Humane World for Animals

Formerly called
Humane Society International

Humane World for Animals' position on REACH revision

Nearly two decades after its introduction, REACH[1] is set for revision with the goal to offer a more simplified and modern legislative framework to further boost EU's competitiveness without compromising the protection of human health and the environment. On paper, REACH was intended to promote alternatives to animal testing (Article 1) and limit new animal testing to a 'last resort' (Article 25), but in reality animal testing continues to be a first resort in many cases,[2] driven by long lists of animal-based information requirements that are rigidly enforced by EU regulators despite a growing global trend towards next-generation risk assessment (NGRA) based on nonanimal methods (NAMs). While the Chemicals Strategy for Sustainability quite rightly noted that *"safety testing and chemical risk assessment need to innovate in order to reduce dependency on animal testing but also to improve the quality, efficiency and speed of chemical hazard and risk assessments"*, its laudable vision is unlikely to become a reality so long as tick-box animal testing remains the foundation of the EU's regulatory and chemical safety paradigm under REACH.

Humane World for Animals recommends substantive revisions to REACH articles and information requirements with a view to modernising the EU's approach to chemical safety assessment and future-proofing its regulatory framework to keep pace with the rapidly evolving safety science landscape.[3,4] Our recommendations include procedural, comitology and structural changes to REACH to better integrate the full suite of available NGRA and NAM-based tools for prioritization[4], bioactivity and exposure assessment; introduce more flexible, efficient, and test-agnostic information requirements; introduce improved approaches to chemical grouping, read-across, weight-of evidence, and waiving. Together, these approaches can limit substantially any need for the generation of new animal data whilst preserving high standards of protection of human health and the environment. These will also contribute to the simplification EU is aiming for, and limit any financial and administrative burden for the industry, without compromising the health of European citizens.

The forthcoming revision also needs to consider the on-going work and extensive resources made available from the EU and the Member States to advance the regulatory use of non-animal approaches, such as PARC, and most importantly to develop an EU Roadmap towards phasing out the use of animals for chemical safety assessment. The Roadmap marks a landmark opening for advanced chemical safety assessments, cultural change in the scientific world, and regulatory transformation. We highly encourage

1 Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals.
2 Macmillan et al. (2023). The last resort requirement under REACH: From principle to practice. Regulatory Toxicology and Pharmacology 147: DOI: 10.1016/j.yrtph.2023.105557
3 Pereira et al. (2022). REACHing for solutions: Essential revisions to the EU chemicals regulation to modernise safety assessment. Regulatory Toxicology and Pharmacology 136: https://doi.org/10.1016/j.yrtph.2022.105278
4 Berggren & Worth (2023). Towards a future regulatory framework for chemicals in the European Union - Chemicals 2.0. Regulatory toxicology and Pharmacology 142: DOI: 10.1016/j.yrtph.2023.105431

the Commission to build the required flexibility into REACH via this revision such that the short- and long-term goals of the Roadmap can be seamlessly integrated into REACH, and the phase-out of animal testing for chemical safety assessments can occur within the boundaries and towards the objectives of REACH.

Humane World for Animals cannot support Commission proposals that would inevitably increase animal testing under REACH, such as the introduction of new or expanded standard information requirements, e.g. for polymers and endocrine disruptors, and chemical safety assessment extension to 1-10 t/y band.

Further, a crucial point is enhancing transparency, improving access to data and facilitating data sharing. The discussions and decisions during various regulatory processes e.g. substance evaluation, should be transparent and available in order to act as a center for knowledge and lessons learnt both for industry and regulators. In addition, we propose ECHA to further facilitate and simplify the data sharing process amongst registrants to prevent them from opting out from the joint submission, in the case where this will cause generation of unnecessary animal data. Proper use and exchange of existing data, including the use of the Common Data Platform for Chemicals Regulation, under the One Substance One Assessment (OSOA) will benefit the industry and save a significant number of animals from unnecessary testing.

