Harm-Benefit Analysis According to Directive 2010/63/EU, Article 38: What Does It Mean and How To Realize It?

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Summary

This paper will attempt to address what a harm-benefit analysis of a project, taking ethical considerations into account, actually means in practice. Different stages of the harm-benefit analysis will be described, including: determining all the facts that are relevant to assess the benefits of the experiment and the burden on the animals; classifying the predicted benefit in degrees (comparable to the classification of harm), for example 'small', 'medium' and 'high'; and the competent authority must determine and assess the relevant criteria of the evaluation independent of the statements by the experimenter. It will be pointed out that a project can only be authorized if the benefit outweighs the harm. The weighing of competing interests has to be transparent and the competent authority must give a justification for its decision. In addition, this paper will describe how to decide when there are still doubts and will emphasize that if expert opinions are needed, their impartiality is crucial. Finally, principles and ethical conceptions which can be useful in weighing conflicting interests will be described.

Keywords: harm-benefit analysis; classification of benefit; independent and impartial evaluation; outweighing of benefits; transparency

Introduction

One of the most important regulations in Directive 2010/63 is Art. 36 No. 2: "Member states shall ensure that no project is carried out unless a favourable project evaluation by the competent authority has been received in accordance with Art. 38."

Project evaluation in accordance with Art. 38 means

- an evaluation of the objectives of the project, especially the predicted scientific benefits
- an assessment of the compliance of the project with the requirement of replacement, reduction and refinement
- an assessment and assignment of the classification of the severity of the procedure
- a harm-benefit analysis or cost-benefit analysis of the project taking ethical considerations into account

The question arises: What does "harm-benefit analysis of the project (...) taking into account ethical considerations" mean?

I shall try to give an answer in the following 12 points.

1. Fair balancing of harm and benefits

Harm-benefit analysis means a fair balance between the costs for the laboratory animals and the benefits for humans (and perhaps animals, too).

Consideration No. 39 of the Directive states: "The likely harm to the animal should be balanced against the expected benefits of the project."

The materials to Article 7 paragraph 3 of the former German Animal Protection Act state: "Before an experiment on animals can be permitted, the likely pain, suffering, and harm of the animals must be balanced against the objective of the experiment and its prospected benefits." (translation mine).

The German Union "Veterinarians for protection of animals" states in its Paper No. 50: "An animal experiment can only be permitted, if its omission is worse than its execution because its benefit is higher than its harm." (Tierärztliche Vereinigung für Tierschutz e.V. [TVT], translation mine).

2. Determination of all relevant facts

Before costs and benefits can be fairly balanced, the competent authority must determine all facts that are relevant for such an evaluation.

All facts that are relevant for the classification of the experiment as "mild", "moderate" or "severe" must be determined completely (authorization of an animal experiment is unlawful, if the decision by the authority is based on untrue or incomplete facts).

Also, all facts that are relevant for the evaluation of the benefit must be determined completely.

3. Classification of the predicted benefit

It is necessary to classify the predicted scientific benefits in three or four categories, according to the classification of pain, suffering, distress, and harm.

The process of weighing up the costs for animals against the benefits for humans is transparent and well-founded, if not only pain, suffering, distress, and harm are determined by the three degrees "mild", "moderate" and "severe", but also the predicted benefits are determined by comparable degrees like "small", "medium" and "high".

Criteria for this classification must still be determined, as well as concrete examples (like in Annex VIII of the Directive).

4. Certainties vs. likelihoods

It has to be taken into account that pain, suffering, distress and harm of laboratory animals are always (or often) certain whereas the predicted benefits are only more or less likely and can only be realized in the near or not so near future.

If an animal experimenter says that the planned procedure will have benefits concerning avoidance, prevention, diagnosis or treatment of certain diseases, the following questions must be answered:

- What's the degree of probability that these benefits will really be achieved?
- In which time frame can these benefits be achieved?
- How many people can make use of these benefits?
- In case of benefits concerning a disease: How severe is this disease? Can it already be cured or is it incurable up to now?

Before making a decision about whether the experiment is to be authorized or not, the degree of probability to achieve the predicted benefits must be determined.

But even if this is possible, a great unsolved problem will remain: How to balance benefits that are more or less probable and can only be achieved in the near or not so near future against pain, suffering, distress, and harm that will occur for sure and at once?

5. Independent project evaluation by the competent authority

The competent authority itself must assess the costs and benefits and classify them in comparable or corresponding degrees. This cannot only be done by the experimenter or other persons involved in the study.

According to Directive 2010/63/EU Art. 36 No. 2, the project must be evaluated by the competent authority itself. The experimenter may propose a certain evaluation, but he does not have the final say.

