Rethinking the 3Rs: From Whitewashing to Rights

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1 Introduction: Widespread Acceptance and Regulatory Failure of the 3Rs

Few other issues have prompted as many legislators to adopt legal instruction on the “proper” use of non-human animals (hereinafter referred to as animals) in medical and scientific research. Today, the 3Rs (replacement, reduction, and refinement of animals in scientific procedures) are globally accepted by a vast majority of states (Blattner, 2014); and prominent international organizations, such as the World Organisation for Animal Health (Terrestrial Animal Health Code, 2018, Article 7(8)(3)) and the Council of Europe (Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, 1986, Articles 6(2), 7 and 8). Widespread acceptance of the 3Rs is a notable achievement, since animal law is a relatively young field of law, and attitudes about the human-animal relationship diverge sharply across societies.

As progressive as this established body of law appears, the rules governing research on animals—especially the 3R maxim that dominate this legal landscape—suffer from regulatory failure. First, and most importantly, despite widespread commitment to replace and reduce animals in research, the number of animals used for experimental purposes worldwide is now the same as it was in the 1980s (the number dropped in the 1990s and 2000s but has been rising ever since; Bayne et al., 2015, p. 3; European Commission, 2013; Taylor, 2013; Taylor et al., 2008; Taylor and Rego, 2016). Second, though the principle of refinement demands that the severity of experiments be diminished, countries are reporting a rising number of research procedures done on animals who are forced to endure the most severe experiments (e.g., *Neue Zürcher Zeitung*, 2016). There is reason to believe that refinement, which seeks to ameliorate the conditions of animals used for a research procedure, fails to fulfill their basic welfare needs. For example, pursuant to the United States’ *Guide for the Care and Use of Laboratory Animals*, a pig who weighs up to 50kg can be housed for up to five years on 15 square feet (0.9m²), without any

access to the outside (National Research Council Institute for Laboratory Animal Research, 2011). The Guide states that thereby “animals can turn around and move freely without touching food or water troughs, have ready access to food and water, and have sufficient space to comfortably rest away from areas soiled by urine and feces” (p. 63). On 15 square feet, however, a pig cannot possibly exhibit normal behavior. No human of the same weight is expected to behave naturally in a 0.9m² elevator and certainly not for a period of five years. Overall, this overview of the achievements of the 3Rs suggests that both in qualitative and in quantitative terms, adopting the 3Rs has not decreased animal suffering.

At the same time, societal demands for better protection of animals are more common than ever before (European Commission, 2016). According to the most recent polls, citizens are increasingly concerned about the welfare of animals used in science and agree that more needs to be done to replace their use (Clemence and Leaman, 2016; European Citizen’s Initiative, 2016; Funk and Rainie, 2015; Jones, 2017). Despite these demands and the reasonable doubts they cast on the potential of the 3Rs to lead to the ultimate replacement of animals in research (see below), the 3Rs continue to be a popular policy tool for legislators and research facilities that use them as an example of their efforts to ameliorate the suffering of animals in research. The worldwide acceptance and simultaneous failure of the 3Rs seem to have turned the maxim, intentionally or not, into a means of whitewashing the images of those profiting from research vis-à-vis the public: scientists, research industries, and regulators. In light of these developments, this chapter takes a functional-comparative approach to scrutinize whether and how we can meet the rising societal demands for replacement. It specifically examines whether the 3Rs bear the potential of meeting this goal, and if so, what reforms are necessary, or whether the 3Rs should instead be abrogated.

2 Abrogating the 3Rs?

The widespread acceptance of the 3Rs, alongside their simultaneous failure, forces us to ask whether the 3Rs should be retired. In 2015, people across the European Union (EU) launched the European Citizens’ Initiative, *Stop Vivisection*, and expressed, with over 1,150,000 signatures, their desire for a paradigm shift away from the use of animals. The European Citizens’ Initiative is a political means at the EU level that makes it possible for 1 million citizens to participate in developing EU strategies, by prompting the European Commission (EC) to

propose a legislative act. The *Stop Vivisection* initiative demanded the use of animals for research purposes be abolished, which would have necessitated abrogating Directive 2010/63/EU (European Parliament, 2010), and with it, the 3Rs. The EC responded to the initiative by issuing a communication that effectively ignored these demands, arguing that the Directive also had replacement as a long-term goal, but that animal research cannot be banned because, “a ban [...] would likely export the biomedical research and testing outside the EU to countries where welfare standards may be lower and more animals may be needed to achieve the same scientific result” (European Commission, 2015, p. 3). As an alternative to the proposed abrogation, the EC promised that it would speed up the expected progress of the 3Rs by sharing knowledge, developing and validating new alternatives, strengthening enforcement, and entering a dialogue with the scientific community, for example, by organizing a conference devoted to this issue (see Holley et al., 2016, on knowledge sharing in the EU). Undoubtedly, these steps may help to enforce Directive 2010/63/EU more effectively, but they do not respond to the criticism that the 3Rs suffer from structural deficits that lead to the perpetuation of animal use in science. In effect, the steps envisaged by the Commission, like the 3Rs as they stand, are unlikely to bring about the full replacement of animal models.

