

SUSTAINABLE SCIENCE: THE 3RS

A 3RS LEARNING SCENARIO

Author(s)

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Summary

This learning scenario immerses students to the 3R principles, and how these principles have been the basis of the development of a European legislation on the use of animals in experimental laboratories. In addition, students will be taught how the 3Rs principles are important for science and illustrate the need to focus on the development of alternative methods that respect the use of animals in clinical trials.

Key elements

<i>Key Element</i>	<i>Suggestions</i>
Subject	Biology, Biotechnology, Law, English (for Italian schools), Citizenship and Constitution.
Topic	The 3Rs: Replacement, Reduction and Refinement of Animal use in science.
Age of students	15-18 (depending on the school curriculum)
Preparation time	The estimated time that teachers will need in order to prepare for the implementation of this Learning Scenario is approximately 1-4 hours. According to the feedback received by teachers who have tested the scenario in their class, it is advisable to consider dedicating 4 hours.
Teaching time	The estimated time teachers will need for the implementation of this Learning Scenario in class is between 4 and 11 hours, depending on the volume of resources that will be used.
Online teaching material	<p>Padlet https://padlet.com</p> <p>Google forms https://docs.google.com/forms</p> <p>Edmodo https://www.edmodo.com or</p> <p>Google Classroom https://classroom.google.com</p> <p>Prezi https://www.prezi.com/</p> <p>EU Survey https://ec.europa.eu/eusurvey</p> <p>Tuvalab https://tuvalabs.com/</p> <p>eTwinning https://www.etwinning.net/it/pub/index.htm</p> <p>CHEMSPIDER In Silico Models for Toxicity Prediction https://www.chemspider.com/#</p> <p>QSAR - A free Software, that helps to statistically relate the biologic activity of a substance to its physical-chemical structure https://qsartoolbox.org/</p>

Key Element	Suggestions
Offline teaching material	Personal Devices: Laptops, Tablets, Smartphones, LIM with internet connection
Resources used	<ol style="list-style-type: none"> 1. Newspaper article citing the use of animals in the experimentation https://www.corriere.it/salute/reumatologia/09_maggio_26/artrosi_nuova_cura_3cde4708-49df-11de-8785-00144f02aabc.shtml?refresh_ce-cp 2. The 3R Principle: Replace, Reduce, Refine https://www.youtube.com/watch?v=onqmtKnNsmY 3. Can we do science without animal testing? https://www.youtube.com/watch?v=2hxUMpYFo_Y 4. The failure of animal experiments https://www.youtube.com/watch?v=Mo25wUKNySg 5. Why animal testing doesn't work https://www.youtube.com/watch?v=8OPIn-wxmbM 6. Padlet https://it.padlet.com/ 7. Direttiva 2010/63/UE dell'Unione Europea (hyperlink) 8. D.LGS. del 4 marzo 2014, n. 26 (hyperlink) 9. EURL ECVAM (https://ec.europa.eu/jrc/en/eurl/ecvam) 10. SYRCLE https://vimeo.com/142124487# 11. FELASA http://www.felasa.eu/working-groups/working-groups-present/ 12. Italian 3R Center https://www.centro3r.it/en 13. List of other 3R European centers https://norecopa.no/overview-of-european-3r-centres 14. Decreto ministeriale 07 giugno 2019 http://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2019&codLeg=69552&parte=1%20&serie=null 15. In Silico Model for toxicity prediction (45:14) https://www.youtube.com/watch?v=db3sqA8-RUU 16. Evolution of the Healthcare Sector (03:55) https://www.youtube.com/watch?v=iQj9LnyL1xM 17. The future of medicine is inside these chips (05:54) https://www.youtube.com/watch?v=wYxqc7tZG-s 18. Journal ALTEX https://www.altex.org/index.php/altex 19. Altweb http://altweb.ihsph.edu 20. ProTox-II http://tox.charite.de/prottox_II/index.php?site=home 21. ProTox-II informations and tutorial http://tox.charite.de/prottox_II/index.php?site=fag 22. TFEU https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT 23. China Will No Longer Require Animal Testing On Cosmetic Products https://www.vogue.co.uk/article/china-lifting-animal-testing-laws

