**Question for written answer E-003397/2014**
**to the Commission**
Rule 117
**Andrea Zanoni (S&D)**

Subject: Vivisection, alternative/replacement tests and activity of the European Chemicals Agency (ECHA)

Under Article 4 of Directive 2010/63/EU on the protection of animals used for scientific purposes, Member States must ensure compliance with the principle of replacement, reduction and refinement. Under the same directive, Member States must ensure, at national level, the promotion of alternative approaches and the dissemination of information thereon (Article 47(4)). In Italy, until 28 March, Legislative Decree 116 of 1992 will be in force (implementation of the previous Directive 86/609/EEC). This decree clearly stipulates that experiments must not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available. Under the same decree, the approval of projects should include an assessment of the aims of the project that justify the use of animals and an analysis of the harm and benefits deriving from the project, in order to understand whether, also taking ethical considerations into account, the harm done to the animals in terms of suffering, pain, distress or lasting harm is justified by the expected outcome in terms of benefits for humans, animals and the environment.

ECHA has published a document on the implementation of Regulation (EC) No 1907/2006 (REACH, Articles 50 and 51), entitled 'Decision on a compliance check of a registration pursuant to Article 41(3) of Regulation (EC) No 1907/2006' in which some in vivo tests are required when alternatives to such tests exist (eye and skin irritation or acute toxicity) and others are required when the use of animal models could be avoided (such as skin sensitisation and mutagenicity tests). This is not the first time ECHA has failed to properly present alternative and replacement methods to animal testing and is all the more serious in that Article 13 of the REACH Regulation clearly states that priority is to be given to means other than vertebrate animal tests, through the use of alternative methods, for example, in vitro methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances.

In view of the above, can the Commission clarify why ECHA has suggested, as a reference test, the in vivo model in spite of the existence of valid alternatives that do not involve the use and killing of animals? Why, in this document, is the use of in vitro methods only suggested in the final notes? What measures does the Commission intend to take to ensure that ECHA does indeed use alternative methods to replace animal testing as provided for by the REACH regulation and by Directive 2010/63/EU?