Given these economic fears and political constraints that continue to inform the debate on the replacement of animals in research, it may be more effective to use the worldwide acceptance of the 3Rs as a foundation for working towards a paradigm change, through a *foot-in-the-door* strategy. Theoretically, the 3Rs have many advantages over other types of regulatory approaches. They are simple and intelligible, easily understandable, and catchy. They enjoy a general application, paired with refined conceptualization (compared to the very general objective of avoiding *unnecessary animal suffering* that leaves even more room for interpretation). The 3Rs take an integrative approach by incentivizing innovation, accommodating the interests of various stakeholders, and not discrediting the purposes of research, such as finding causes, treatments, and cures for diseases or enabling novel scientific insights. The 3Rs consider the sentience and suffering of animals a baseline and respond to the needs of animals beyond physiological suffering, such as their needs for social interaction and mental stimulation. Based on the hypothesis that the 3Rs are theoretically expedient, it is worth exploring the potential of this principle to mature into a more viable concept for the future of animal law, in particular with regard to its capacity to preempt the use of animals in research.

3 Reform Proposal 1: Reverse Hierarchy of the 3Rs

Most countries claim that a minimum number of animals should be used to obtain scientific knowledge, but the language of the replacement principle is regularly laxer than that of refinement. For example, in the EU, Directive 2010/63/EU determines that “Member States shall ensure that, *wherever possible*, a scientifically satisfactory method or testing strategy, not entailing the use of live non-human animals, shall be used instead of a procedure” (emphasis added, European Parliament, 2010, Article 4). But given that the Directive fails to determine the probability of possible alternatives, how accessible they ought to be, and the need to invest into them, the norm fails to incentivize researchers to divest from animal research. According to Article 13 of Directive 2010/63/EU, replacement is only necessary if alternatives are recognized under EU law. In addition, legislators often do not necessarily mean replacement in an absolute sense when they call for replacement measures; instead, the use of seemingly *less sentient* animals, like rodents or fish, are readily accepted as a form of replacement (e.g., German Animal Welfare Act 2006, Section 7a(2)(5); India Prevention of Cruelty to Animals Act, Animal Welfare Board of India, 1982, Prevention of Cruelty to Animals Act, 1982, Section 7(2)(e); US Guide for the Care and Use of Laboratory Animals, National Research Council, 2011, p. 5; Scientific Committee on Health Environmental and Emerging Risks, SCHEER, 2017, p. 15).

This clearly runs counter to Russell and Burch’s (1959) definition of replacement as “any scientific method employing non-sentient material” (Chapter 5) and fails to give those animals, whose capacity to sentience is still disputed, the benefit of the doubt (challenging the view that non-human animals lower on the zoological scale lack sentience: Tomasik, 2014). Such lax provisions give ample room for regulatees to avoid actual replacement, and they increase the possibility that certain research procedures may never be replaced. Given the lax practice in replacement and strong accentuation towards reduction and refinement, there seems to be an implicit hierarchical understanding of the 3Rs that gives refinement and reduction priority over replacement (Gerritsen, 2015, p. 38). The marginalization of replacement is especially disconcerting if one looks at the 3Rs from an “animal use” perspective, as seen in Table 6.1.

It is this framework that allows animal researchers to discharge their duties under the 3Rs by engaging in refinement (and marginal reduction) alone. The political and legal preoccupation with refinement and reduction shifts the focus away from where it should be, i.e., on replacement. So, if we continue to accept that legislators and institutions simply refine and marginally reduce the

TABLE 6.1 Refinement and reduction support the use of animals for research procedures and only replacement bears the potential of phasing out animal research in the long term.

	Refinement	Reduction	Replacement
Use of animals	+	+	–

use of animal models—only replacing them “wherever practical” and thereby conceiving themselves as fulfilling their 3R duties—we will end up perpetuating the use of animals in experiments. Contrary to what many practice, the 3Rs ought, however, be interpreted to mandate that replacement be given primary consideration. As the above-mentioned polls show, citizens’ opinions increasingly pressure legislators to come up with a workable plan to phase out the use of animals in research, which necessitates insisting on the replacement of animals in research (see also Goldberg and Locke, 2004). To bring about this paradigmatic change, the 3Rs should be understood hierarchically, where the first goal is replacement, the second reduction, and the third refinement. The imperative for this reversal is based on a historical, teleological, and evolutionary interpretation.

A *historical interpretation* of the 3Rs relies on Russell and Burch’s foundational work on the principle. Russell and Burch, the founders of the 3Rs, clearly stated that the humanitarian problem lies in the severity with which animals encounter stress and the high number of animals affected, and that the very purpose of the 3Rs is to tackle these (Russell and Burch, 1959, p. 93; Blattner, 2014). Russell and Burch further stated that “refinement is never enough, and we should always seek further for reduction and if possible replacement” (Chapter 4). Because replacement does not appear to be a priority of the 3Rs even though it is an explicit goal of the tripartite principle, the law must give more weight to this element when it applies the principle in the future.