Key Element	Suggestions
	<p>24. New UK and China cooperation on reducing laboratory animal use-October 2018 https://www.nc3rs.org.uk/news/new-uk-and-china-cooperation-reducing-laboratory-animal-use</p> <p>25. Introducing Ethical Evaluation of the use of Animals in Experiments in the near East. Alternatives to Laboratory Animals https://www.researchgate.net/profile/Askin_Yasar/publication/46169058_Introducing_Ethical_Evaluation_of_the_Use_of_Animals_in_Experiments_in_the_Near_East/links/5808623208aefaf02a2c69a2.pdf</p> <p>26. The Evolution of Animal Welfare and the 3Rs in Brazil, China, and India - J Am Assoc Lab Anim Sci. 2015 Mar; 54(2): 181–191. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4382623/</p> <p>27. India- Prevention of Cruelty to Animals Act 1960 as amended in 1982. https://docs.google.com/document/d/122lOXj5_VSt_dUbDTJeihN8M2f0xrq866RIKJGLcwpo/edit?pli=1</p> <p>28. Organizations of relevance to animal research https://norecopa.no/more-resources/organisations</p> <p>29. Ethics dumping https://theconversation.com/ethics-dumping-the-dark-side-of-international-research-88675</p> <p>30. Medical Experiments of the Holocaust and Nazi Medicine https://remember.org/educate/medexp</p> <p>31. Tuskegee Experiment: The Infamous Syphilis Study http://www.history.com/news/the-infamous-40-year-tuskegee-study</p> <p>32. The 2030 Agenda for Sustainable Development https://sustainabledevelopment.un.org/post2015/transformingourworld</p> <p>33. The Ispra JRC Summer School visit programme https://ec.europa.eu/jrc/en/eu-science-outreach-programme/schools</p> <p>34. DLGS 107 of 2015 http://www.alternanza.miur.gov.it/index.html</p>

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Aim of the lesson

- Learn about the right of animals to be protected from their indiscriminate use in science.
- Discover how the 3Rs principles were introduced for the first time in the European legislation and implemented into each Member State.
- Learn about the career profile of a practitioner who applies the 3Rs in their work.
- Examine how STEM subjects can guarantee employment in the professions of the future.

Trends

- Project-based learning: students get fact-based tasks, problems to solve and they work in groups. This kind of learning usually transcends traditional subjects.
- Collaborative learning: a strong focus on group work and interaction.
- Critical thinking and problem solving.
- Lifelong learning: learning does not stop after leaving school.
- Open source learning: teachers copy, share, adapt, and reuse free educational materials.
- STEM learning and familiarization with STEM-related careers: increased focus on Science, Technology, Engineering and Mathematics. Through this Learning Scenario students will be introduced to various STEM-related careers.
- Peer Learning: students learn from peers and give each other feedback.
- Cloud Based Learning: data, tools, software is all online and can be reached and modified from different devices.
- Mobile learning and ICT literacy: we get access to knowledge through smartphones and tablets. It is learning anytime, anywhere.
- Learning with the use of visual media: images and multimedia are more powerful than verbal stimuli.
- BYOD (Bring your own device): students bring their own mobile devices to the classroom.

21st century skills

This lesson plan favours the development of 21st century skills as it: invites students to question the ethical correctness of the use of animals in the sciences; induces them to confront themselves by answering some guiding questions; stimulates their creativity in finding alternative solutions to the use of laboratory animals; causes them to work together collaborating.

Lesson Plan

Name of activity	Procedure	Time
Starting lesson	Students divided into groups of 5, and read a newspaper article citing the use of animals in experimentation (https://www.corriere.it/salute/reumatologia/09_maggio_26/artro_si_nuova_cura_3cde4708-49df-11de-8785-00144f02aabc.shtml?refresh_ce-cp). Following, they discuss the uses by answering some guide questions (see Annex 1). A representative of each group will present the answers to the whole class.	60'
Lesson on the 3Rs	a. Students watch one or more of the following videos that introduce the 3Rs principles and the possibility of doing science	60'

Name of activity	Procedure	Time
	<p>without animal testing, which in some cases are even unsuccessful.</p> <p>1. The 3R Principle: Replace, Reduce, Refine (04:03) https://www.youtube.com/watch?v=onqmtKnNsmY The movie describes the history, the development and the meaning of the 3R principle.</p> <p>2. Can we do science without animal testing? (03:41) https://www.youtube.com/watch?v=2hxUMpYFo_Y New science and technological innovation are producing viable alternatives to help replace, reduce and refine animal testing, as sources of data and evidence for scientific assessments. Not only can these tools help reduce animal suffering but with time it could also produce better data that more closely reflect what happens in humans, animals and the environment.</p> <p>3. Why animal testing doesn't work (02:51) https://www.youtube.com/watch?v=8OPIn-wxmbM</p> <p>b. Using as a resource the videos just watched, the students cooperate in creating a Padlet (https://it.padlet.com/) in order to accurately define the meaning of each of the 3 Rs of the principle proposed by Russell and Burch in 1959 (Replacement, Reduction and Refinement).</p>	
<p>Know the legislation and the role of the European Union: take care of the animals</p>	<p>The teacher shows a brief Power Point presentation (see Annex 2) to inform students about the European legislation for the use of laboratory animals, making a historical excursus. From the presentation it will emerge that the principles proposed by Russell and Burch (The Principles of Humane Experimental Technique, 1959) are the basis of the European Union Directive 2010/63/EU on the protection of animals used for scientific purposes (Direttiva2010/63/UE dell'Unione Europea) and that this directive was implemented in Italy with the Legislative Decree of 4 March 2014, 26 (D.LGS. del 4 marzo 2014, n. 26).</p>	10'
<p>Search on the web</p>	<p>As homework, students divided into groups of 5 look for information on the web relating to the main centres, institutions and working groups active on the European and national territory in the promotion, dissemination and implementation of 3Rs (see some examples in the list below). Research can be facilitated by providing some useful web site links and key questions, such as "Where is the centre?" and "What does the centre primarily do?".</p> <ul style="list-style-type: none"> • EU Reference Laboratory for alternatives to animal testing (EURL ECVAM) is an integral part of the Joint Research Centre (JRC), the science and knowledge service of the European Commission. EURL ECVAM is a big research centre created as a reference Lab under Directive 2010/63/EU and whose scientists support to the 3Rs giving scientific advice to the policy makers sitting in the European Commission in Brussels. (https://ec.europa.eu/jrc/en/eurl/ecvam). 	30'

