



Animal Welfare Body
Stazione Zoologica Anton Dohrn
Rules and Regulations

Art. 1 - Constitution

1. Within the activities of the Stazione Zoologica Anton Dohrn (hereinafter also referred as SZN) and for the purposes set forth below, the Animal Welfare Body is set up - hereinafter referred to as “the Body” or “AWB” - in transposition of Article 25 of Legislative Decree 26/2014 ***“Attuazione della direttiva 2010/63/UE sulla protezione degli animali utilizzati a fini scientifici”*** of the Italian Legislation.

Art. 2 - Purpose and duties of the Animal Welfare Body

1. The AWB will evaluate, approve and monitor projects that require the use of the animals verifying that they comply with the principles of ethical and scientific standards established by the regulations in force. In particular, the Body - under Italian Legislative Decree 26/2014 - will perform the following tasks:
 - a. Support of the scientific and technical staff dealing with animals on matters relating to the welfare of animal species in relation to their acquisition, accommodation, care and use.
 - b. Support of the scientific and technical staff assigned to the use of animals for a better application of the principles of replacement, reduction and refinement (the 3Rs), keeping them informed of technical and scientific developments and promoting their Continuous Professional Development; the AWB also define and review internal operational processes for monitoring, reporting and assessment in relation with the welfare of animals housed and/or utilized at the SZN.
 - c. Provide with opinions on research projects that require the use of the species covered by Italian Legislative Decree no. 26/2014 and any subsequent amendments, also by informing the ‘Person Responsible for the Project’.
 - d. Submit via electronically certified mailing systems projects’ proposals to the Italian Ministry of Health (i.e. the National Competent Authority), and at the same time notifying the Person Responsible for the Project. The proposal to be submitted should include: *i*) the Scientific Proposal (also called the

- 'Project'; *ii*) a non-technical summary of the project as set out in Article 34 of Legislative Decree no. 26/2014; and *iii*) a schematic overview of the proposal as set out as indicated in Allegato VI (i.e. Annex VI) of Italian Legislative Decree no. 26/2014.
- e. Monitoring of the development and the outcomes of the authorised research projects taking into account the effects on the individual animals utilized, as well as identifying and advising on elements that further contribute to the application of the principles of the 3Rs.
 - f. Provide advise on possible rehoming of animals including the appropriate socialization of animals which may have to be rehomed.
 - g. Document the activities carried out by the AWB in the relevant registers and keep records for a period of six (6) years.
2. In order to issue the opinions referred to in paragraph 1 letter d, the Animal Welfare Body of the SZN will assess:
- a. the correct application of the legislation in force;
 - b. the need for the use of species covered by Italian Legislative Decree 26/2014 in terms of the technical and scientific relevance of the project;
 - c. obligations arising from European and international regulations, from the pharmacopoeias for drug development and safety, and toxicology assays on any chemical and natural substances used;
 - d. the possibility of replacing one or more procedures by alternative methods referred to in Article 1, paragraph 2, of Italian Legislative Decree no. 26/2014;
 - e. the adequacy of the training and the suitability of the professional roles of the users specified in the project;
 - f. the adequacy of the harm/benefit analysis provided.

Art. 3 - Composition

1. The Animal Welfare Body of the SZN consists of five (5) to seven (7) members, including the officers required by law and high profile scientific experts in the field

- of animal welfare; membership should include, where useful and appropriate, a member with expertise in the field of bioethics. The majority of the experts should be people not enrolled among the personnel of the Stazione Zoologica Anton Dohrn and belonging to other national and/or international Organizations and/or Academia.
2. The members of the Animal Welfare Body are appointed by the Executive Board of the SZN upon recommendation of the President of the SZN.
 3. Pursuant to art. 25 of Italian Legislative Decree no. 26/2014, the Body is made up of:
 - a. the SZN Person responsible for the welfare and care of animals used in experiments;
 - b. the SZN Designated Veterinarian designated in compliance with art. 24 Italian D.lgs. 26/2014;
 - c. a member of the scientific community from within the SZN;
 - d. from two (2) to four (4) independent experts external to the Stazione Zoologica Anton Dohrn.
 4. Members of the SZN Animal Welfare Body remain in office for five years and may be reappointed for a further term.

Art. 4 - Organisation of the AWB

1. The Body shall designate a Chairman and a Secretary on the occasion of the first meeting.
2. The Chairman of the Animal Welfare Body is acting to:
 - a. warrant compliance with this Rules and Regulations, and with the guidelines and operating procedures set-out specifically by the AWB; warrant a good performance of the activities undertaken by the Animal Welfare Body also in the sake of further recommendation set forth by European Community;

- b. convenes the meetings of the AWB at least 10 days in advance except where justified on grounds of urgency for which 48 hours' notice are sufficient;
 - c. ensures the implementation of motions adopted by the Body;
 - d. prepares an annual report on the SZN AWB activities to be presented to the Executive Board of the SZN.
3. The Secretary assists the Chairman in relations with the relationship with the National Competent Authority and is responsible for filing the documentation submitted.
4. The Body sets internal guidelines and specific operating procedures in line with current national and EU legislation and other rules whenever available and this Rules and Regulation.
5. The AWB shall meet at least twice a year and whenever necessary, taking into due consideration the time required for providing opinions.
6. AWB meetings may also be held online; all members will be provided with the agenda and the documents to be discussed beforehand.
7. The motions of the SZN AWB do not replace the legal, ethical and moral responsibility of those who are tasked with decision-making.

Art. 5 – Archival of Documentation

1. All the documents prepared with the assistance of the secretarial support of the Body and archived and kept by the Central Secretary Office of the SZN also for the purposes of supervision, in addition to this regulation must necessarily include:
 - a. the guidelines and operating procedures for the SZN Animal Welfare Body, including any revisions;
 - b. the registers with notes of any advice given and related decisions;
 - c. all correspondence;
 - d. the curriculum vitae of all the members of the SZN Animal Welfare Body, together with any declarations of incompatibility in individual cases;

- e. the agenda and minutes of meetings;
- f. a copy of the projects and of any opinion provided;
- g. a copy of the annual activity reports, opinions and all motions adopted;
- h. all other documents required by the regulations and operating procedures.

Art. 6 - Duties of the Members of the Body

1. The members of the SZN Animal Welfare Body:
 - a. cannot delegate to third parties in their stead;
 - b. have the duty to guarantee and ensure sufficient time for the preparatory study of documents to be discussed at meetings.
2. Members of the SZN AWB are bound to secrecy regarding the records relating to their activity.
3. Members of the Body shall refrain from voting on matters regarding which there may be a direct or indirect conflict of interest.
4. Members of the Body may submit a supplementary or dissenting report on specific matters, to be annexed to a document approved by the Body.

Art. 7 - Voting and Resolutions

1. The SZN AWB may pass resolutions if a quorum of half the appointed members plus one is reached. Legitimate absences are not accounted for in the calculation of the quorum.
2. Resolutions are passed by an absolute majority of those entitled to vote.
3. Voting shall be by open ballot with a show of hands. Any exceptions must be identified, regulated for and approved unanimously before the vote.
5. After the vote has been taken, the Chairman shall ascertain and proclaim the outcome.

Art. 8 - Financial Aspects

1. The members of the SZN Animal Welfare Body carry out their duties on a voluntary basis. Travelling expenses of the external members of the AWB will be covered by the SZN.

Art. 9 Transitional Norms

1. For regulatory questions not covered by this Regulation, the legal provisions in force shall apply where compatible.
2. This Regulation shall be enforced from the date of its approval by the Executive Board of the SZN.