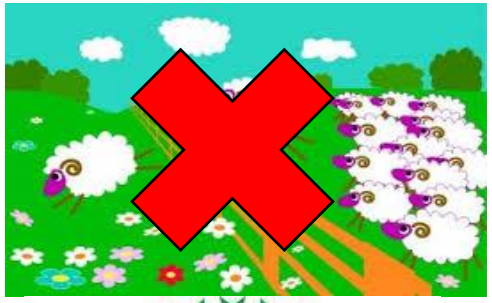
  - Free choice: Even if a GMO obtained an authorization, consumers, farmers and factories must have the freedom to choose between a product with or without GMOs.
  - Labelling: To maintain free choice, a GMO product must be correctly labelled, so the consumer can take a decision correctly informed.

  - Traceability: The consumer must have the information of the route from the producer to the seller.

Legal reference framework

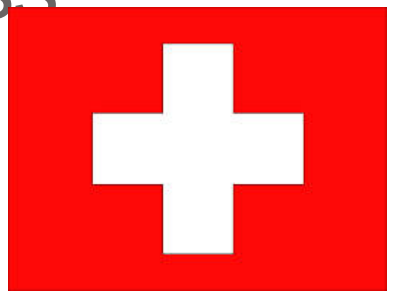
- Other protection means:
  - Safeguarding clause: Politicians can forbid a product if they estimate it is dangerous or not enough known.

  - Coexistence, buffer zones, isolation distances: It must exist a «buffer» zone between GMO culture and non-GMO culture. Distance of this zone is regaulated differently in each country. In Europe, it goes from 15m in Sweden to 800m in Luxembourg.



  - Zones sans OGM: A state has the possibility to decide that a zone is to be protected and has to be GMO-free.

Legal reference framework: Swiss legacy (general)



- In Switzerland:
  - Classification: the organism is classified in 4 categories (depending on its dangerousness) and the activities made with the organism are also classified.
  - Protection purpose: The federal office of public health investigate, collaborating with other federal offices, autorisation demands: it gives autorisation only if all risks for health and environment is eliminated.
  - Duty to inform: communicate is necessary, any change, accident, research has to be signaled to the autorities.
  - Notify/ Ask authorization: Authorization is limited (10 years) and the product is watched closely. A product can be removed if we have good reasons to believe that the GMO presents a danger for health or environment.
  - Provide guarantee (to cover potential damage)

Legal dispositions able to be applied at our example

- Ordinance 814.911 on the Handling of Organisms in the Environment of 10 September 2008 (Status as of 1 June 2012)
  http://www.admin.ch/ch/e/rs/814_911/index.html
- Ordinance 814.912 on Handling Organisms in Contained Systems of 9 May 2012 (Status as of 1 May 2013)
  http://www.admin.ch/ch/e/rs/814_912/index.html
- Topic of SECB (Swiss Expert Committee for Biosafety) on transport, import and export of biological substance that contain GMOs http://www.efbs.admin.ch/en/transport/index.html

The purpose of these ordinances is to protect humans, animals, the environment and its biologic diversity from threats resulting form the use of organisms, their metabolites and their waste.

These ordinance regulate the use of organisms in general but contains also specific paragraphs about genetically modified organisms.

Legal dispositions able to be applied at our example

What we understand from the law depends of the manner we interpret the law:

- According to aim and function (In this case we care of the purpose of the ordinances: protect humans, animals and environment and we are more responsabilized about how we assume this protection)
- Historically
- Grammatically (In this case we only take care of the letter in the law and respect carefully all its sentences)
- Systematically

Legal dispositions able to be applied at our example

- **Definitions:** The third article contains definitions of terms used in the ordinance. In fact a first role of these ordinances is to clarify facts to which they can be applied.
- Study of risks
  - Danger evaluation
    - Organisms
    - Waste
    - For human being
    - For animals
    - For environment and biological diversity
- Classification

Diligence duty: everyone must act with counsciousness and precautions that the situation demands to avoid that ogranisms or their waste put in jeopardy humans, animals and the environment and its sutainable use.