We urge the European Commission to consider these points to achieve a modern and consistent regulatory framework. Finally, Humane World for Animals proposes 5 policy actions which are essential for the simplified, advanced and long-lasting REACH. We encourage you to read those carefully in the following Annex.

Humane World for Animals

Formerly called
Humane Society International

Annex: Recommended Policy Actions for REACH Revision

The revision of REACH, where the European Commission proposal is expected by the end of 2025, will play a strategic role for the chemicals risk assessment and the chemicals market, which is the second largest market globally, thus crucial for the Clean Industrial Deal. The EU is committed to boost competitiveness while offering a simplified legislative framework to reduce the administrative burden for the industry, while still maintaining the safety of human health and the environment. The long-awaited revision of this cornerstone regulation is a unique opportunity to shape EU chemicals policy towards a more science-driven and streamlined safety assessment process, and to phase out reliance on animal methods in ensuring the protection of human health and the environment. The significant complexities of REACH mean this will require a substantial effort from policy makers to ensure EU citizens benefit from greater health protections, whilst streamlining the regulatory burden on industry. Proposals for the REACH revision have the potential to impose a higher demand for animal testing; however, this runs counter to the objectives of REACH, namely "to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation." Therefore, it is imperative that policy makers engage with animal protection NGOs to ensure the objectives of REACH can be met without the need for additional animal testing.

Humane World for Animals recommends the following 5 policy actions to secure the EU's goals, a future proof REACH revision, while ensuring an alignment of regulatory advancement with technological advancement, along with an improved protection of human health and the environment. These policy actions will prevent unnecessary animal testing and support the chemicals industry by providing information aiming for faster and better regulatory decisions.

1. Offer a substance-tailored REACH legislative framework to integrate non-animal methods	
The issue	The structure of the REACH legislative requirements is currently rigid and prohibits the integration of new methodologies. As a result, regulators tend to reject safety assessments that do not use the specified animal tests and animal methods continue to be enshrined as "the gold standard" in toxicity testing. The flexibility theoretically allowed by Annex XI, while conceptually sound, faces practical and interpretative issues that limit its effectiveness. Although Annex XI permits waiving tests based on scientific necessity, using existing data, Weight of Evidence (WoE), or non-animal methods, it fails to fully acknowledge cases where testing is irrelevant. Because of its ambiguity, Annex XI waivers are rarely used and more rarely accepted. As a result, the rigid structure of Annexes VII–X often

	overrides the provisions in Annex XI, limiting the adoption of scientifically justified, animal-free testing strategies tailored to specific chemical properties, thus inhibiting efficient implementation of REACH.
The solution	Ensure implementation of the adaptations described in Annex XI to increase use of scientifically sound waivers and to facilitate integration of non-animal new approach methodologies into testing approaches. Remove the reference to specific test methods from Annexes, other than as potential examples. The development of test methods, notably of non-animal methods, is progressing faster than the legislative changes. Further, the Regulation should allow the use of scientifically suitable test methods All information requirements under REACH should be method-agnostic and accompanied by precise, method-neutral descriptions. This will ensure legal clarity and flexibility, allowing the use of the most scientifically appropriate and up-to-date methods to meet data needs. This will encourage a shift from checklist compliance to science-driven regulatory decisions. Remove any reference to animal models where alternatives are already scientifically validated, currently for skin corrosion/irritation, serious eye damage/irritation, skin sensitization, acute fish toxicity and bioaccumulation. For all SIRs, the adaptation should highlight that “Where the in vitro/in silico methods (and combinations) are not applicable or sufficient for classification and risk assessment, prediction should be made using adaptation options under Annex XI. Only where no adaptation is feasible, a testing proposal for an in vivo study must be submitted. The biological relevance and limitations of any in vivo method must be carefully considered. All decisions must be transparent, scientifically sound, and ethically justified.” In the adaptations, clarify regulatory text to support waiving of standard studies (both short- and long-term) when exposure-based or risk-based justifications exist, to align with the adaptations in Annex XI. This should reflect better clarification in the use of scientific rationale and chemical safety assessment data (e.g., low risk characterization ratios, non-PBT profiles) to demonstrate that further testing is not required. Consider redundancy of existing information requirements. The list of SIR under REACH is quite extensive and, in many cases, prescribes tests that assess identical or similar sub-endpoints, or tests that may not add value with respect to overall risk assessment. This is the case for reproductive toxicity (OECD TG 414 vs OECD TG 443); 2nd species testing for pre-natal developmental toxicity assessment; and, for aquatic ecotoxicological assessments, the need to test on multiple trophic levels vs evaluation of cross-species sensitivity comparisons, and

