A sheep in wolf's clothing

Why does the harm-benefit analysis not get grip on ethical issues in animal research

Copenhagen, DK
Nov. 8th 2022

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Why the title?
HBA in Directive 2010/63/EU

The harm-benefit analysis (HBA) has been introduced with great expectations. **BUT: Could it develop impact since its introduction in EU member states?**

Outline

Article 38 (2) d Directive 2010/63/EU: Project Evaluation

a **harm-benefit analysis** of the project, to assess whether the **harm** to the animals in terms of suffering, pain and distress is **justified** by the **expected outcome taking into account ethical considerations**, and may **ultimately benefit** human beings, animals or the environment;

- **Introduction**
- **Analysing the HBA**
    - Inner morality of law
   - Problems of the HBA
- **Conclusions**

By drawing from "Ethics of Law," I will argue that the HBA in its present formulation cannot get grip on ethical issues in animal research.

Morality of law
Eight routes to disaster (Fuller 1963)

The first and most obvious [route to disaster] lies in a failure to achieve rules at all, so that every issue must be decided on **an ad hoc basis**. The other routes are: (2) a **failure to publicize**, or at least to **make available to the affected party** the rules he is expected to observe; (3) the **abuse of retroactive legislation**, which not only cannot itself guide action, but undercuts the integrity of rules prospective in effect, since it puts them under the threat of retrospective change; (4) a failure to make rules **understandable**; (5) the **enactment of contradictory rules** or (6) rules that require conduct **beyond the powers** of the affected party; (7) introducing such **frequent changes** in the rules that the subject cannot orient his action by them; and finally, (8) a failure of **congruence between the rules as announced and their actual administration**.

Fuller, The Morality of Law 1963, 39
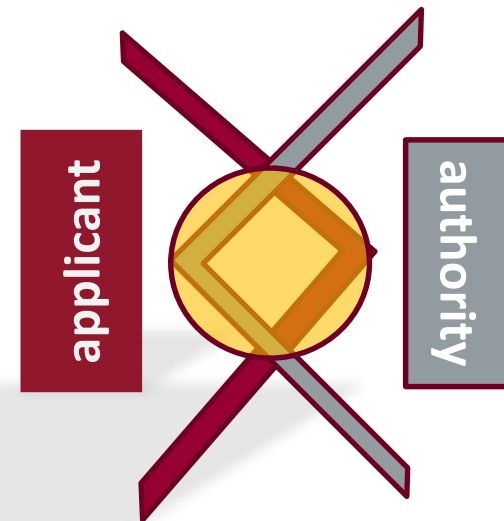
Morality of law
Eight routes to disaster (Fuller 1963)

Certainly there can be **no rational ground for asserting** that a man [person, H.G.] **can have a moral obligation to obey a legal rule** that... [follows the routes of disaster; H.G.]...

Can such routes of disaster be identified in the HBA as presently formulated in the directive?

...in the sense that applicants might have a l**egal but no rational ground** for having the moral obligation to obey the legal rule (HBA)...

applicant

authority
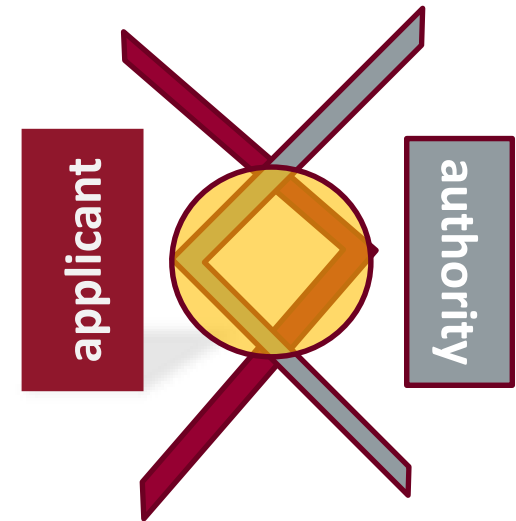
Morality of law
List of criteria

