THE CHALLENGE OF ANIMAL BIO-OBJECTS AND STARTING POINTS FOR FUTURE GOVERNANCE

BACKGROUND

A number of developments in biotechnology have led to novel relations and various life forms challenging the boundaries between the human and the animal. Biotechnological innovations have produced living objects of animal origins that defy established categories and are therefore hard to regulate by traditional policy practices and related instruments. Chimeras, hybrids, genetic resources, transgenic and cloned animals, and in-vitro meat are perfect examples of biological objects posing challenges to policy makers.

In the face of this development, current ethical and legal vocabularies and their concepts as sense-making tools found within the policy practice should be critically re-examined. Newly engineered animal bio-objects fall in-between the categories that have thus far provided a firm grounding for most legal, institutional and ethical thinking and practice. Thus, starting out new policy actions with a strict animal-human boundary does not work in today’s post-genomic world, for two reasons:

a) New kinds of animal-human hybrid mixtures proliferate in experimental labs, producing previously unseen forms of life that are hard to categorize with old sense-making vocabularies.
b) Even the current animal experiments are full of problems of regulation and ethical concerns, not properly addressed by institutions and conceptual tools deployed today.

At worst, inaccurate and non-neutral concepts already ethically loaded steer the process of governance toward wrong measures, conclusions and political instruments.

CURRENT UNDERSTANDING

The vocabularies and key categories used, such as “the human” and “the animal”, relate directly to how novel entities will be framed as policy objects and how they will be eventually institutionally located and then regulated.

New forms of animal derived life should be accepted as categories of life, thus also as new categories of policy objects, not reducible to already institutionalized domains of life in political, ethical or legal discourses.

To help in adopting a more neutral approach to form the basic set of new tool-box helping governance effort, we propose the new framework of “Bio-Objects” with one key principle and two key operational concepts.

1. Principle of neutral language: new forms of life should be free of ethically biased initial labeling. The concept of “bio-object” could be used in describing any new form of life until its meaning is stabilized, regardless of its origin in within species taxa and type of biotechnology used.

2. Bio-Objectification: the first moments of debate on what is at stake in the new bio-object should include a democratic and inclusive sense-making protocol beyond purely science-based and advisory board driven argumentation.

3. Bio-identification: the debate closure, with decisions on the institutional location of the bio-object, should be transparent and clearly mandated.

FUTURE TARGETS FOR POLICY

We claim the outdated scripts of current ethico-political frames can be overcome and aligned with new bio-objects to get the governance they deserve by following three new targets for policy.

Target 1 Introducing “bio-object” as a more accurate and up-to-date concept for newly emerging, unregulated and experimental forms of life, providing a neutral starting point for policy planning and governance.

Outcome 1 New vocabularies and ethico-legal categories that do not take the human-animal binary as the primary starting point for policy and governance planning. Critically assessing all other key reference categories currently used to describe and operationalize animal life forms (natural, artificial, natural behaviour, suffering, etc)

Target 2 Using “bio-objectification” process as the first phase in sense-making of the new experimental life-form.

Outcome 2 A democratic, open way of discussing what is at stake with the new bio-objects from multiple angles, not reduced to expert hearings and scientific advisory boards

Target 3 Using “bio-identification” as the conceptual moment of debate for the closure and decisions on its governance, where rights and responsibilities are delegated.

Outcome 3 Transparent identification of the institutional location of governance over the new bio-object and related mandates of power.

KEY CHALLENGES IN CURRENT GOVERNANCE INSTRUMENTS INCLUDE

1. Outdated and inaccurate categories of political, ethical and legal identification of new hybrid objects of governance (sense-making operating only with the human-animal axis).

2. The pressing need for new frames of ethico-political deliberations on bio-objects that move beyond current institutional divisions of human vs animal experimentations.

3. The critical analysis of the (speciest) idea of human dignity, which constitutes the basis of our legal and ethical frameworks, as far as it is based on the belief of a radical distinction between human and animals.

4. Identification of the institutional location of novel bio-objects within established topologies of governance at both national and EU-levels.

Contemporary animal experimentation has moved far beyond the use of individual animal bodies as models for human disease. Current ubiquitous use of transgenic animals, cybrids and xenotransplantation and the progressive use of converging technologies put new demands on practice, policy and ethics.
The process through which animal bio-objects are made and subsequently regulated can be seen to be shaped by two recursive processes, those of bio-objectification and of bio-identification. Closure, at least temporarily around a specific bio-identity allows stabilization of both bio-object and governance regimes. The processes are described below:

### REGULATING “THE MAKING OF” BIO-OBJECTS

1. **BIO-OBJECTIFICATION PHASE**
   - Starting out the sense-making with neutral vocabulary not implying an outdated, species specific understanding on new modalities of life
   - Selecting the right reference categories for identification
   - Commensuration (fitting new entities in old categories)

2. **BIO-IDENTIFICATION PHASE**
   - Debating the use of animals, and developing alternatives, in biotechnological procedures
   - Deciding on the research purposes for which new technologies are desirable and should be allowed
   - Deliberating on the legal and ethical status of animals and the new ontological categories
   - Developing new regulatory measures

### REGULATING “READY” BIO-OBJECTS

3. **STABILIZED BIO-OBJECTS**
   - Identification of the institutional location of the bio-object
   - Identification of the mandate of the institution over bio-object at hand
   - Using institutionally available tools to craft the policy and governance structure
CASE STUDIES

1. EXPERIMENTAL ANIMALS
In the case of animals used for experimental research purposes, there is a variety of justifications articulated for the use of animals in research, typically based on a radical distinction between humans and animals and their interests. These justifications are re-introduced when new technological developments challenge the traditional boundary between human and animals, between natural (natural behavior) and unnatural.