A *teleological interpretation* also suggests that the law must reverse the hierarchy of the 3Rs. Indications of this interpretation already exist under current legislation. The *Council of Europe’s Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes* states in its preamble that its parties are “[r]esolved to limit the use of animals for experimental and other scientific purposes with the aim of replacing such use [...] in particular by seeking alternative measures and encouraging the use of these alternative measures” (Council of Europe, 1986). In Directive 2010/63/EU,

the EU expressed its wish to, “achiev[e] the final goal of full replacement of procedures on live animals for scientific and educational purposes” (European Parliament, 2010, Recital 10). If we interpret the 3Rs based on these stated purposes, replacement must be our top priority. Article 4 of Directive 2010/63/EU, which details the 3R commitments, begins by stating the duty of replacement and, thereby, implies a reverse hierarchical understanding of the principle, as well. Article 13 of the Directive further guides the choice of methods in the scientific and educational use of animals and—unlike the previous regulation, Directive 86/609/EEC (Council of the European Communities, 1986)—does not require replacement methods to be “reasonably, and practically available” (Article 7(2)). Instead, replacement methods are recognized as non-animal methods or testing strategies, even if they are not reasonably and practically available. This wording change, strictly interpreted, means alternatives should be required even where they are costly, have never been used by the researcher, or are not available at the researcher’s home institution.

The polls introduced herein show that the global community has never been more concerned about animals’ well-being than it is today. As a consequence of this burgeoning global conscience, we are witnessing the rise of the general principle of animal welfare, which is developing into a norm of customary international law (Bowman, Davies, and Redgwell, 2010, p. 678; Brels, 2012, p. 37; Sykes, 2014; Trent et al., 2005, p. 77). International documents and the laws of over 60 states worldwide make clear the general moral commitment and the legal requirement that animals be treated humanely and spared suffering (Blattner, 2016, pp. 304–308). The general principle of animal welfare underlines the goal of animal protection as an intrinsic interest of animals. In other words, the suffering of animals matters to the law because it matters to animals (Bolliger, Richner, and Rüttimann, 2011, p. 24–25, n. 14; Leondarakis, 2001, p. 29). Importantly, the general principle of animal welfare not only mandates proper treatment of animals while using them; it also encompasses the aspiration of states to preempt any violation of their intrinsic interests.

Another global principle that requires regulatory frameworks to shift emphasis on animal replacement is the precautionary principle. The precautionary principle commonly applies in decision-making processes and entails that, where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason to postpone cost-effective measures to prevent damage. The prime application of the precautionary principle is in environmental law where it covers animals who form an integral part of an ecosystem (Montreal Protocol on Substances that Deplete the Ozone Layer, 1987; United Nations, 1992, Article 8h, 14(1)(d); United Nations General Assembly,

1992, Article 15; World Charter for Nature, 1982, Article 12(b)). But, as the EC states, “in practice, [the] scope [of the precautionary principle] is much wider, and specifically where preliminary objective scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community” (Commission of the European Communities, 2000; see also World Health Organization, 1994, Article 5(7)). The precautionary principle demands that we err on the side of caution to prevent dangerous effects on animal health, replacing animals in research rather than regulating and, thus, perpetuating their use by refinement and reduction. We must thus decide in favor of animals wherever and whenever actions impair, or likely will impair, their physical and psychological health and life (Gerick, 2005, p. 213; Kuhlau et al., 2011). An *evolutionary* interpretation, based on the general principle of animal welfare and the precautionary principle therefore indicates that replacement should be given primary consideration among the 3Rs.

4 Reform Proposal 2: Qualitative Balances of Interests, Harm-Benefit Analyses, and Proportionality Tests

Even if replacement is given absolute preference, the 3Rs are still likely to fail because in most jurisdictions they enjoy only relative validity. Researchers do not refine the conditions of animals, do not reduce the number of animals used, and do not replace animals as the primary research model (even where alternatives exist) if human interests justify that decision. The *Swiss Animal Welfare Act 2005*, for example, states that “[p]ain, suffering or harm may be inflicted on or anxiety caused to a non-human animal only if this is unavoidable for the purpose of the experiment” (Article 20(1)). The issue here is that the purpose of the experiment is the only determinant in deciding whether animal suffering is unavoidable, or so-called necessary. The suffering inflicted on animals during experimentation is seen as a *prima facie* harm, but its justifiability—and hence its legality—is fully determined by the purpose of the experiment. Animals’ interests in not suffering, by contrast, do not enter the judgment on necessity.

The *Swiss Animal Welfare Act* seems to have taken a step in the right direction by further providing that animal experimentation is impermissible “if, in relation to the anticipated gain in knowledge, it inflicts *disproportionate* pain, suffering or harm [on the animal]” (emphasis added, Article 19(4)). Similarly, under the United Kingdom’s *Animals (Scientific Procedures) Act 1986*, the

Animals in Science Regulation Unit will assess whether the harms caused by an experiment are “justified by the expected outcome” (emphasis added, Section 5B(3)(d)). This is also the case with Article 38(1)(b) of Directive/2010/63/EU (European Parliament, 2010). These and other laws claim that they determine the legality of an experiment conducted on animals not only by evaluating the necessity of an experiment but by weighing all interests at hand. Such norms bring to application what is sometimes known as the balance of interest tests, harm-benefit analyses, or the proportionality principle.