Criterion RoL	Understanding	Criterion met?
General	Not ad hoc or case specific	
Public	Accessible and not secret	
Prospective	Enacted beforehand	⊗
Understandable	Clear and not opaque	⊗
Non-contradictory	Consistent with other rules	⊗
Possible commands	Ought implies can	⊗
Stable	No frequent changes	⊗
Congruence	Administration matches rule	⊗
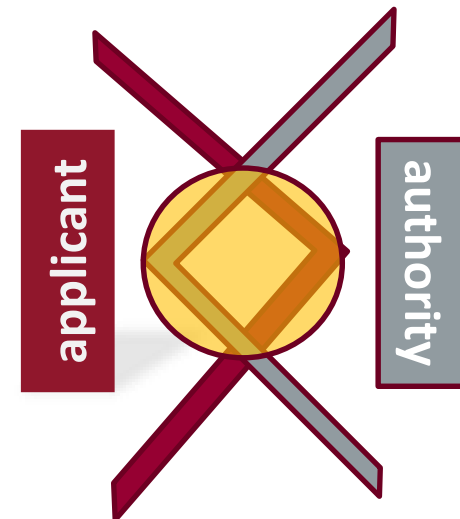
Lacking a **standardized, explicit methodology** that is enacted **prospectively**, **runs the risk of going beyond what is legally required** in the project evaluation: This **might violate the principle of legality** (i.e., that **authorities** are only allowed to take **decisions** on the basis of **applicable law**).

Morality of law
Understandable vs. opaque

...only understandable rules can guide the decision:

Is it clear/intelligible what has to be done in a HBA?

- Clear to the applicant and the authority/committee members?

a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is **justified** by the **expected outcome taking into account ethical considerations**, and **may ultimately benefit** human beings, animals or the environment;

- What does "justified" mean?

- In how far do "outcome" and "benefit" hang together?

- What is it to take "ethical considerations into account"?

- What is the timeframe for "may ultimately benefit"?

Morality of law
Understandable vs. opaque: Belgium

Belgish example: "However, the **European Directive does not state, in any specific way, how to conduct an HBA and how to make sure that benefits will truly outweigh the harm**. Therefore the **practical implementation of HBA is not clear for many project applicants and members of ethics committees**. For this reason, Brussels Environment, in cooperation with the Brussels Commission for Animal Experimentation, has **developed an HBA** which has been **integrated into the current project evaluation template**." (GDLA 2022)

- It is far from clear what one has to do when carrying out an HBA.

⇒ Criterion „understandable": **Not OK**

Since the committee/national authority/applicants are not provided with a clear methodology, the principle is violated.

standardized, explicit methodology that is enacted prospectively

Morality of law
Ought implies can: Knowledge vs. benefit

messerli Research Institute

> **...only rules that prescribe actions within the power of the affected can guide the decision:**

Can actual benefit (that is asked for) be achieved by the applicant/project?

Assessment of projects with **early applied benefits**, such as **a new vaccine to deliver improved health for humans**, where the **benefits** can be easily recognised and may even be quantifiable, in terms of **patients affected, lend themselves much more readily to a harm/benefit assessment** than a project where **advancement of knowledge** in a particular scientific discipline is the primary benefit expected. (NCA 2013, 21)

Systematic problem

- **benefits** are **typically NOT the outcome** of projects; knowledge not benefit!

- **Research is "necessary, but not sufficient"** to achieve applied **benefits** (Eggel/Grimm 2018): **Knowledge vs. benefit**

...only rules that prescribe actions within the power of the affected can guide the decision:

Can a HBA be prepared by applicants to be carried out by the competent authority afterwards?

Pragmatic problem: *What* goes *how* into *which* equation?

Theoretical problems: Incommensurability

Weighing of **non-comparable**, sometimes abstract benefits arising from different types of research programmes is **very difficult** to perform objectively. (NCA 2013, 22)

Comparing (i.e. weighing) of non-comparable benefits and harms is not only difficult, **but logically impossible**. => misguided idea in the HBA

Morality of law
Ought implies can

…only rules that prescribe actions within the power of the affected can guide the decision:

Can a HBA be prepared by applicants to be carried out by the competent authority afterwards in a transparent and clear-cut manner?