Legal dispositions able to be applied at our example

- Confinement: existence of a physical or a chemical barrier between the environment and the organism.
  - GMOs: must be confined if:
    - Category 3 or 4 (not our case: our organism is class 1)
    - Contain a gene that induce a resistance to an antibiotic used in human medicine (this is our case, our E.Coli strain is resistant to kanamycin)
    - Invasive (I think it is not our case)

Legal dispositions able to be applied at our example

- Confinement → restrictions
  - Sample-holder: We have to think about the sample-holder in order that it guarantees that the bacteries inside are never in contact with air, water or anything that will return to the environment.
  - Transport
    - 3 layers: confinement, absorption, exterior wrapping: To transport our prototype we have to think what we wrap with what in order that we can both use it and respect the law.
  - Waste gestion: Waste must be either autoclaved or inactivated with 80% alcohol.
  - It makes us aware of our responsibilities (We have to name a responsible of biological safety.)
  - It forces us to communicate (We have to notify the authorities all our activities and maybe ask an autorisation to use our prototype in the environment.)

→We were looking what we are allowed to do and we discover that the legal demands forces us to think *HOW* to continue our research and build our prototype.

Legal dispositions able to be applied at our example

- Communication
  - Notification before the beginning of an experiment
    - Designation of a person responsible of biological safety.
    - Description
    - Evaluation
  - Information if :
    - Accident
    - Break of the confinement
- Ask for an authorization

Conclusion

- Legal framework is both
  - Strict (it gives restriction for the design)
  - Blurry (because it is not completely adapted)
- It ask our critical responsibility:
  - Evaluation
  - Interests weighing
- The subject is delicate, the following steps will depend of this. Our solution is to avoid problematic by informing correctly and collaborate with legal experts.

Conclusion – opening

- The law is not the only legislator.
- We have not to forget society's opinions:
  - Society has its own normative system (ethics, what is politically correct, …)
  - It also has its own penalty system
  - Even if it is totally legal!
  - Example: PNR59

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13 juin 2008 14:17; Act: 13.06.2008 14:30

Champ d'OGM détruit par des inconnus

Quelque 35 personnes ont pénétré par la force vendredi matin dans le site de l'Institut de recherche Agroscope à Zurich-Reckenholz.

on off

0 Recommander

0 Tweeter

0 +1

par E-Mail

Sur ce sujet

: L'agriculture devrait jouer les prolongations sans OGM

: Les députés rejettent le projet de loi sur les OGM

Une faute?

Signalez-la nous!

Ils ont partiellement détruit un champ d'essai de blé génétiquement modifié.

Cinq d'entre eux ont été arrêtés peu après dans les environs, a indiqué la police. Il s'agit de Suisses, deux hommes et trois femmes, âgés de 29 à 39 ans. Le montant des dégâts et les motifs de l'action ne sont pas encore connus.

C'est sur ce site près de Zurich que des essais controversés d'OGM sont effectués. (keystone)

Essai controversé

L'Université de Zurich et l'Ecole polytechnique fédérale de Zurich (EPFZ) ont planté 2000 m2 de blé transgénique sur ce site ce printemps. Le blé a été traité pour résister aux champignons parasites. Il s'agit d'étudier la qualité du blé et la biosécurité.

Cet essai est effectué dans le cadre du programme national de recherche PNR 59 «Utilités et risques de la dissémination des plantes génétiquement modifiées». Le Département fédéral de l'environnement l'a autorisé.

Un recours contre ce projet est néanmoins pendant, mais il n'a pas d'effet suspensif. Il a été déposé par douze organisations de défense de l'environnement, des consommateurs et des paysans, dont Greenpeace et Bio Suisse.

(ats)

A national research programm about GMOs took place in Switzerland, during this research a field was cultivated with GMO wheat. The project was totally legal, respectful of conditions edicted by the law and had obtained all the necessary authorizations. But after a private denunciation, a journalist revealed what was cultivated there and it created a scandal. People came at night and destroyed the field. In doing so, they did not respect the elementary security precautions and contributed in spreading the GMOs outside, hazarding a contamination of the surrounding.

The mistake of the researcher was to have only cared about law and have forgotten society's opinion. Our subject is delicate, we have to be aware of society's opinion, respect them and inform society, if we do not want to create a scandal.

References (mostly in french)

- http://fr.wikipedia.org/wiki/Organisme_génétiquement_modifié
- http://www.alnatura.de/de/gesetzeslage-und-zulassung-von-gentechnisch-veraenderten-organismen-gvo
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- http://www.efsa.europa.eu/fr/topics/topic/gmo.htm