Pursuant to these tests, animal experiments are evaluated in a two-step procedure. Regulators require the purpose of an experiment to be indispensable (final indispensability), and they require the means to achieve this end to be indispensable (instrumental indispensability or harm-benefit analysis) (Peters, 2012, p. 34ff.; e.g., *German Animal Welfare Act 2006*, Section 7(1)(1); *Swiss Animal Welfare Act 2005*, Article 17). Final indispensability is an analysis of the purpose and legitimacy of an experiment, which answers the *if* question. Instrumental indispensability, on the other hand, answers the *how* and largely refers to the principle of proportionality (e.g., *German Animal Welfare Act*, 2006, Section 7(1)(2)). The proportionality analysis includes the elements of suitability (means must be able to achieve desired ends), necessity (no milder means are available to achieve the end), and proportionality *strictu sensu* (Bolliger and Rüttimann, 2015, pp. 71–73). This final proportionality, *strictu sensu* evaluation includes a duty to diligently balance interests affected by the act at hand and conforms to the harm-benefit analysis (Ferrari and Gerritsen, 2015, p. 140) but with respect to means as opposed to ends.

Let us turn to final indispensability first. Before weighing interests, decision-making bodies usually follow a system that classifies expected harms inflicted on animals. For example, there is a five-step classification system in Canada (Canadian Council on Animal Care, 2011), in New Zealand (New Zealand Government, 2010, Section 2(1)), and in Israel (Kolman et al., 2014, pp. 202–203), a four-tiered scheme in Singapore (National Advisory Committee for Laboratory Animal Research, 2004, Article 5(4)(2)(b)) and the EU (European Parliament, 2010, Articles 15 and 16); and the Philippines has a three-step pain categorization system (Philippines Law on the Use of Animals in Research, 1999, Article 5(2)). Most of these classification schemes determine harm or pain levels based on the severity of a procedure or its duration, or a combination of the two. Article 15 of Directive 2010/63/EU, for example, assesses projects as non-recovery, mild (short-term mild pain, suffering, or distress), moderate (short-term moderate or long-lasting mild pain, suffering, or distress), and severe (severe or long-lasting moderate pain, suffering, or distress) (European Parliament, 2010). To best evaluate harm, psychological spheres of animals must also

be considered because inducing fear or anxiety in an animal negatively affects their well-being (e.g., Council of Europe, 1979, preamble; Swiss Animal Welfare Act, 2005, Article 3(b)(4)).

In contrast to harms, benefits are neither classified nor categorized. For instance, in the UK, where stricter harm-benefit analyses are said to prevail (Perry, 2007, p. 43), benefits are described in a very broad manner, by answering questions such as, what data or products may be acquired by the work, what scientific questions will be answered, what knowledge gaps will be filled, who will benefit from the work, and how and when the benefits will accrue. Quite telling in this respect is the need for scientists to “[e]xplain why the benefits go beyond ‘it would be nice to know’” (UK Home Office, 2014, p. 126; see also European Parliament, 2010, Article 38(2)(a); UK Home Office, 2016, pp. 9–11). Scientifically speaking, to offer benefits, a research project must produce recognizable results of scientific value (e.g., Austrian Animal Welfare Act, 2004, Section 4(3)(a)). From a societal perspective, however, only socially desirable objectives can be pursued in an experiment. Saving labor, time and costs or duplicating research cannot, *prima facie*, be weighed against animals’ interests (e.g., German Animal Welfare Act, 2006, Section 7a(2)(5)).

Though these rules on final indispensability serve an important purpose and help prevent the most unnecessary and atrocious research procedures, they effectively leave untouched the great bulk of research. For example, the societal objectives of curing diseases or producing new scientific knowledge typically operate as a *carte blanche* that legitimate every form of animal exploitation and give the 3Rs only relative validity. But simply dropping the words *cancer research* cannot and should not automatically justify the use of animals. We must introduce a scheme that evaluates the importance of the research, its contribution to the expected goal, and the likelihood of its success; and we must be wary of approving research projects that simply ensure a research facility’s survival and the preservation of jobs, while perpetuating the exploitation of animals (arguing that “[c]onducting animal experiments is a convenient and highly effective way for these researchers to gain career prestige and job security, and for the universities who employ them to obtain lucrative research grants. There is a *quid pro quo* relationship between research institutions and those giving the grants”, Greek and Greek, 2004, p.25). No research that goes beyond “it would be nice to know” is, by itself, morally or legally weighty enough to justify the immense suffering of animals in research. Peters (2015) proposes categorizing human interests into small, moderate, and great benefits to introduce a level field for evaluating human benefits versus animal harms (p. 97). Having precise knowledge about both burdens and benefits allows us to weigh more systematically the importance of the interests at hand, and makes it more obvious when marginal scientific interests

seek to trump animals' fundamental interests in life and bodily and mental integrity.