Name of activity	Procedure	Time
	<ul style="list-style-type: none"> • SYRCLE (Systematic Review Centre for Laboratory Animal Experimentation) that through a Systematic Review on animal studies makes the translatability on human beings of the results obtained with animal models allowing the reduction of the number of animals used in the experiments (See video https://vimeo.com/142124487). • FELASA¹¹ (Federation of European Laboratory Animal Science Associations) that represents common interests in the furtherance of all aspects of laboratory animal science (LAS) in Europe and beyond. (http://www.felasa.eu/working-groups/working-groups-present/). • Centro 3R, an Italian inter-university centre for the promotion of the 3Rs in teaching and research (https://www.centro3r.it/en) that is formed by several members as the Universities of Genoa, Pisa and Pavia and The Polytechnic Universities of Turin and Milan (the list of other 3R European centres is available here). • An Italian working group for the promotion of alternative methods to the use of animals for scientific purposes established in June 2019 by the Ministry of Health, pursuant to article 37 of the legislative decree 4 March 2014, n. 26 (Decreto ministeriale 07 giugno 2019; http://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2019&codLeg=69552&parte=1%20&serie=null). Within the working group there are several delegates from the Ministry of Health, Health Superior Institute, National Reference Centre for Alternative Methods, Health and Care of Laboratory Animals, Conference of Italian University Rectors and Institute for Scientific Research and Treatment, and several experts on alternative methods, bioethics and in vivo animal testing. The meeting of the group will be monthly, and every six months will have to present a report to the minister. <p>The collected information will be shown to the rest of the class through a Power Point.</p>	
Alternative methods	<p>Through this activity, students can acquire some skills for the basic use of alternative tools to in vivo experimentation.</p> <ol style="list-style-type: none"> 1. Starting from a stimulus question (<i>What alternative methods do we have in order to limit the use of animals in experimentation?</i>) students are eager to watch the following videos on alternative methods: <ol style="list-style-type: none"> a. In Silico Model for toxicity prediction (45:14) https://www.youtube.com/watch?v=db3sqA8-RUU b. In Vivo, in Vitro, in Silico: Why Computer Modelling is the Next Evolution of the Healthcare Sector (03:55) https://www.youtube.com/watch?v=iQj9LnyL1xM 	60'

Name of activity	Procedure	Time
	<p>c. The future of medicine is inside these chips (05:54) https://www.youtube.com/watch?v=wYxqc7tZG-s</p> <p>2. After that, students divided into group of 5 go more in depth of the topic of alternative methods by reading a scientific article carefully selected by the teacher. Interesting articles can be found in the following websites:</p> <p>a. Journal ALTEX – Alternatives to Animal Experimentation publishes open access academic articles on the development and implementation of alternatives to the use of animals for scientific purposes and informs on international developments in this field. ALTEX is the official organ of CAAT, CAAT-Europe,</p> <p>b. the Doerenkamp-Zbinden Chairs, EUSAAT and The Transatlantic Think-Tank of Toxicology. https://www.altex.org/index.php/altex</p> <p>c. Altweb, the Alternatives to Animal Testing Web Site, was created to serve as a gateway to alternatives news, information, and resources on the Internet and beyond. Altweb now is the U.S. home of the journal ALTEX: Alternatives to Animal Experimentation, which is the official publication of the Johns Hopkins Center for Alternatives to Animal Testing (CAAT). http://altweb.jhsph.edu</p> <p>Students have a week to finish work at home and to expose it to the rest of the class through a power point presentation.</p> <p>3. At the end of the presentations, students are guided to discuss the importance of improving alternative methodologies and how these are strictly linked to the STEM (data analysis, computing, artificial intelligence, simulation, gaming) and to the development of new technologies. Students are led to reflect on the importance of studying STEM within the school curriculum also in consideration that the practice of the 3Rs will be one of the important jobs of the future (become the scientists of the future), so there are career opportunities in becoming knowledgeable in this area.</p>	
Simulation activities	<p>To understand the application of in silico models students can experience a basic simulation activity on the toxicity of simple known molecules that are included in some online Databases which can be freely downloaded:</p> <ul style="list-style-type: none"> • ProTox-II - Prediction of Toxicity of Chemicals, a virtual lab for the prediction of toxicities of small molecules: http://tox.charite.de/prottox_II/index.php?site=home • For a description of the server, methods and tutorials, go to the following link: http://tox.charite.de/prottox_II/index.php?site=fag 	60'
Research	3Rs: the state of the art nowadays in European and non-European countries. What is our role?	120'