Consideration No. 39 of the Directive states: "Therefore, an impartial project evaluation independent of those involved in the study should be carried out as part of the authorisation process of projects involving the use of live animals."

This is in contradiction to the judgment of the Higher Administrative Court in Bremen of December 11, 2012. The Court states: The authority is only allowed to make a plausibility check. It is not allowed to replace the experimenters' benefit evaluation by its own. Concerning the assessment of the benefits – and also concerning the question whether the requirement of replacement, reduction and refinement has been met – the experimenter must have the final say because of his freedom of research (translation and interpretation mine; note: the freedom of research is granted by the German Constitution).

This judgment is made on the basis of the old German Animal Protection Act. The new law – which has been drafted to implement the Directive 2010/63/EU – will probably come into force in spring/summer 2013.

The Directive states clearly that the competent authority has to make its project evaluation "independent of those involved in the study" (Consideration No. 39). Therefore it is impossible that the authority is bound on an assessment or evaluation made by the experimenters.

The authority must assess the predicted scientific benefits independently of what the experimenters say. Furthermore, the authority has to assess whether there are still unused methods to replace, reduce or refine the experiment, also independently of what the experimenters state.

So, the German Administrative Court of Bremen must change its jurisdiction because national laws of member states must be interpreted in accordance with the Directive.

In order to assess the scientific benefits and whether there are still unused methods to achieve these benefits without animals, with fewer animals or with less pain, suffering, distress, and harm, it might be necessary to consider expertise. This is in the line with the Directive, which states that the competent authority shall consider expertise *in particular* in the following areas (see Article 38 No. 3):

- scientific use for which animals will be used including replacement, reduction and refinement in the respective areas
- experimental design, including statistics where appropriate
- veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate
- animal husbandry and care, in relation to the species that are intended to be used

6. Benefits must outweigh the harm

For a favorable project evaluation, the competent authority has to make sure that the benefits outweigh pain, suffering, distress, and harm. This means that the benefits must be higher or more important than the costs for animals (Hirt, Maisack and Moritz 2007, 296).

Art. 38 No. 2 states that pain, suffering, distress, and harm must be justified by the expected outcome.

A justification is only possible if the outcome is so important that it outweighs pain, suffering, distress and harm. This means

that the benefit must be so great that it is not only equal to pain, suffering, distress, and harm but greater.

Most of the legal justifying reasons are based on the principle that a harmful action can only be justified if its benefit is greater than its harm (or: if it is carrying more weight).

This means practically:

– If pain, suffering, distress, and harm are assessed as "mild", the predicted benefits must be important enough to be assessed as "medium".
– If pain, suffering, distress, and harm are assessed as "moderate", the predicted benefits must be important enough to be assessed as "high".
– If pain, suffering, distress, and harm are assessed as "severe", the predicted benefits must be important enough to be assessed as "very high".

This chart is in accordance with Directive Art. 15 No. 2, which generally prohibits severe pain, suffering or distress that is likely to be long-lasting. Such pain, suffering, distress, and harm are to be assessed as "very severe". They could only be justified by a benefit assessed as "very, very high". This might be nearly impossible. Therefore the safeguard clause in Art. 55 No. 3 can only be applied in extreme exceptional cases.

7. Transparency

Procedural compensation: The scientific benefits on the one side and pain, suffering, distress, and harm on the other side are positions that can hardly be compared. They are incommensurable. The harm-benefit analysis required by Art. 38 No. 2 will therefore often lead to arguable or doubtful results. So, compensation is required. This compensation is to organize the administrative process in a way that is as transparent and comprehensible as possible (Art. 38 No. 4: "The project evaluation process shall be transparent. [...]").

What are the potential procedural flaws in the course of consideration?

1. No consideration
   This means that the competent authority does not weigh up or appreciate the values.
2. Deficiency in the consideration
   This means that there are important facts (for example, facts to assess the benefits as "medium" or facts to assess pain, suffering, distress, and harm as "moderate"), but the authority has not made them out or does not take them into account.
3. Another flaw is to make decisions on the basis of untrue facts or not in accordance with the law or up-to-date scientific knowledge.
4. Another flaw is to underestimate or overestimate one of the conflicting interests.

8. The authority must give a justification for its decision

The authority has to describe in detail all facts taken into account and all considerations that were important for its decision. Eventual flaws in the course of the consideration cannot be detected without such a statement.

9. How to decide when there are still doubts

How to decide when there are still doubts whether the predicted benefit is great enough to outweigh pain, suffering, distress, and harm? Does the authority then have to give the authorization anyway? Or do they have to deny it?

There are scientists who say "*in dubio pro libertate*", meaning that the authorization must be given even if doubts are remaining. In my opinion, the authorization must be refused if reasonable doubts are remaining and cannot be removed.