A further failing within harm-benefit evaluations is that the tests are regularly affected by referring to the legal tools that encapsulate those interests, rather than by the interests themselves. Scholars and individuals around the world have frequently exposed the risks of endowing humans with rights, while endowing animals only with protections. When experiments are evaluated, rights of humans, such as the freedom of research (e.g., Council of Europe, 1950, Article 10) or the freedom to choose an occupation and the right to engage in work (e.g., European Convention, 2000, Article 15), are juxtaposed against (animal) protections (e.g., the 3Rs). The fact that certain interests are legally recognized either as rights or as protections, establishes a disparate and unequal footing for the affected parties. Protections are effectively undermined when confronted with rights in a balance of interests, because they are a weaker legal tool. Consequently, protections only take effect where the rights of humans leave room for them. The *Swiss Animal Welfare Act* (2005) is a prime example of this automatic trumping. It requires anyone who handles animals to ensure their well-being "as far as the intended purpose allows" (Article 4(1)(b)). This not only renders research quintessentially a utilitarian endeavor; but, more notably, it creates a structural deficit to the detriment of animals. The balance of interests ends up being merely perfunctory and legitimizes, in essence rubber-stamps, the exploitation of animals (Ferrari and Gerritsen, 2015, p. 140; Gerritsen, 2015, p. 38).

A prime example of the inherent deficiency created by rights versus protection is the German state objective of animal protection. Prior to the amendment of Article 20a of German Basic Law, scholars viewed the *German Basic Law* as a "constant obstacle" (Evans, p. 326) to the effective protection of animals and were hopeful that the constitutionalization of animal protection, even if it would not create justiciable rights, would put animal protection on par with constitutional rights, as regards governmental value judgments (Gerick, 2005, p. 120). Judiciary practice established since the norm's amendment in 2002, however, shows that the state objective is regularly subordinated to constitutional rights (German Administrative Court, 2006; German Constitutional Court, 2009; German Constitutional Court, 2006; see further Eisen and Stilt, 2017, note 25). The deficiency again is that the balances of interests do not even examine the interests that underlie legal tools. They fail, for example, to acknowledge that what we may be balancing are interests in not being tortured versus interests in making economic profit. Instead, these tests balance interests only with reference to legal tools that protect those interests (rights versus protections)—a practice that structurally favors all human interests in using animals, over all interests of animals in not being used.

The first step towards ensuring a less biased balance of interests is to clearly differentiate between a scientific evaluation of whether animals are required to obtain a scientific result, and an ethical evaluation of whether it is morally justifiable in each individual case to inflict a certain kind of suffering upon an animal for a certain kind of desired objective. The second step to reforming these tests is leveling the position of competing interests, by establishing a reliable framework for a qualitative and non-speciesist balance of interests. Such a qualitative balance of interests demands that identical interests be viewed identically, regardless of the holder of the interest, i.e., be it the interests of humans or the interests of animals (Ferrari and Gerritsen, 2015, p. 139; Robertson, 2015, p. 102). Balancing qualities of the interests at stake should, in principle, prevent marginal research interests from trumping interests in bodily integrity.

5 Reform Proposal 3: Animal Rights

5.1 *Why Reverse Hierarchies and Upgraded Balances of Interests Do Not Suffice*

Even if replacement is considered the primary aim of the 3Rs, and even if we considerably revamp the balance of interests test, the 3Rs will likely continue to fail. The odds against this test are so high because its logic is flawed. The golden standard in animal experimentation is the animal model. The animal model poses ethical problems, has never been validated as a research method, and is strongly criticized for lacking sufficient predictive value to draw inferences about human models (e.g., Baker, 2016; Bailey, Thew and Balls, 2014; Greek and Menache, 2013; Knight, 2011; McIvor, 2019, Chapter 5 in this Volume). Despite these apparent flaws and the structural deficiencies of the animal model, under the 3Rs, a non-animal model not only needs to be as “effective” as the animal model, but (unlike the animal model) it actually needs to work. As Greek points out, this means we are “[w]aiting to abandon a test that does not work until we can find one that does” (Greek, 2015). A recently published report by the *Scientific Committee on Health Environmental and Emerging Risks* (SCHEER) on the need for non-human primates in research even posits that alternative models, which are to be validated against existing animal models, will require—from a legal perspective—using more animals in the validation process (SCHEER, 2017, pp. 20, 56). The odds are thus high that the 3Rs will perpetuate the use of animals in research. A final and crucial *lex ferenda* change that may overturn this deeply ingrained imbalance requires restructuring protections as rights.