Name of activity	Procedure	Time
	<p>a. Starting on the concept of animal welfare as enshrined in Article 13 of the Treaty on the Functioning of the European Union (TFEU) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT) which recognizes animals as sentient beings, students understand that the legislation of all countries must be in line with that.</p> <p>b. Students divided into groups of 5 carry out research on the web to learn how other European countries (also on the basis of the nationality of origin of the different students) have responded to the 2010 European decree based on the 3R principle (Direttiva 2010/63/UE dell'Unione Europea) in their national legislation.</p> <p>c. Students will be asked to compare the legislation and research by non-European countries using the resources provided by the teacher. Students work in pairs and summarize the content of the articles.</p> <ul style="list-style-type: none"> • China Will No Longer Require Animal Testing On Cosmetic Products (https://www.vogue.co.uk/article/china-lifting-animal-testing-laws) China has required animal testing of cosmetics and related products, but it is reported that this will not be required from 2020. • New UK and China cooperation on reducing laboratory animal use-October 2018 (https://www.nc3rs.org.uk/news/new-uk-and-china-cooperation-reducing-laboratory-animal-use); • Introducing Ethical Evaluation of the use of Animals in Experiments in the near East. Alternatives to Laboratory Animals, 38(4), 331-336. Izmirli, S., Aldavood, S. J., Yasar, A., & Phillips, C. J. C. (2010). • Turkey became an official candidate to join the EU in 1999, which required it to align its legislation in order to make it compatible with the EU legislation, before eventually becoming a Member State. As part of the candidature, several different laws and regulations concerning the use of animals in research came into force in Turkey. • https://www.researchgate.net/profile/Askin_Yasar/publication/46169058_Introducing_Ethical_Evaluation_of_the_Use_of_Animals_in_Experiments_in_the_Near_East/links/5808623208aefaf02a2c69a2.pdf • The Evolution of Animal Welfare and the 3Rs in Brazil, China, and India (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4382623/); • India- Prevention of Cruelty to Animals Act 1960 as amended in 1982 (https://docs.google.com/document/d/122IOXj5_VSt_dUbDTJeihN8M2f0xrg866RIKJGLcwp0/edit?pli=1). 	

Name of activity	Procedure	Time
	Organizations of relevance to animal research to see how they are distributed in different countries. (https://norecopa.no/more-resources/organisations)	
Ethics debate	<p>a. Became aware of the fact that while the European Union is very active on the 3Rs, other regions are evolving on this and others are starting to question themselves, students are split in groups to develop an ethical debate choosing one of the following items:</p> <ol style="list-style-type: none"> 1. How can we avoid '<i>ethics dumping</i>', a European Commission coined phrase to describe the export of unethical research practices to locations with weak legal frameworks and ethics compliance mechanisms? (https://theconversation.com/ethics-dumping-the-dark-side-of-international-research-88675) 2. There have been several examples in the past of cases of human being exploitation in research like medical experiments of the Holocaust (https://remember.org/educate/medexp) or the Tuskegee experiment (http://www.history.com/news/the-infamous-40-year-tuskegee-study). After the World Medical Association's Declaration of Helsinki, it is clear that inflicting severe harm on human beings for the purpose of research is one of the most serious cases of human rights abuse possible. Will we ever get to say the same thing about animals? 3. The 2030 Agenda for Sustainable Development is an action program for people, signed in September 2015 by the governments of 193 member countries of the United Nations. It incorporates 17 Sustainable Development Goals, SDGs, for a total of 169 "target" or objectives that the countries have committed to achieve by 2030 (https://sustainabledevelopment.un.org/post2015/transformingourworld). Animals are not considered at all. Can we tolerate it? 4. How can we develop solidarity across students in Europe to communicate to our politicians that animal testing is not acceptable at all? <p>The report of the debates will be discussed in plenary. Conclusions will be shared through the eTwinning platform with other classes from other countries and eventually presented to members of the European Parliament, politicians from non-European countries and possible stakeholders.</p>	120'
Create a questionnaire	Based on the collected information, students will formulate a series of questions to be submitted to researchers during the research Centre visit or the meeting with the experts (or alternatively the webinar).	60'

Name of activity	Procedure	Time
<p>Meeting with experts</p>	<p>Students will visit a research centre for alternatives to animal testing or participate in an event organized at school where one or more experts in the field will illustrate the methods and new technologies used in their laboratories. See the 3Rs European centres list for the contacts (https://norecopa.no/overview-of-european-3r-centres).</p> <p>The JRC has recently launched a school visit programme where schools can request to visit the JRC Ispra and a specific laboratory (https://ec.europa.eu/jrc/en/eu-science-outreach-programme/schools).</p> <p>Alternatively, a webinar could be organized for the meeting with an expert in the field. All the aforementioned activities can be considered in Italy as school-work alternation activities (decree 107 of 2015, http://www.alternanza.miur.gov.it/index.html).</p> <p>Otherwise, if no 3R centres are available, it is possible to contact an animal lab at the local university. All European universities are definitely aware of the 3R legislation and lab researchers would be able to talk about their practice with students.</p>	

Assessment

The assessment will be carried out using both summative and formative evaluation methods that allow a broad approach to the learning process useful for the continuous improvement of the teaching - learning process.

