

Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance)

CHAPTER IV
AUTHORISATION

Section 2

Inspections

Article 34

Inspections by the Member States

- 1 Member States shall ensure that the competent authorities carry out regular inspections of all breeders, suppliers and users, including their establishments, to verify compliance with the requirements of this Directive.
- 2 The competent authority shall adapt the frequency of inspections on the basis of a risk analysis for each establishment, taking account of:
 - a the number and species of animals housed;
 - b the record of the breeder, supplier or user in complying with the requirements of this Directive;
 - c the number and types of projects carried out by the user in question; and
 - d any information that might indicate non-compliance.
- 3 Inspections shall be carried out on at least one third of the users each year in accordance with the risk analysis referred to in paragraph 2. However, breeders, suppliers and users of non-human primates shall be inspected at least once a year.
- 4 An appropriate proportion of the inspections shall be carried out without prior warning.
- 5 Records of all inspections shall be kept for at least 5 years.

Article 35

Controls of Member State inspections

- 1 The Commission shall, when there is due reason for concern, taking into account, *inter alia*, the proportion of inspections carried out without prior warning, undertake controls of the infrastructure and operation of national inspections in Member States.
- 2 The Member State in the territory of which the control referred to in paragraph 1 is being carried out shall give all necessary assistance to the experts of the Commission in carrying out their duties. The Commission shall inform the competent authority of the Member State concerned of the results of the control.

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3 The competent authority of the Member State concerned shall take measures to take account of the results of the control referred to in paragraph 1.