	extrapolation approaches[5]. Ensure that the implementation plan of the upcoming Communication on the EC Roadmap phasing out animal testing for chemical safety assessments is included in REACH legal text, e.g. in Article 13(2) as suggested. This will bring coherence among the different policy legislations, and ensure that latest scientific advancements for safety assessment are timely applied. Further, a new scientific committee, comprised of independent experts in NAM/NGRA-based safety assessment of chemicals, need to be created to enable the rapid uptake and regulatory use of animal-free approaches. Such a committee would better equip ECHA and Member States to deal with topics related to animal testing, such as testing proposals, review of waiver requests, and review of current practices to ensure they are in line with the last resort principle. Such a committee could support the development of an ambitious reduction and replacement strategy and roadmap and provide independent advice and recommendations to foster and increase the use of non-animal methods by registrants that would fit within the agency's overarching mandates.
Recommendations for modifications in Articles	Article 13 (2) *(2)These methods shall be regularly reviewed and improved* ***to prioritize non-animal approaches and further reduce the need for vertebrate animal testing. In doing so, the recommendation of the EC Roadmap for phasing out animal testing shall be considered, as soon as available.*** *The Commission, following consultation with relevant stakeholders, shall, as soon as possible, make a proposal, if appropriate, to amend the Commission Regulation on test methods adopted in accordance with the procedure referred to in Article 133(4), and the Annexes of this Regulation, if relevant, so as to* ***ensure the continued replacement or reduction of animal testing, with the ultimate aim of phasing it out.*** *Amendments to that Commission Regulation shall be adopted in accordance with the procedure specified in paragraph 3, and amendments to the Annexes of this Regulation shall be adopted in accordance with the procedure referred to in Article 131.*
2. Optimize the Dossier and Substance Evaluation processes to improve efficiency	
The issue	In practice, compliance checks have become data gap checks only, and additional animal testing is requested to tick every box without consideration of whether that information is needed to reach a safety determination. Unnecessary generation of new studies lead only to financial and administrative burden for the industry, and additional suffering of animals.

[5] Pereira et al. (2022). REACHing for solutions: Essential revisions to the EU chemicals regulation to modernise safety assessment. Regulatory Toxicology and Pharmacology 136: https://doi.org/10.1016/j.yrtph.2022.105278

The solution	Before reaching the point of a request for a new study it should be investigated whether there is a potential risk to human health and/or the environment and need for additional data. To avoid conducting animal tests that may not be relevant or add value for decision-making or risk management, the role of Dossier Evaluation and Substance Evaluation under REACH should be critically examined. During the Substance Evaluation process in REACH, there are three conditions[5] that should be met to justify the generation of additional data: 1. A potential risk to human health or the environment exists 2. The potential risk identified needs to be clarified, and 3. The information requested has a realistic possibility of leading to improved risk management measures Optimising and merging the Dossier Evaluation and Substance Evaluation processes could greatly expedite the risk management process under REACH. Such a process begins with an open dialogue between registrants and the previously proposed ECHA scientific committee on NAMs to ensure that dossiers are fit-for-purpose. Registrants can then discuss with committee experts how best to address any identified issues, clarify their risk assessments and, if needed, what an appropriate NAM-led testing strategy could be. We propose to amend Article 44 (Criteria for substance evaluation) to include the need for additional data based on the three above-mentioned conditions.