As a form of formative assessment peer assessment or peer review provides a structured learning process for students to critique and provide feedback to each other on their work.

The Assessment will be therefore carried out continuously in the various modules through different methods in relation to the various activities proposed.

Create a Padlet and/or Presentation

- Evaluation of group work (the ability to work in a group is fundamental in research and professions in the STEM field)
- Students will have to create a Padlet to perform presentations in the classroom (self-assessment; peer review/evaluation; evaluation by the teacher)
- Formative assessment in addition to summative assessment (evaluation by teacher)

Create and / or answer questionnaires

- Students' progress will be assessed with an online Kahoot quiz and/or an online quiz and with feedback from students.
- Students divided into groups, carry out the questions of a Kahoot quiz for each group, then exchanging them, the different Kahoot quizzes are proposed to the other groups (Peer review/evaluation)
- The teacher can carry out the formative and summative assessment

Debate

- Debate grading rubric: https://ar.cetl.hku.hk/am_debate.htm#6, and/or <http://www.csun.edu/~ds56723/phil338/hout338rubric.htm>
- Formative assessment in addition to summative assessment (evaluation by teacher)

Student feedback

The students were asked to complete surveys prior and after the implementation of the Learning Scenario, in order to give feedback to their instructors about the content and the activities. Specific points of concern for the students include the below:

- While the topic is considered very interesting and enjoyable by the vast majority of the participating students, some basic information in order to introduce them to it could be given in students native tongue in order to explain terminology better.
- Based on student feedback and taking into consideration students' age, teachers are advised to be cautious and not expose their students to unsettling information or too graphic content.
- In addition to the topic which exposed students to new ideas, knowledge and perspectives, students were very interested in the acquisition of practical skills and the creation and use of surveys.
- Several students responded that the topic introduced them to materials about science but also research methods and project-like activities that were new to them. This provides teachers with the opportunity to think how to incorporate in their lesson information about STEM related careers.

Teacher's remarks

- While an estimated time for the Learning Scenario has been indicated by the authors, teachers are advised to improvise according to the resources they intend to use. During this process, they are advised to consider the age of their students, previous knowledge and the language of the materials.
- Teachers can consider inviting external experts from research centres or Universities, in order to inform their students about the topic but also the technology used (e.g. virtual labs). However, it is preferable to allocate separate hours in research, implementation and use of technical tools, so students have time to process all the information.

About 3Rs project

This Learning Scenario has been created in the framework of the 3Rs project. The 3Rs project is building learning activities for secondary schools to introduce the principles of the 3Rs - the Replacement, Reduction and Refinement of animal use in science. Students will develop their critical thinking and science literacy skills by exploring topics such as ethics in science, how the European Union is protecting the welfare of laboratory animals, and what high-tech non-animal tools are available as alternatives. The learning activities are available for teachers in a Massive Open Online Course (MOOC), organised by the European Schoolnet Academy.

The 3Rs project has been funded by the European Commission's Joint Research Centre under a European Parliament Pilot Project. This document has been prepared by European Schoolnet (a network of 34 European Ministries of Education which aims to bring innovation in teaching and learning), in collaboration with ECORYS (international company providing research, consultancy and management services) and SYRCLE (Systematic Review Centre for Laboratory Animal Experimentation).

ANNEXES

Annex 1

Questions:

- According to you, is it the same using animal models or tissues from the same patient that needs to be treated in order to conduct experiments?
- Do you think it is ethically correct to use any type of animal for experimentation or would you make any distinction?
- Does it make sense to experience the effect of a molecule on an animal rather than on humans? Is it certain that a molecule that is effective in animals is also effective in humans?
- Do you think there is any legislation regarding the use of animals in scientific experimentation?
- What could be done to reduce its use in Science?
- Can animal models be replaced?
- Is there an Italian Law about the obligation of public and private Italian Institutions to fully inform workers and students about their right to conscientious objection to scientific or educational activities involving animals? (Law 413/1993)

Annex 2

Presentation about the 3Rs presentation (see below).



European
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Legislation for the protection of animals used for scientific purposes



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Legislation for the protection of animals used for scientific purposes

The principles of the 3Rs

These principles, first proposed by William M.S. Russel and Rex L. Burch in 1959 in their book «The Principles of Humane Experimental Technique», concern the ethical aspects in the use of animals in scientific experiments.