Systematic problem: achieving benefits is not within the power of the applicant => promise dimension

Pragmatic problem: Unclear *what* goes *how* into *which* equation?

Theoretical problems: Incommensurability

…these problems turn the **HBA (in its present formulation) into a mission impossible** that has still to be carried out in every project evaluation.

Morality of law
Congruence vs. mismatch
of rules and their administration

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… rules that are announced can only guide decisions if they are administered as intended:

How they are intended, is rather unclear…

Sweden: "Through in-depth analysis of 18 applications and decisions of ethical reviews, we found that there are **recurring problems** within the ethical review process in Sweden. **Discrepancies between demands set by legislation and the structure of the application form** lead to **submitted information being incomplete by design**. In turn, this **prevents** the Animal Ethics Committees from being able to fulfill their **task of performing a harm–benefit analysis** and ensuring Replacement, Reduction, and Refinement (the 3Rs). (Jörgensen et al. 2021)

…**comparable projects** might be **evaluated differently** in different member states until a standardized, explicit methodology that is enacted prospectively

Conclusions

- As long as it is unclear how to carry out the HBA, project evaluations are on shaky grounds in this regard

- Rejecting projects on the basis of the HBA therefore becomes a risky enterprise for authorities

- …what if an applicant's proposal is rejected on the basis of the HBA and she decides to file an appeal?

- Lacking a standardized, explicit methodology that is enacted prospectively and can be referred to, the rejection might not hold (for good reasons).

The HBA in its present formulation is (for good reasons) a sheep in wolf's clothing that cannot get grip to solve the ethical issues in animal ethics.

Conclusions

"Certainly there can be **no rational ground for asserting** that a man [person, H.G.] **can have a moral obligation to obey a legal rule** that… [follows the routes of disaster; H.G.]"

Fuller 1963

…but how to get a standardized, explicit methodology that is enacted prospectively is still an open question.

Solution

Discourse model and metric model
(Grimm/Olsson/Sandøe 2019)
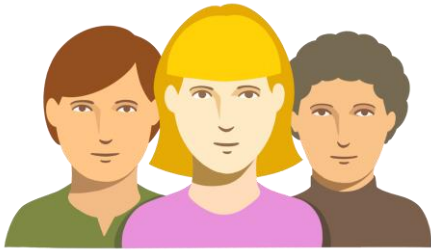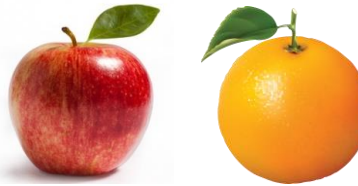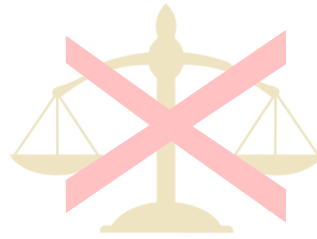
| Discourse model | Merge the two… | Metric model |
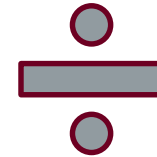
- Following a clear and **transparent procedure**

- Addressing **criteria** that are **defined** beforehand

- **Document reasons** pro & con

- Decision **at the discretion of the committee**

- ~~"taking into account ethical considerations"~~

Thank you very much for your attention!

Special thanks to : Norbert Alzmann, Matthias Eggel, Erich Linder, Vera Marashi, Anna Olsson, Peter Sandøe, Svenja Springer

Morality of law: Clear methodology
The minimum of necessary clarity (Grimm et al. 2019)

HBA: What needs to be clear…

- a procedure that transparently **aggregates total harms and benefits** into a final HBA outcome

- a defined **set of criteria** which comprise the **harm and benefit dimensions** to be included

- the relative **weights/importance** of the individual criteria (modulating factors)