5.2 *Prohibitions as Rights?*

Some scholars argue that animals already have at least some rights by arguing that prohibitions are negative freedom rights of animals. Section 85 paragraph 1

of the *New Zealand Animal Welfare Act* (1999), for example, provides that “[n]o person may carry out any research, testing, or teaching involving the use of a non-human hominid unless such use has first been approved by the Director-General and the research, testing, or teaching is carried out in accordance with any conditions imposed by the Director-General” (Section 85(1)). From the general prohibition on using hominids for research, testing, or teaching, some infer that hominids have the right not to be infringed in their life and bodily and mental integrity. Wagman and Liebman (2011), for example, argue that “the ban on certain conduct seems to grant the affected animals the ‘right’ to be free of such conduct. Because of animals’ status as property in every jurisdiction, those rights are naturally limited” (pp. 261; see also McCausland, 2014, p. 27; Robertson, 2015, pp. 3, 5; Sunstein, 2004, p. 99; Waldau, 2011).

If we look at the laws that regulate research on animals, there are several prohibitions that could be posited as negative freedom rights. According to Article 8(2) and (3) of Directive 2010/63/EU, there is a prohibition of the use of great apes and non-human primates for research purposes (cf. European Parliament, 2010, Recital 18). Exceptions are stated in Article 8(2)(a) and (b) for non-human primates and in Article 55(2) for great apes. The *Australian Policy on the Use of Non-Human Primates for Scientific Purposes* (National Health and Medical Research Council, 2003), which declares that research on great apes is legal under narrow conditions, is also sometimes considered to enshrine a freedom right of great apes to not be used in research. Similar prohibitions/rights exist in Austria, Belgium, the Netherlands, Sweden, Switzerland, the UK, and other states (Goldner, 2014). Another type of negative freedom right can be seen in the EU-wide prohibition of experiments that result in severe pain, suffering, or distress for animals and which are likely to be long-lasting (European Parliament, 2010, Article 15(2)). However, these prohibitions are undermined when Member States choose to allow such procedures temporarily (European Parliament, 2010, Article 55(2)–(3)). Member states may, however, decline to adopt exceptions, which scholars support by arguing that certain levels of suffering should not be permitted under any circumstances, regardless of any likely or aspired benefits (Zurlo, Rudacille and Goldberg, 1996). Another type of prohibition is the ban on subjecting vertebrates to research without anesthesia when experiments result in serious injuries (European Parliament, 2010, Article 14(1), Sentence 2). Prohibitions may also preclude certain purposes from justifying animal use in research. Under Puerto Rican law, for example, animal experiments are prohibited if they are done for educational purposes (e.g., Puerto Rico Animal Welfare Act, 2008, Article 19(b); see also Swiss Animal Welfare Ordinance, 2008, Article 138(2)).

Prohibitions are a major step forward for animals, making certain species of animals unavailable to human disposition. In this sense, prohibitions

effectively preempt balances of interests: None of the specified procedures are *prima facie* available to be overridden by human interests. But these prohibitions apply only to a minority of animals (e.g., to iconic or endangered animals) and continue to be undermined by broad exceptions, which in turn promote the continuing use of a majority of animals in research.

5.3 *The Need for Animal Rights*

The whole idea that the duties of some can be translated into the rights of others (to whom the duty is owed); and, thus, that prohibitions are negative freedom rights of animals, is disputed in legal scholarship (Curnutt, 2001, pp. 19ff., 26ff.; Raspé, 2013, p. 282). Contrary to Wagman and Liebman's perspective is the view that specified norms are prohibitions, no more, no less. Rights are only established by unequivocally identifying them as such (e.g., "hominids have a right to life and a right to bodily and mental integrity"). Instead of opting for limited prohibitions that are undermined by numerous and sweeping exceptions, the only way to begin attending to the fundamental interests of animals is to establish rights for them. Rights are those rare tools that ensure that interests are qualitatively balanced, and that the balance is egalitarian and non-speciesist. As Peters (2016) argues: "[A]nimal rights would allow a fair balancing in which the proper value of fundamental animal interests (such as the interest to live) could be integrated. Animal rights would therefore preclude the current routine sacrifice of fundamental animal interests in favor of trite human interests" (p. 49). The demand for fundamental rights for animals is neither utopian nor far-fetched; it is the only option available to move away from our prevailing perfunctory consideration of animals. Particularly in research, where balance of interest tests prevail, establishing rights for animals is indispensable if we seriously want to start envisaging an end to their use in experimentation.

Another notable aspect about rights is that they ensure that rights holders have a sphere of absolute unavailability. In human rights law, this is known as the very substance of a right that may not be restricted or impaired in any way (e.g., European Economic Community, 1957, Article 2; Swiss Constitution, 1999, Article 36(4)). Because animals, under the laws of most states, are denied rights, human interests in exploiting animals take categorical precedence over their most fundamental interests, such as life and freedom. Introducing a sphere of inviolability for the most fundamental interests that animals possess is necessary, if we want to truly take their interests seriously and live up to our recognition of their intrinsic value (Peters, 2015, p. 72). A number of laws already recognize that the interests of animals matter because these interests