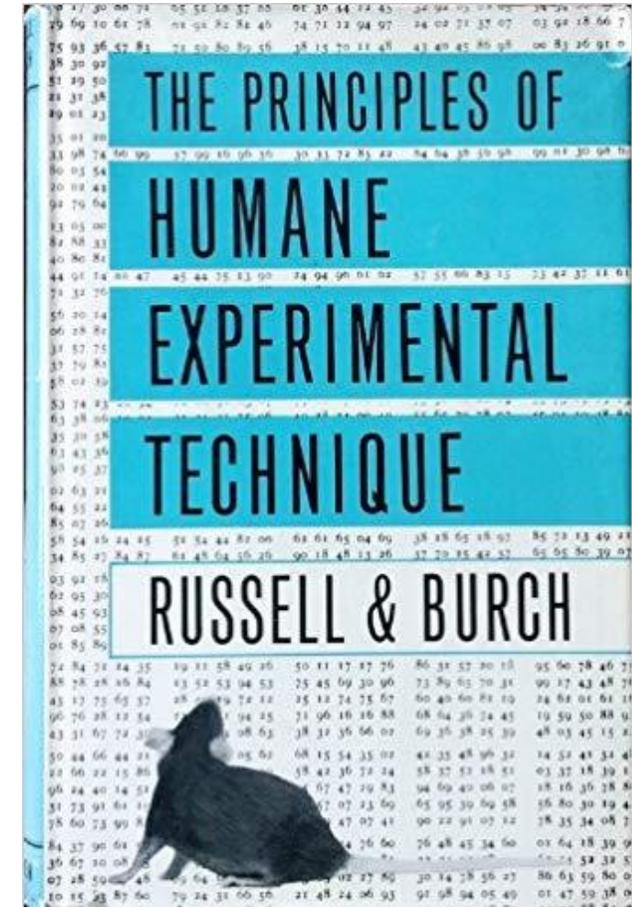
The 3Rs are the initials of:

REPLACEMENT: replacement (even partial) of animal testing with alternative methods of comparable validity

REDUCTION: reduction in the number of animals used for a specific study

REFINEMENT: improvement of experimental design to reduce stress and suffering to animals

The principles of the 3Rs do not oppose animal experimentation. Their goal is to promote **responsible experimentation**.



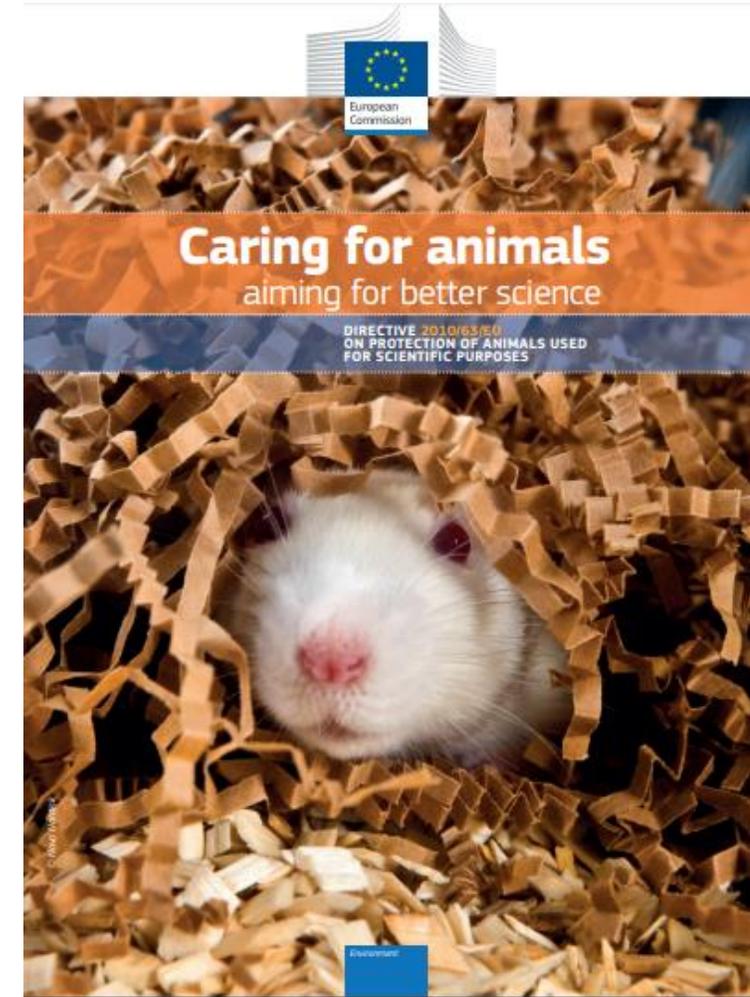
Legislation for the protection of animals used for scientific purposes

European Union Directive 2010/63 / EU

The principles proposed by Russell and Burch are the basis of the **European Union Directive 2010/63 / EU** on the protection of animals used for scientific purposes, supporting **replacement, reduction, and refinement** (the 3Rs) .