Bio-objects and the need for new vocabularies
In general, we can identify two typical approaches to new technological developments in the field of experimental animals: following existing frameworks and categories as used for animals for experimental research; and drafting new regulatory frameworks.

1. The first involves a strategy of commensuration. For example, when regulating animal experiments, key-issues are based on the ethical principles based on the three R’s, and deliberated through a cost-benefit calculus. Animal integrity is, in light of these issues, discussed, typically with little success. Boundaries between human and animals, between natural and unnatural, and between unusual and normal, need to be the central issues in such debate.

2. At the same time, re-interpreting legal categories contributes to bio-objectification and -identification. The second strategy makes it possible to re-introduce new justifications, such as ones based on the social understanding of animals and the imbalance between human interests and animal integrity. The re-opened policy debate can then be used to critically assess the use of animals. Although this might lead to a ritual dance, in which same arguments are repeated, open-ended debates will contribute to rethink and think through the different narratives framing the new bio-object, leading finally to its stabilization.

2. HYBRIDS
Genetic modification of organisms is now commonplace, and a large proportion of these practices involve the mixing of human and animal DNA, cells and tissues. About one third of all animal experiments involve some form of trans-gene engineering. Moreover, since the 90s, xenotransplantation research has aimed at filling the gap in the number of tissues and organs needed for transplantation, with the help of “humanized” animal donors. Biomedicine has been taking a step further and developing human admixed embryos – cybrids – in order to advance basic research in embryology, therapies in regenerative medicine and stem cell research and therapy.

The need for inclusive bio-objectification
It is fair to suggest that these interspecies embryos are particularly vulnerable to hyperbole in scientific, media, regulatory and political domains. However, studies have shown how current examples from the stem cell area concerning interspecies embryos and “re-programmed” stem cells (iPSC), unlike e.g. xeno-transplantation, have not been objects for either a public or political debate. This silence is alarming as it is framed by biomedical policy discourse, embedded in hopes for the future in terms of medical treatments for severe diseases, where questioning the technologies is also seen as threatening this promising future. Thus, these important new technologies get marginalized in a political and ethical context. A better dialogue between science, politics, ethics and policy bodies and public involvements is called for, aiming at new modes of bio-objectification, through “re-politicizing” biomedical research. This may in turn be done through the introduction of the framework suggested here.

3. IN VITRO MEAT
Bio-identification processes around In Vitro Meat seek to shift boundaries around what constitutes ethical animal husbandry to include a model in which muscle tissue that have been cultured from cells is considered meat. In Vitro Meat technology involves an ontological assertion over the status of the tissue that has been grown within a constellation of issues around normal eating, healthy eating, ethical eating, environmentally friendly eating and appropriate eating.

Shifting bio-identification of IV-meat
Core to the claims of the leading proponents of the technology today is the ontological status of In Vitro Meat as being the same as animal meat as it is known today. If it is not meat then it enters the same category as tofu, textured wheat protein and others as a meat-alternative, and subsequently will fail to change the diets of the majority of people. The 2013 press conference, in which a cultured beef burger was cooked and tasted was intended to stabilise the meaning of In Vitro Meat through association with familiar symbolism around food - plates, chef’s whites, lettuce - while retaining the newness of innovative capacity through technological solution.

The consequences of shifting bio-identification
In Vitro Meat is narrated by proponents as a technology with the potential to re-position the socio-ethical relationships between humans and agricultural animals from one of ‘mass slaughterer and mass consumed’ to ‘technically advanced meat curator and mass consumed but not mass slaughtered’. The move does not challenge the normalcy of meat consumption but reconfigures meat consumption in what is presented as an environmentally and ethically superior format.
USING THE BIO-OBJECT FRAMEWORK IN RRI POLICY-MAKING

With the Bio-Object framework, we aim to introduce a value-neutral concept as a starting point for further debate on the status of new entities. Even though the Bio-Object framework is a first attempt to break through these traditional categories and stalemates of governance, further steps are required. The RRI-policy making framework includes concepts that bring in opportunities to face the challenges that we address when using the Bio-Object framework. Both frameworks share the will to achieve transparency and democratic deliberations in science policy, the conceptions of engagement, education, and open access can function as incentives for re-politicizing debate and facilitating ongoing debate.

LESSONS LEARNED FOR FUTURE POLICY

1. Traditional boundaries and dichotomies cannot identify the ontological status of new bio-object categories such as hybrids, cybrids, in-vitro meat, or genetic resources.

2. Commensuration (using old categories to describe new life forms) risks bypassing fundamental debate on the desirability of new technology and the status of animals as novel bio-objects.

3. There is a need to re-politicize bio-medical research: bringing back noise in bio-identification by re-introducing a variety of narratives to bio-identify the object correctly.

4. There is a need to reconsider and break through the traditional dichotomy of animal-human by introducing value-neutral terms such as Bio-Object as a starting point for sense-making within policy practice.