matter to them, i.e., that animals have to be protected for their own sake. The Dutch Animal Welfare Act (*Wet dieren* 2011) in this context expresses “recognition of the intrinsic value of the animal” (preamble). Directive 2010/63/EU (European Parliament, 2010) enshrines that “[a]nimals have an intrinsic value which must be respected” (Recital 10) and that they “should always be treated as sentient creatures” (Recital 12). The intrinsic value of animals is also recognized under German law (German Animal Welfare Act, 2006, Section 1); and the preamble to the *Latvian Animal Protection Law* (1999) states that “[t]he ethical obligation of humankind is to ensure the welfare and protection of all species of animals, because every unique being is in itself of value”. Article 3 litera a of the *Swiss Animal Welfare Act* (2005) speaks of the “[i]nherent worth of the animal that has to be respected”. Thailand’s *Ethical Principles and Guidelines for the Use of Animals* (National Research Council of Thailand, 1999) states that “[a]nimal users are to be aware of the value of life of animals” (Principle 1), and that “animal users need to be aware that animals are living beings just as humans are living beings” (Principle 4). The recognition of the intrinsic value of animals is not only ethically relevant, but it carries legal implications (Peters, 2015, p. 70) and should result in rights that protect these individuals’ core interests. Recent case law in India shows that animal rights are on the rise and that they are readily implementable. The High Court of Kerala (2000) declared: “[L]egal rights shall not be the exclusive preserve of the humans which has to be extended beyond people thereby dismantling the thick legal wall with humans all on one side and all animals on the other side” (N.R. Nair and Ors v. Union of India (UOI) and Ors, 2000); and, “animals are born with an equal claim for life without any cruelty to them. Perhaps if this right was given proper recognition by the human-beings, there would have been no necessity to bring on the statute book of the said Act” (People for Animals and Ors. v. State of Goa and Ors, 1997).

Establishing rights, and thereby an essence of inviolability, has a number of implications. Akin to Principle 5 of the *Nuremberg Code* (1949), experiments will not be conducted, “where there is an a priori reason to believe that death or disabling injury will occur” because it violates the core content of a right to life and bodily and mental integrity. And analogous to Principle 8 of the Helsinki Declaration (World Medical Association, 2013), the primary purpose of medical research to generate new knowledge cannot take precedence over the rights and interests of individual research subjects. Today, the duty to rehabilitate animals—sometimes known as the fourth R—could be taken as a useful starting point in this respect. Recital 14 of Directive 2010/63/EU states that methods should avoid death (of animals) as an endpoint. Killing

an animal used for a research experiment is only permitted if they remain in or have recurrent moderate or severe pain, suffering, distress, or lasting harm (European Parliament, 2010, Article 17(2); Government of India, Ministry of Environment and Forests, 2007, Annex 6). Article 17 paragraph 3 of Directive 2010/63/EU further states: “Where an animal is to be kept alive, it shall receive care and accommodation appropriate to its state of health.” India’s *Guidelines on the Regulation of Scientific Experiments on Animals* determine that “investigators are responsible for the aftercare and/or rehabilitation of animals after experimentation” (Government of India, Ministry of Environment and Forests, 2007, Annex 6). If states today are willing to determine that death of animals used in research should be avoided, it is not unreasonable to consider the possibility that they will grant animals a right to life in the future. Thereby, the rehoming duty would be explicitly reframed as a manifestation of a right to life, akin to Principle 5 of the *Nuremberg Code* (1949). A deficiency of current rehoming provisions, however, is that researchers are nudged to use the method that causes lasting moderate and severe pain, so they can put the animal down without having to care for or accommodate them after the conclusion of the experiment. To counter these unwarranted disincentives, the costs of aftercare and/or rehabilitation of animals post-experimentation should be budgeted as a part of research costs when an application is filed (as required by Government of India, Ministry of Environment and Forests, 2007, Annex 6, Principle 4).

5.4 A Paradigm Shift?

Animal rights implemented in law would create a paradigm shift because they offer specific advantages over protections. Instead of merely establishing specific and context-dependent prohibitions, rights operate more broadly and are less determinate. This confers advantages to the rights holder, because rights are applicable in a myriad of situations. For example, a right to bodily and mental integrity applies to the general question of whether use of an animal in research is justified. If the answer is yes, then the question must be asked whether and how this right can be guaranteed in research (e.g., by carrying out research that does not inflict any form of suffering, including death). Moreover, animals are empowered by rights because they, by being actionable, grant them access to stronger legal tools of enforcement (Edmundson, 2014, pp. 345ff., 350; Goldner, 2014, p. 53ff.). Only the enforced duty of others to respect the right in question renders its worthiness palpable (Edmundson, 2014, p. 360). Establishing a right of animals to life and bodily and mental integrity would stop perpetuating the use of animals for research and enable us to achieve the primary goal of the 3Rs: the ultimate replacement of animal models.

While funding animal-free alternatives will undoubtedly contribute to this goal, as well (see e.g., Swiss Animal Welfare Act, Article 22(2); European Parliament, 2010, Recital 46), only a paradigm change in the law of animals in research will stop incentivizing research facilities to continue experimenting on animals and will start enabling them to put all their efforts into finding ethically sound (and more scientifically sound) alternatives to the use of animals.