- **operational factors** to identify and measure how well each criterion is fulfilled

applicant
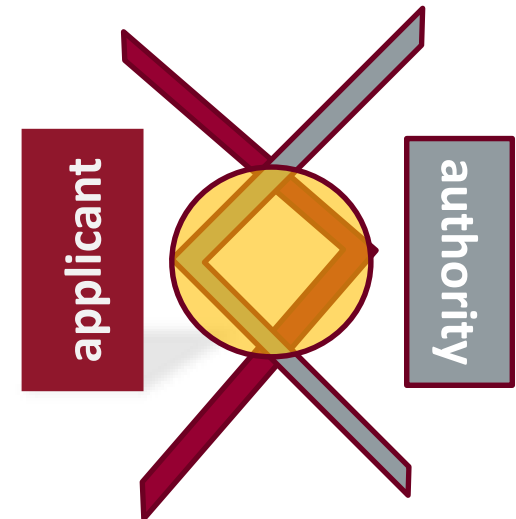
authority

Transparent interchange of applicant and the competent national authority: Both would speak about the same thing when speaking about the HBA!
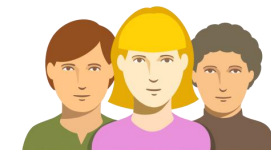
Discourse model
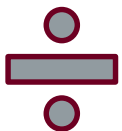
Metric model

- NCA 2013: National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes Working document on Project Evaluation and Retrospective Assessment Brussels, 18-19 September 2013

- GDLA 2022: Guidance Documents Laboratory Animals: https://leefmilieu.brussels/sites/default/files/user_files/2.guidance_for_harm-benefit_analysis.pdf

Testbox: expertise and representation

1. **Scientific & Science-related expertise**: includes members with s... expertise/background and with expertise in experimental design or experimental procedures, research techniques and statistical an... statistician or a person with expertise in statistics
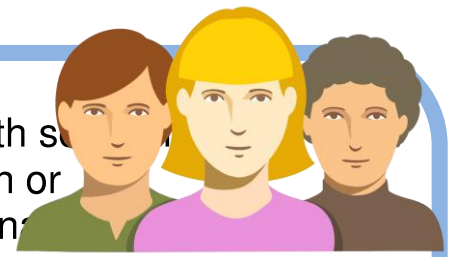
2. **Veterinary & Animal health and welfare**: inclu... for overseeing the health, welfare, housing and ... designated veterinarian.

3. **Legal expertise:** Including lawyers, judges and members with a degree in Law.

4. **Ethics:** includes members with expertise/experts in ethics [in the Danish committee, a member appointed by the Board of Animal Ethics]

5. **Alternatives to animal experiments:** members with expertise in alternatives to animal experiments/research or alternative methods.

6. **Other technical expertise:** only in Denmark - one member appointed by the Danish Research Council for Technology and Production and 1 member from the Danish Industry.

7. **Representation of special interest groups**
   - 7.1. **Animal welfare/protection:** representatives of animal protection' or welfare' non-profit organizations [NGOs]/associations or appointed by these associations to represent their interests
   - 7.2. **Patients:** only in Denmark – one member appointed by a patients' association

8. **Society representation:** includes references to "lay persons", public interest representatives or independent persons.

Discourse model: evaluation in committees

Lit: ANIMPACT

Ethics in the Directive 2010/63/EU

Discourse model and metric model (CH)
(Grimm/Olsson/Sandøe 2019)

The idea of the harm-benefit analysis (HBA)

Instrumental essentiality

Is the proposed experiment appropriate and necessary to achieve the research goal?

3Rs, but goal is out of question

Goal-related essentiality

Is the goal of the experiment sufficiently important to justify the harms caused to the animals?

Goal is in question, even if in accordance with the 3Rs

Health

Knowledge

Life Quality

S/P/D

Duration

Alzmann, N. (2010), Table 14:
Overview on the use of different categories in the analyzed catalogues of criteria

1) Unter der Voraussetzung dass bei der Einteilung der Schweregrade die Beurteilung anhand des Schweizer Belastungskataloges durchgeführt wurde, in dem die Dauer zur Einstufung des jeweiligen Belastungsgrades mit einbezogen wird.
2) Nicht Teil der Checkliste zur Güterabwägung bei Scharmann und Teutsch, über diese Aspekte soll der Versuchsansteller jedoch im Vorfeld reflektieren.
3) Die Thematik der Alternativen behandelt Maisack ausführlich im Vorfeld der Nutzen-Schaden-Abwägung
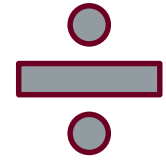4) Belastung durch Haltungsbedingungen fließt in den „Actual discomfort" ein.