3. Increase grouping of substances, computational models, read-across, waivers	
The issue	The increased information requirements for low tonnages, the registration of polymers and the introduction of new information requirements e.g. endocrine disruptors will increase the demand for animal testing. Therefore, it is crucial to increase the acceptance and use of non-testing approaches and scientifically sound waivers.
The solution	Apply read-across to identify groups with same hazard properties such as endocrine disrupting activity. Grouping of endocrine disruptors (EDs) is possible and can generally be conducted like grouping of substances based on structure to identify chemicals with common activities affecting other endpoints[6]. Implement new approaches (e.g. the bio-elution method), currently used by the industry for read-across and grouping of metals, and investigate their relevance to group EDs and polymers. Expand recognition and use of computational tools (e.g., QSARs, read-across) and in silico waiving as viable alternatives to traditional testing. For endpoints, such as

[6] https://pub.norden.org/temanord2025-513/temanord2025-513.pdf

	acute oral toxicity, suitable and well-characterized in silico approaches, such QSAR, can be used (cfr. CATMoS, Mansouri et al. 2021). Clear indication to prefer non-animal methods should therefore be reflected. Also in this case, the respective adaptation should stress adherence to the last resort requirement: “An in vivo study shall only be conducted if in vitro, in silico and combination of those methods are not applicable or adequate. If in vivo testing is needed, it must follow a transparent, well-documented, and ethically justified rationale, with full consideration of the relevance and limitations of in vivo methods”. Where human exposure by inhalation or dermal routes is considered relevant, acute toxicity shall first be assessed using QSAR, read-across, and weight-of-evidence based on Annex VII data. Integrate Next-Generation Risk Assessment (NGRA) concepts, including exposure-driven and hypothesis-based approaches. To do so, toxicokinetics data play a crucial role. Therefore, we strongly support the introduction of in vitro TK requirements. TK data are essential for: 1. Interpreting both animal and non-animal data, 2. Enabling accurate in vitro to in vivo extrapolation (IVIVE), 3. Predicting internal exposure and systemic effects, 4. Supporting the transition to New Approach Methodologies (NAMs). In vitro and in silico TK data will greatly enhance human relevance, support integrated risk assessments, and align with the EU roadmap to phase out animal testing. Initial investments in capacity and guidance are outweighed by long-term benefits in efficiency, relevance, and ethical responsibility. Increase regulatory use of exposure-based approaches. Rather than questioning their applicability a priori, attention should be directed toward breaking the current cycle in which limited regulatory acceptance of exposure data discourages both their generation and quality improvement. This lack of incentive hinders broader submission and ultimately reinforces the scarcity of usable data. Proactive efforts are needed to improve regulatory acceptance of exposure assessments. Strengthening these aspects is essential for the consistent and scientifically robust application of exposure-based waivers All these approaches, when carefully evaluated, allow the use of existing data and limit substantially any need for the generation of new data.
4. Reinforce the interpretation and implementation of ‘last resort’ requirement	
The issue	Article 25 states that animal testing should be undertaken only as a last resort. This unfortunately is often not that case. Animal test methods are still favored without the evaluation of alternative approaches. Prioritising the use of non-animal methods by enforcement of the “last resort” requirement will facilitate improved efficiency of chemical safety assessment.

The solution	Include clear requirements to ensure that animal testing is indeed considered as last resort. Make sure that all available non-animal approaches have been explored and found insufficient, evaluate the necessity of the testing, address the ethical oversight and proportionality to human health and the environment. Establish a scrutiny body to check the application of the requirement, such as a scientific committee on the application of NAMs. We propose to include criteria to define and describe the last resort for easier enforcement. If these criteria are found not suitable to be included in Article 25, we highly encourage that they will be considered in updated ECHA guidance documents. Such criteria should be closely followed in all procedures, including in the evaluation of testing proposals. Therefore, testing proposals should be required for all vertebrate tests at all annex levels, with registrants having to demonstrate that every effort has been made to comply with the last resort requirement prior to any consideration or request for further animal testing. This will ensure not only that all alternatives have been exhausted and encourage nonanimal assessments, but also ensure that any animal testing conducted contributes to the overall goal of protection of human health and the environment. This aspect is crucial also for enhancing transparency in the decision-making process (see action point 5)
Recommendations for modifications in articles	Article 25 (1) *In order to avoid animal testing, testing on ~~vertebrate~~* ***intact animals including their embryonic life stages****, animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.* ***The last resort requirement implies:*** ***- There is no suitable and appropriate non-animal approach: proof that non-animal approaches have been explored and found insufficient, following a traceable assessment of validity and limitations Testing on animals should be assessed in its limitation, and should be permitted only if no alternative provides equally reliable or conclusive results.*** ***- Proven testing necessity: testing is only conducted when a result is critical to a conclusive assessment, regardless of the availability of appropriate testing alternatives.*** ***Ethical oversight and proportionality: transparent decision-making procedure including assessment which demonstrates that not conducting animal testing would have a disproportionate risk to human health and/or the environment compared to animal suffering.***