If industries cannot now devise alternatives to animal models, then certain types of research procedures simply should not be carried out until we find alternatives. When the *Helsinki Declaration* (World Medical Association, 2013) came into force, legislators deemed acceptable the burden of looking for alternative models to research on humans. The same change of research procedure is, on the basis of a non-speciesist ethic, reasonable to demand from industries that currently rely on animal models. This route is not utopian but was taken by lawmakers before, such as when the EU decided to give full effect to the *Cosmetics Directive* (European Commission, 2013, p. 3). When discussing the potential postponement of the 2013 marketing ban on cosmetics, since replacement methods for all animal models were not yet available, the EC argued that postponing the ban would “diminish determination to swiftly develop alternative test methods. Past experience demonstrates clearly that animal testing provisions in the cosmetics legislation have been a key accelerator in relation to the development of alternative methods and have sent a strong signal far beyond the cosmetics sector and far beyond Europe” (European Commission, 2013, p. 6). Instead of conceiving rights for animals as a scientific regression, industries will be incentivized to finally spur innovation towards ethically sound and economically accessible alternatives.

The *EU Cosmetics Directive* has had a positive spill-over effect into other areas of animal experimentation, alongside further national bans on cosmetics testing, including Australia (Australian Government, Department of Health, 2018), India (Government of India, Ministry of Health and Family Welfare, 2005, Section 148C), Israel (Israeli Cruelty to Animals Law 1994, Article 2(d); prohibiting cutting into live tissue), Guatemala (Guatemalan Animal Welfare Act 2017, Article 54), New Zealand (New Zealand Animal Welfare Act 1999, Section 84A), South Korea (South Korea Animal Protection Law 2007; in force 2019), and Taiwan (Business Cosmetics, 2016). In September 2016, the Dutch parliament changed its policy on animal research law in an unprecedented way. The parliament passed a motion to phase out all experiments on non-human primates and declared that by 2025, it aims to operate by testing methods that do not make use of animals. The policy areas in which the use of animals must be phased out until 2025 include regulatory testing of chemicals,

food ingredients, pesticides and (veterinary) medicines and biological products, such as vaccines. In the areas of fundamental research, applied and transitional research, as well as education and training, by contrast, no such specific reference date has been announced. The government's next step is for the Dutch National Committee for the Protection of Animals Used for Scientific Purposes (NCad, 2016) to plan a schedule that phases out experiments on animals (which applies to all of the above areas). NCad clearly puts emphasis on innovation and the development of new research methods rather than the abrogation of animal research; yet, its move is historical and will hopefully set a precedent for other states to follow. These developments show that the unavailability of animals for research does not equate with an end to research and advances for human benefit but instead, it heralds the beginning of an ethically and scientifically sound future for research. If devised as rights instead of bans, these regulatory changes would create more secure and justiciable ground for animals and could enable us to work more effectively towards a paradigm change in research.

6 Concluding Remarks

The 3Rs are a primary example of regulatory failure, and yet the concept enjoys an unparalleled acceptance among states and research institutions worldwide. Instead of abrogating the 3Rs (which is demanded by a growing number of citizens), it would be better to leverage the 3Rs' widespread acceptance to enable regulators to fulfil their unachieved regulatory goals and meet the growing demands of citizens for a more just relationship with animals.

This chapter proposed means of bringing about paradigm change, that, although few, are powerful. First, regulators must reverse the hierarchy of the 3Rs, based on a historical, teleological, and evolutionary interpretation, with replacement taking precedence. Second, regulators must introduce qualitative balances of interests, so identical interests are viewed identically, regardless of the interest holder. As a result, marginal scientific or prestige interests cannot trump interests in life and bodily and mental integrity. Third, animals must be accorded explicit rights to life and bodily and mental integrity, based on our legal commitment to protect them for their own sake (intrinsic animal protection), for the following reasons: rights grant more power to rights holders than interests do to interest holders, rights require special justification, give effective weight to animal interests in balancing tests, make the core interests of animals inviolable to human exploitation, and operate broadly. Although

rights will preclude undertaking many research practices that are currently conducted on animals, they spur innovation and help make research more effective and accessible. As the EC (2013) stated with respect to cosmetics, “the possible risks from the 2013 marketing ban can be turned into an opportunity for the Union to set an example of responsible innovation [...] with positive impact beyond Europe” (p. 6). The very same opportunities are available to us in research more generally if we begin to embark on a road of innovation and progress.

If these adjustments are incorporated, we anticipate that the 3Rs can offer a valuable approach to overturning the deeply ingrained default rule of animal experimentation and to incrementally phase out the use of animals in research. But “[f]ully reaping the potential of alternative methods is a challenging endeavor that will require a shift in thinking of all involved” (European Commission, 2013, p. 6; inertia of continued animal use is acknowledged in Innovate UK, 2015, p. 14). Legislators must empower scientists and research institutions to take the full replacement road by designing the best possible legal framework for it and by giving them the necessary financial incentives and education to pursue replacement, instead of holding them morally responsible for the continued use of animals, which is in fact a regulatory failure.

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