V.   Criterion is used
n.v.   Criterion is not used
         Benefit categories
         Animal categories
         Husbandry conditions
         Qualification/monitoring
         Intrinsic value

Kriterium / Autor		Porter 1992	dCB&T 1994	Scharmann/Teutsch 1994	Mand 1995	Stafleu et al. 1999	Maisack 2007	SAMW/SCNAT 2007
Nutzen	[1a] Gesundheit	V.	V.	V.	V.	V.	V.	V.
	[1b] Grundlagenforschung	V.	V.	n.v.	V.	V.	V.	V.
	[1c] Ökonomisch motiviert	n.v.	n.v.	n.v.	n.v.	V.	n.v.	n.v.
	Umwelt/Lebensqualität	n.v.	n.v.	n.v.	V.	n.v.	V.	V.
	Gesundh. v. Tieren	V.	V.	V.	V.	n.v.	V.	V.
	Beitrag zu 3R	n.v.	V.	n.v.	n.v.	n.v.	n.v. 3)	V.
	[10] Zeit bis Nutzbarmachung	n.v.	n.v.	V.	n.v.	n.v.	n.v.	n.v.
[6]	Wahrscheinlichkeit… …der Nutzbarmachung	V.	V.	n.v.	n.v.	n.v.	V.	V.
	…das Ziel zu erreichen	V.	V.	n.v.	V.	V.	V.	V.
	Übertragbarkeit auf den Menschen	n.v.	V.	n.v.	V.	V.	n.v.	n.v.
	[16] Veröffentlichung	n.v.	n.v.	n.v.	n.v.	n.v.	n.v.	V.
Schaden	[2] Schmerzen/Leiden/ Schäden und Distress	V.	V.	V.	V.	V.	V.	V.
	[13] Schaden differenziert in physisch/psych./sozial	n.v.	n.v.	V.	n.v.	n.v.	V.	n.v.
	[11] Schmerz: Intensität in Verbindung mit Dauer	n.v.	V.	n.v.	V.	n.v.	V.	V.
	Belastungen durch Haltung/Transport			durch Haltung		durch Haltung in Vorbereitung od. im Experiment		
	[3] Dauer der Belastung							
	[12] Dauer in Bezug zur Lebensspanne							
	[4] **Tierzahl**							
	[5] **Komplexität**							
	[14] **Alternativen/**weniger/ schonender möglich?							
	Weitere TVers. z. Folge?	n.v.	n.v.	n.v.	n.v.	n.v.	n.v.	V.
	[7] **Haltungsbedingungen**	V.	V.	n.v. 2)	V. verfeinert	n.v. 4)	V.	V.
	[8] **Qualifikation**	V.	V.	n.v. 2) auch Anz.des Personals	V.	V.	n.v.	V. 3R-Kenntnisse
	spezif. Tier-Kenntnisse							V.
	[15] **Nachsorge, Über- wachung, Betreuung**	V.	V.	n.v. 2)	V.	V.	V.	V.
	[9] **Intrinsischer Wert**	n.v.	n.v.	n.v.	n.v.	V.	n.v.	n.v.

