Structural aspects of the ethical assessment: assumptions and implications on animal protection and societal distrust

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Introduction
Multi stakeholder processes and related decisions are complex, especially as all actors play their legitimate role. The generally hold premises that rational partners in multistakeholder decisions processes will end up in a rational defendable decision, in line to their prescribed task as committee appears hard to proof in real world empirical cases (Paula…). The new EU directive 2010/63/EU gives us the opportunity to reflect on 20-30 years of assessment procedures, and to list the factors that facilitate or obstruct the integrity of the ethical review process on animal experimentation.

In my presentation I will address some of the main factors from a system point of analysis that constrain a balanced ethical assessment.

Towards a justifiable decision to use animals in research:
I define *justifiable* in this approach as the realization of an acceptable decision for the maximum number of relevant stake holders. Speaking about animal experiments relevant stakeholders will be the animals, the scientists, the industry, and the citizen/patients/consumers. The interests of the animals are usually voiced by animal protection groups and veterinarian, although with a different focus (wellbeing versus health).

Arbitrariness in assessment process:
When the same or comparable proposal has been assessed differently in two locations, the accusation of an arbitrary decision process might arise, nurturing all kinds of conspiracy stories, reducing trust in society regarding the formal structures of decision making around animal experiment. And in addition scientists might intend to shop at several assessment committees for approval. Hence the opposite of what is intended by animal protection legislation. There are several routes to increase consistency in ethical assessment: (a) standardization of assessment protocols, (b) standardization of the cut off line. What is not acceptable? (c) standardization on the role and accountability of the assessment committee. All three relate to each other and variation in one will multiply the effect in the other routes.

A) Standardization of assessment models
There are lists, cubes, credit points and decisions trees. Each has its own structural advantages and draw backs, not to speak about combinations.

- Lists secure that all committees will check and discuss the same criteria, however the order and individual weight are implicit. The 3 Rs might be regarded as a simple check list, but conflict arises when one stakeholder consider replacement more important than reduction. The list doesn't guide in a specific direction, and is sensitive for local history and cultural commitment.
- Matrix/Cubical makes clear which combination of grades of suffering versus grades of scientific quality (and grades of medical benefit) are acceptable: e.g., the more acceptable is the level of animal suffering when paired with higher medical benefit *and* a higher quality of research (Bateson, 1994}. Gives an direction in balancing suffering against knowledge and therapeutic application.

- Credit points adds weight to multiple aspects, makes more explicit that relevant aspects in the ethical decision can compensate each other. Final grade count and the order of the order criteria considered will not change the picture. All aspects should be independent of each other, as otherwise the criteria are counted/weighed double.
- Decision tree emphasizes the decision points (is this is of moderate scientific importance or substantial scientific importance, if moderate than go to ….). The order is important, as the first decision step might bring you already to a refutation of the proposal. So the next decision points will not be discussed anymore. If the positive answer to the question whether there exists an alternative with less suffering involved, will decline the proposal for an animal experiment: subsequent criteria of scientific value will not be taken into the assessment. Decision tree offers opportunities to include in the beginning of the path legal or political constrains on animal use, e.g., no chimpanzees, only biomedical research for health interventions etc.

A decision model might standardize the elements taken into account and the weight given to some, facilitating a procedural justifiable decision by a better standardization. However, the formation of the assessment committee might color to a large extent the balance toward positive (or negative) decisions. At least three types of formation bias can be distinguished, which are sometimes introduced on political grounds:

- *personal contribution by members to the decision process*: personal bias related to relevant differences in world view (makeable world, given world), position taken regarding the ethical "good world" (anthropocentrism, biocentrism).
- *Professional contribution by members to the decision process:* are members chosen to represent that professional expertise (veterinarians, ethical experts, legal, experts sociologists)
- *Political contribution by members to the decision process:* Do members take a up a political role, arranging voting coalitions to obstruct political unfavorable outcomes of the decisions to be taken (liberal position: less rules to reduce costs by big industry, or more rules to make animal experiments more expensive)

Paula and .. found in a international comparison of the "ethical" assessment committee in USA, Australia, Germany, France…. that all formations showed a specific bias, blocking a genuine ethical discussion on the edge of the argument, and leaving the committee on a level of technical safety constraints or health constraints. They concluded that for a norm finding assessment committee the relevant pro, con and intermediate positions must be carefully balanced to avoid lock in decisions. To organize one's opposition to reach better widely supported decision is not new. In a sense it is comparable to the Trias Politica, the solution Montesquieu proposed to organize democracy in multiparty political decision-making (to avoid arbitrariness of the elite, make the conflict of interests transparent and split the roles of executive and the parliament).