Directive 2010/63/EU was adopted on 22 September 2010 as a revision of the **Directive 86/609/EEC**.

Let's take a step back!



Legislation for the protection of animals used for scientific purposes

Council Directive 86/609/EEC

The Directive introduced for the first time legal provisions in the EU to eliminate the disparities in laboratory animal protection laws among member nations.

The directive outlines principles such as:

- ✓ reduction in the number of animals used in research;
- ✓ guidelines for the adequate care of animals;
- ✓ elimination of unnecessary pain, suffering, distress or lasting harm;
- ✓ avoidance of unnecessary duplication of experiments.

While the provisions of the directive are specific, it is left to each member nation to determine how these provisions will be enacted and enforced.

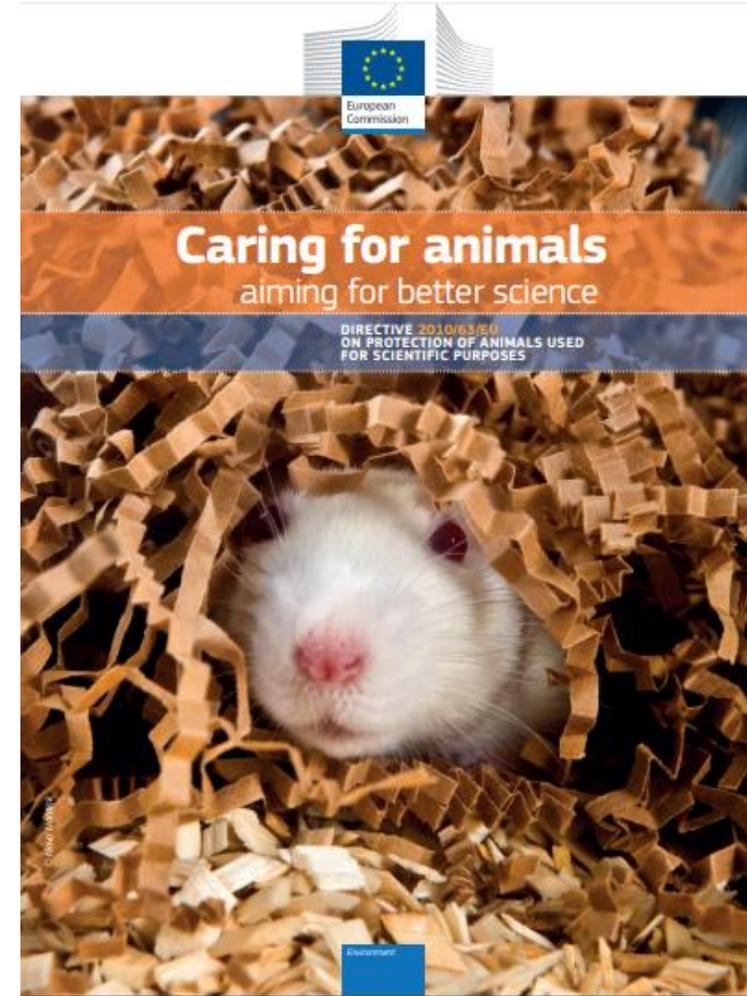
The directive also provided that every 3 years each member nation must submit a report on the number of animals used in research.

Legislation for the protection of animals used for scientific purposes

European Union Directive 2010/63 / EU

Compared to the **old directive**, in Directive 2010/63/EU:

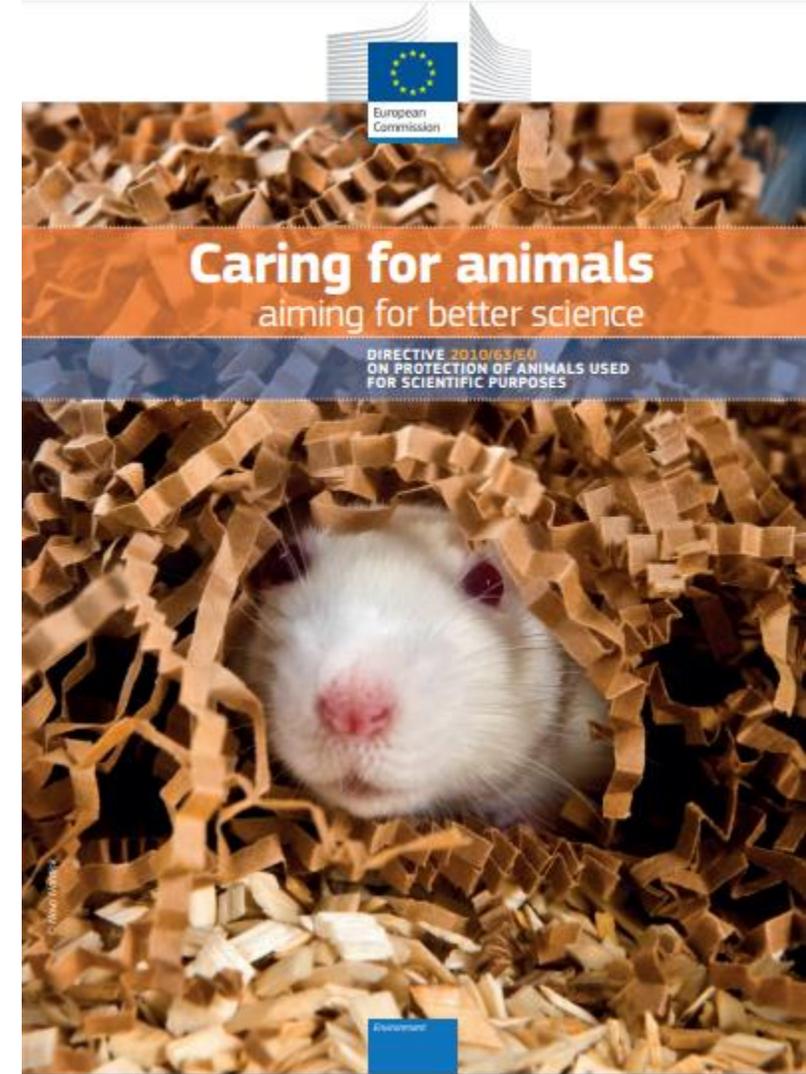
- The **scope** is wider, including *foetuses* of mammalian species in their last trimester of development and *cephalopods*, as well as animals used for the purposes of *basic research, higher education and training*.
- It lays down **minimum standards for housing and care**, regulates the use of animals through a *systematic project evaluation* requiring inter alia *assessment of pain, suffering distress and lasting harm* caused to the animals.



Legislation for the protection of animals used for scientific purposes

European Union Directive 2010/63 / EU

- It requires regular risk-based **inspections** and improves **transparency** through measures such as publication of non-technical project summaries and retrospective assessment.
- It promotes the development, validation and implementation of **alternative methods** through the establishment of a Union reference laboratory for the validation of alternative methods supported by laboratories within Member States and requiring Member States to promote alternative methods at national level.



Legislation for the protection of animals used for scientific purposes

Regulation (EU) 2019/1010

Regulation (EU) 2019/1010 on the **alignment of reporting obligations** in the field of legislation related to the environment:

- amends in its Article 6 Directive 2010/63/EU to improve *transparency* and *reporting obligations*.
- amends Articles 43 and 54 of the Directive by foreseeing a **central, open access EU database** for the *publication of Non-technical Project Summaries*, and for some Member States, the *publication of the results of Retrospective Assessment* of projects.
- provides a central, open access EU database for the *publication of annual statistics*.



Legislation for the protection of animals used for scientific purposes

Legislative Decree of 4 March 2014, n. 26

European Union Directive 2010/63 / EU was implemented in Italy with **Legislative Decree of 4 March 2014, n. 26** that regulates the use of animals for scientific purposes in Italy.

According to this rule:

- all research projects involving the use of vertebrate animals and certain invertebrates, such as cephalopods, must be authorized by the Ministry of Health and carried out within authorized user establishments.
- the use of animals is permitted only when the research project manager is able to demonstrate and document the impossibility of achieving the desired result using another method of scientific experimentation that does not involve the use of live animals.



Legislation for the protection of animals used for scientific purposes

Legislative Decree of 4 March 2014, n. 26

- Procedures to be favored are those that:
 - require the least number of animals;
 - use animals with the least ability to feel pain, suffering, distress or prolonged damage;
 - are able to minimize pain, suffering, distress or prolonged harm;
 - offer the greatest chances of satisfactory results;
 - have the most favorable relationship between damage and benefit.
- the development, validation, acceptance and application of "alternative methods", the procedure that avoids the use of animals in scientific experimentation, are first time promoted.



References

- Legislation for the protection of animals used for scientific purposes
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- Regulation of Animal Research, Science, Medicine, and Animals, 2004.
[\(https://www.ncbi.nlm.nih.gov/books/NBK24650/\)](https://www.ncbi.nlm.nih.gov/books/NBK24650/)
- [EU directive 2010/63](https://eur-lex.europa.eu/eli/dir/2010/63/oj) (<https://eur-lex.europa.eu/eli/dir/2010/63/oj>)
- [Italian D.LGS. del 4 marzo 2014, n. 26](https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2014-03-04;26!vig=) (<https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2014-03-04;26!vig=>)

About the 3Rs project

This Learning Scenario has been created in the framework of the 3Rs project. The 3Rs project is building learning activities for secondary schools to introduce the principles of the 3Rs - the Replacement, Reduction and Refinement of animal use in science. Students will develop their critical thinking and science literacy skills by exploring topics such as ethics in science, how the European Union is protecting the welfare of laboratory animals, and what high-tech non-animal tools are available as alternatives. The learning activities are available for teachers in a Massive Open Online Course (MOOC), organized by the European Schoolnet Academy.

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