5. Enhance transparency, improve reporting, access to data, and facilitate data sharing	
The issue	Due to limited transparency and collaboration in the chemical safety assessment, often there is repetition of animal testing for the same substances or substances with similar properties. Further, processes such as compliance checks address only data gaps by following a box-ticking approach without examining the necessity of generating these data. Even though the Article 117(3) report is published every three years and provides information on the options used to fulfil information requirements (e.g. experimental data, data waivers, read-across, etc), it does not publish specific instances where an adaptation was submitted and the data considered acceptable, or the data rejected[7]. Additionally, greater transparency in reporting the number of animals used for chemical testing is also requested, including detailed breakdowns by country and sector, as well as animal uses outside the EU to comply with EU legislation.
The solution	Enhance transparency and data access, notably through processes such as dossier reviews and substance evaluations, the insights of which can be used as lessons learnt for other registrants. In addition, to enhance further the transparency and monitor better the enforcement of the last resort requirement, the testing proposal when involving any animal testing should be requested for the information requirements for substances in all tonnage bands. Ensure good use of the Common Data Platform for chemicals under One Substance One Assessment, to strengthen the knowledge of chemicals and allow early detection and action on potential risks. Facilitate and improve data sharing processes to prevent registrants to opt out from the joint submission, thus generating new data.
Recommendations for changes in articles	Data sharing: ***Article 27 (4a) For the purposes of REACH registration, potential registrants shall have the right to refer freely to the data of previous registrants when proven that their substance is structurally similar, notably when the data contain studies with the use of vertebrate animals. ECHA should facilitate the dialogue between registrants***. Establish same and improved data sharing processes, as known from the registration process to authorization, restriction, substance evaluation and any other process which may require submission of additional data. Special cost mechanisms should be applied for SMEs on the data sharing agreements for animal and non-animal data, to reduce administrative and

[7] Macmillan et al. (2023). The last resort requirement under REACH: From principle to practice. Regulatory Toxicology and Pharmacology 147: DOI: 10.1016/j.yrtph.2023.105557

cost burden.

The 12-year protection should be reduced to 10 years and allow access to study summaries to all parties after that period.

Transparency:

Article 40 (1) *The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes* ***VII, VIII****, IX and X for a substance* ***for all hazard classes****.*

Article 40 (2) *It shall invite third parties to submit, using the format provided by the Agency, scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal, within ~~45~~* ***90*** *days of the date of publication.*

Reporting:

Article 117 (1) Every 5 yeas Member States are submitting to the Commission a report on the operation of REACH including evaluation and enforcement. When investigating the enforcement of the Regulation, we propose that the Members gather information on the last resort requirement implementation as well. Member States should collaborate with the animal welfare bodies and national committees, responsible for the implementation Directive 2010/63/EU on the protection of animals used for scientific purposes to collect this information.

Article 117 (3) ECHA, every 3 years, is submitting to the Commission a report on the status of implementation and use of non-animal test methods and testing strategies which have been used already in REACH. We propose that ECHA alongside to this current task, to include in their report new proposed appropriate non-animal methods which can be used to generate information on intrinsic properties and risk assessment. This will help to promote non-animal methods and provide the state-of-art of newly developed methods.