Also The Netherlands is restructuring the assessment context according the directive. There will be:

A. National committee: advisory to the Competent authority (CCD) licensing the research proposals.
B. The board and office of the Central Committee on Animal research (CCD) checking and issuing the licenses of animal research projects.
C. 10-26 Animal experimentation committees (DEC) ,Independent from the laboratory and formulating a pre assessment towards the CCD according the standards set by the CCD.
D. Animal welfare body 3Rs and animal health monitoring

The C level was before 2013 advising to the board of the institute housing the laboratories. Private cases against these decisions caused the board of the institute a lot of paperwork. By shifting the licensing to the CCD, the competent authority becomes the liable actor. In order to avoid a power concentration, the A level should play a critical and constructive role against the CCD, being the competent authority and executive. This implies that the composition of the board of the CCD should be unbiased and according relevant expertise. As it concerns an animal protection legislation, the quality of the decisions (jurisprudence) at least 50% of the board members should subscribe a biocentric position. If the main task is defined to assess the ethical justification, relevant lab animal ethicians, expert on alternative methods, statistic expert, animal welfare expert and legal expert should make up at least 50% of the board, against experts from the industry and academic research with animals which might have in respect to their professional background a more instrumental perspective on the use of animals.

The National committee should not take the role of the executive (the ministry, the CCD, the competent authority), but rather the voice of the relevant stakeholders (national and international). A voice balanced against the three pit falls of bias mentioned above. One has to be careful not to mimic a citizen parliament on laboratory animal issues. Such "parliament" is by definition incomparable with an elected parliament, being the only legislative representing the citizens. However, the selection of the relevant stakeholders and their proportional distribution will be important to let this level function as a proactive think tank. It is advisable to include in their task to advice at own initiative towards the competent authority .

Structural system forces:
Complexity and system analysis distinguish two levels of influences on a multistakeholder process: the level of regimes and the level of landscape. Regimes are socio-technological cultures, with specific professional rules, norms and habits. In the case of laboratory animal experiment the academic regime can be distinguished from the industry regime.

- *Industry regime* is characterized by drivers as ales, cost-benefit, shareholders, stock market dynamics (=trust in robustness and sales). For this regime, barriers are the costs of animals experiments (moving to low income countries) administration/market introduction dossiers, publications (diminishes options for patents). As a consequence this cost-benefit driven regime prefers internationally standardized animal methods , resulting in less difficulties with multinational approval of safety- and functionality tests.

- *Academic regime* is characterized by drivers as publication, wide distribution of knowledge, Merton's CUDOS, number of students and PhD grants , and the development of new advanced, not yet standardized and not yet validated methods . Resulting in experiments with more risks for animals. They consider as barriers the restriction on frontier crossing research questions. Seem to regard assessment questions whether there is an alternative, as superfluous. What count is whether their research idea was honored by a grant of the national funding agency.

Both regimes frame their organization and management differently regarding their use of animals. Interestingly the "national committee" is limited by Brussels to focus only on scientific research with animals. Which seem inconsistent with the task of the animal welfare bodies and competent authority authorizing both industrial and academic animal experiments. Both framings should be well balanced incorporated in the competent authority (NL=CCD) and the National committee.

According to Geels (…) regimes are often subdivided in nested sub-regimes. An interesting tension emerged from the Dutch Trend analysis on Animal experimentation (C. Hendriksen, 2010) with respect to the *sub-regime Academic animal research* and *Academic medical research on human*

subjects. Recent developments on minimal dose experiments monitored by genomic microarrays seems to make experiments on human subjects more safer, and in addition closer to the target groups. The drivers for this development in the *sub-regime Academic animal research* are : monitoring real-time physiological processes in human beings closer to more effective health therapies. For the *sub-regime Academic medical research on human subject* the drivers are the extended interventions options of the health providers. However, a barrier is the personal accountability, which is traditionally provided by the negative animal tests. Now, genomic monitoring redefines the health provider as the accountable actor for the possible harm of the patient. The individual health providers in the academic medical regime will therefore stick to experimental safety test on animals, except when their risk on liability will be backed by the medical ethical committee (or national medical ethical committee (CCMO)).

- Landscape refers to the slow changes in the society like demographics. Are we implementing an assessment system according the past or for the future? For this reason we performed two years ago a societal trend analysis for the ministry of Health. What might be the challenges of the future, and how to anticipate to the societal debate on laboratory animal issues 2013-2025?.

An example of landscape change are the demographic changes like a raising number of elderly might induce in the academic and industry regime more research on end of life diseases , and in addition a shift from cure to quality of (end of) life, e.g., minimizing cognitive and motor disabilities (not only physiology, but human-machine interfaces, which require more experiments with non-human primates , dogs, or human beings when permitted by the Medical ethical committees). If the medical ethical committees still demand animal experiments prior to experiments with human subjects , a legal and societal debate might raise. An option to anticipate to these and other human-animal conflicts is by designing the organizational and accountability structures parallel to each other.

Literature:

Bateson (1992) New scientist, 25 April, 33