A favorable project evaluation according to Directive Art. 36 requires that the authority is sure that the predicted benefits are great and important enough to outweigh pain, suffering, distress, and harm.

The former Directive 86/609/EEC Art. 12 No. 2 stated: "Where it is planned to subject an animal to an experiment in which it will, or may, experience severe pain which is likely to be prolonged, that experiment must be specifically declared and justified to, or specifically authorized by, the authority. The authority shall take appropriate judicial or administrative action *if it is not satisfied* that the experiment is of sufficient importance for meeting the essential needs of man or animal." (emphasis mine).

According to the former directive, *the authority had to be satisfied* that there was a scientific benefit great and important enough to outweigh pain, suffering, and distress, even if they will be, or may, severe and long lasting (see Hirt, Maisack and Moritz 2007, 311). The new Directive 2010/63/EU intends not less but more protection of animals.

The question how to decide if doubts are remaining cannot depend on whether pain, suffering, and distress are severe, moderate, or mild. Therefore an authorization can only be given if the competent authority is satisfied that the benefits are important and great enough to outweigh pain, suffering, distress, and harm. It must also be satisfied that the principles of replacement, reduction and refinement are met.

10. Impartiality of expert opinions crucial

In order to compensate the difficulty of outweighing incommensurable positions, it must be guaranteed that external experts have sufficient distance to the interests of those who are involved in the study. Consideration No. 39 of the new Directive states: "an impartial project evaluation independent of those involved in the study should be carried out".

For this reason scientists with a close relationship to persons who might have an economic or other interest in the animal experiment being authorized and realized should not render an expert opinion.

Example:

The Higher Administrative Court in Bremen made its judgment on the basis of an expert opinion. The expert had told the judges that pain and suffering of the primates were "mild", or – at most

– "moderate". This expert is a permanent employee of the "Göttinger Primatenzentrum". He has a leading position there. The "Göttinger Primatenzentrum" is the largest breeder and supplier of laboratory primates in Germany and, therefore, obviously interested in animal experiments with primates being continued. For this reason the impartiality of this expert opinion could be questioned, notably because there have been other expert opinions which came to different assessments.

11. Principles which can be helpful to evaluate animal experiments

Principles that can be deduced from single regulations in the Protection of Animals Act can – perhaps – then be useful to weigh up the conflicting interests.

The Animal Protection Acts (of Germany, Austria and Switzerland) contain some regulations that propose or demand a specific outcome of consideration for certain conflicts between the interests of animals and the interests of humans. These are mainly regulations not for animal experiments but for other conflictive situations.[1] There are also regulations that do not determine an outcome, but describe the way how to balance such conflicting interests.[2]

Often, it is possible to deduce a general principle from such a regulation that forms the basis of this regulation and that can be convenient so solve other conflicts between animal and human interests, too.

In this way, we can deduce a certain number of legal principles that can be used to evaluate animal experiments.

12. Determining the underlying ethical conceptions

Ethical conceptions differ. But the Animal Protection Acts in Germany, Austria and Switzerland are based on some leading decisions that form the basis of the detailed regulations. For a harm-benefit analysis according to Directive Art. 38, we can only use ethical conceptions that are in accordance with these leading decisions.

It is therefore necessary to first deduce the leading decisions that form the basis of the Animal Protection Act. Then, the ethical conceptions that are in accordance with all these leading decisions have to be determined. Others are to be ruled out. We try to apply the law and if we want to do so, we cannot apply ethical conceptions that are conflicting with the leading decisions. (In other words: René Descartes, but also Immanuel Kant are not useful for the interpretation of our present laws.)

Perhaps the ethical conceptions in accordance with the law and its decisions have correlating statements that can be useful for a fair balance. So, let us find the correlating statements of these ethical conceptions that are in accordance with our Animal Protection Acts and then see how we can use them to weigh up the conflicting interests and to achieve a fair balance.

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[1] This group determines for the weighing of certain conflicts already a distinct outcome: e.g., for purposes like "advertising" or "exhibiting animals for show" it is not allowed to inflict pain, suffering, distress, and harm on animals (see Article 3 No. 6 TierSchG 2013). Such a distinct outcome in the field of animal experiments will be found, e.g., for the development or testing of weapons and ammunition, which is prohibited by Article 7a paragraph 3 TierSchG 2013 and for the development of tobacco products, detergents, or cosmetics, which are generally prohibited by Article 7a paragraph 4 TierSchG 2013.

[2] Article 7a paragraph 2 No. 4, sentence 2 TierSchG 2013 states that inflicting pain, suffering, or harm is not allowed if they are inflicted for reasons to avoid workload, time, or monetary costs. This means generally that economical reasons are not sufficient to justify the inflicting of pain, suffering, or harm on animals.