The metric model made in Austria…

Ethics in the Directive 2010/63/EU

Discourse model and metric model
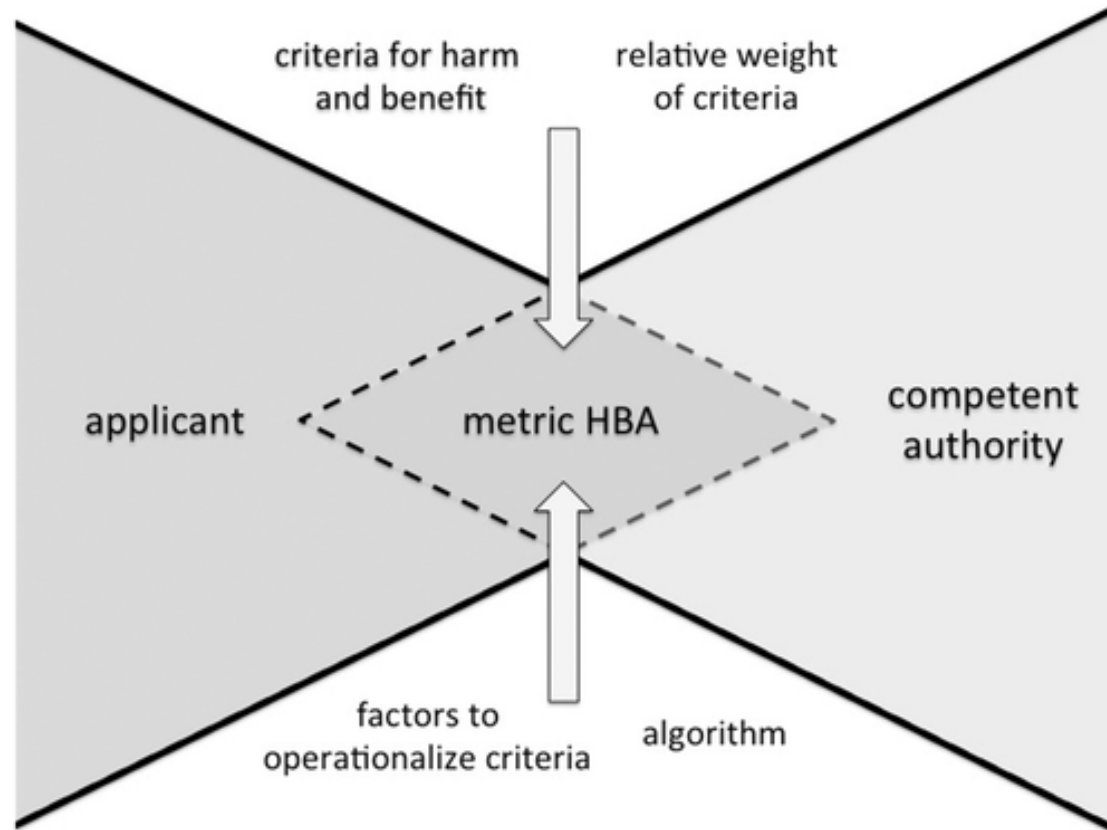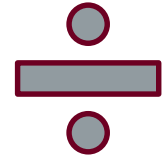(Grimm/Olsson/Sandøe 2019)

Metric models

Figure 2. Components of the metric harm–benefit analysis (HBA) that systematically guide application and evaluation

Turning Apples into Oranges
The Austrian Metric Model

Method of quantification

Benefit/probability

25%	25%	25%	25%
WZ	ÜZ	VD	VW

($\boxed{0}$ + $\boxed{0}$ + $\boxed{0}$ + $\boxed{0}$) /4

($\boxed{0,00}$) /3

harm

WZ = Wahrscheinlichkeit der Ziel-
erreichung
ÜZ = Übertragbarkeit der Versuchs-
ergebnisse auf die Zielspezies
VD = Versuchsdesign
VW = Verbreitung des Wissens

(Tn x SPT)   Summe (n x TZF1 x SPx) für alle Schweregrade

Punkt für den Tod   +   Belastung

0,00	0,00

Gesamtschaden

0,00
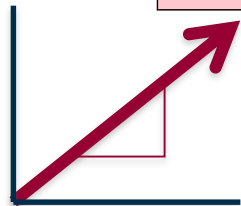
Nutzen   Nutzbarmachung/3   Nutzenfaktor

($\boxed{2,00}$ + $\boxed{0,00}$) x $\boxed{0,00}$

(Wert zwischen 0 und 1,0)   (Wert zwischen 0,17 und 1,0)

Gesamtnutzen

0,00

n   = Anzahl der Tiere
TZF1 = Tierzahlfaktor für 1 Tier
SPx = Faktor für den
zugeordneten Belastungsgrad
Tn   = Anzahl der Tiere die projekt-
bedingt sterben oder getötet
werden
SPT = Schadenspunkt für den Tod
eines Tieres