CONSIDERATIONS ON THE LAW NO. 43/2014 ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES

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Abstract: In order to protect the animals used for scientific experiments and to allow for the progress of research, the European Union adopts measures pursuing to limit experiments on animals and to impose minimal requirements on sheltering and taking care of trusted animals. Thus, Directive No. 2010/63/EU of the European Parliament and Council on the protection of animals used for scientific purposes has been adopted. Romania has transposed it into Law No. 43/2014 on the protection of animals used for scientific purposes, so as to harmonize its legislation in the field with the European Union law. We are talking about a recent normative act, the provisions of which will be analysed in the current study, by making references also to the regulations existing in another European Union states.

Keywords: environment, fauna, animals used for scientific purposes, project authorization, procedure.

1. Introduction

Every year around 12 million animals are used for scientific purposes[1]. This alarming situation has caught the attention of specialists and public opinion, currently more interested in the ethic arguments regarding the relation with animals. At present, it is not forbidden to use animals for testing the safety of food or for bio-medical research, but, in order to protect experimental animals and to allow for the progress of research, the European Union has adopted measures aiming to limit experiments carried out on animals and to increase the minimum standards of their protection. In this context it has also taken place the revision of Directive No. 86/609/EC on the protection of laboratory animals, a difficult process, triggered by the 2002 Decision of the European Parliament and ending with the adoption of Directive 2010/63/EU on the protection of animals used for scientific purposes[2]. The member states had two years for transposing the Directive which fully entered in force on January 1st 2013. Consequently, our attention has been directed towards capturing the novelty element of the regulation elaborated within the European Union, but also the most relevant provisions of the law on transposing the directive into internal law.

2. Considerations on Directive No. 2010/63/EC of the European Parliament and Council on the protection of animals used for scientific purposes

The performance of experiments on animals is an activity strictly controlled by the member states of the European Union and this control has been strengthened together with the entry in force of the Directive 2010/63/EU on the protection of animals used for scientific

[1] *** The fifth report on the statistics of the number of animals used for experimental purposes and other purposes within the EU member states {SEC (2007)1455}.
[2] Published in the Official Journal of the European Union (JOUE) series L, No. 276 from 20th October 2010.

purposes. The new directive continues to promote the responsible use of animals within research, on the benefit of the medical and scientific progress, by preserving the best conditions for the animal welfare. While its ultimate purpose is that of replacing the use of animals within scientific experiments, the directive acknowledges that animals, including non-human primates, are still necessary for scientific purposes. Yet, it is very important that the text states the fact that animals have an intrinsic value, which has to be respected. More expanded and detailed than the former regulation, the new directive has the following declared objectives:

- harmonizing the legislation on the research carried out on animals within European Union;

- bolstering the protection of animals used within scientific procedures, in accordance with the EC Roma Treaty and the 1997 Protocol on the animal protection and welfare[3];

- active promotion and full enforcement of the 3R principles (replace, reduce, refine)[4].

For this purpose, Directive 2010/63/EU specifies more explicitly what is allowed and what it is not, through provisions defining the way and what animals can be used for scientific purposes, with accent on savage animals, non-human primates, cats and dogs. At the same time, it details the allowed objective, based on the 3R enforcement, by acknowledging the contribution of the European Commission and the member states to their development, validation and dissemination. In fact, the directive is clearly based on the 3R principle, in order to replace, reduce and refine the use of animals for scientific purposes, including in the basic research, high education and professional training. Moreover, the Directive defines the facilities for the reproduction and development of experimental animals, by presenting all the requirements of staff, equipment, accommodation and groups for the animal protection, monitoring and welfare ("animal welfare organisations"). At the same time, the text of the directive describes the requirements for the training, education and competences of the staff involved, establishing a system of monitoring by an organisation granting state licenses. For this purpose, the projects involving research done on animals must be evaluated and approved by the competent authority, by means of the system for granting state licenses. At the same time, the directive acknowledges the need for the public to receive objective information regarding the use of living animals and it refers for that matter to measures for improving transparency, such as the publication on non-technical summaries of projects and retrospective evaluation. The text of the directive promotes the development, validation and enforcement of alternative methods, by means of measures such as setting up a European Union reference laboratory for validating alternative methods, upheld by the laboratories within member states, demanding the latter to promote such methods at a national level. Other important domains are also targeted by the text of the Directive, such as the inspections and environment conditions where animals are kept.

[3] The Amsterdam Treaty from 1997 also comprises new rules of the EU on animal welfare.

[4] The principles of "replace, reduce and refine", most frequently known as the "3R Rule" or "3R" are important elements of the ethical approach of the studies carried out on animals. For more details, see Mihai Decun, Alina Bodnariu, *Experimentarea pe animale în România, analizată din perspectivă europeană,* in Revista Română de Bioetică, Volume 7, No. 3, July-September 2009, pp. 19-20.

The new Directive also comprises new provisions, even stricter, regarding the use of animals for bio-medical research, for the purpose of improving the latter's protection. Thus, it provides for some measures meant to consolidate the evaluation of the necessity to use animals for each case taken separately.

Directive 2010/63/EU introduces minimal standards overcoming many of the standards already existing within member states but the latter can preserve their national standards if these insure better conditions for the animal welfare.

For the research community the new directive appears too as an instrument leading to standards of animal welfare in Europe, insuring the harmonization of national standards, improving the quality in science, reducing excessive bureaucracy and contributing to the increase of public confidence in the regulation of research done on animals.

In fact, the aim of the directive is that of creating fair competition conditions in Europe and to reduce the administrative burden if no contribution is made for the animal protection.

Without representing a flawless regulation, the Directive 2010/63/EU expresses the interest of the European Union in protection the welfare of animals used for scientific purposes, an objective stated in its considerations and acknowledged at article 13 of the Treaty on the Functioning of the European Union (TFUE).

3. The legal regime instituted by Law No. 43/2014 on the protection of animals used for scientific purposes

3.1. Object and scope

The Directive 2010/63/UE has been transposed in the Romanian law by means of Law No. 43/2014 on the protection of animals used for scientific purposes[5]. In agreement with the European directive, the Romanian law institutes measures for the protection of animals used for scientific purposes or for other experimental purposes and, for that matter, it provides for norms regulating the following:

- replacement and reduction of animal use for various procedures, as well as improving the methods for growing, sheltering, taking care and using animals for scientific or educational procedures;
- the origin, reproduction, marking, cure, sheltering and killing of animals;
- the activities of animal breeders, providers and users;
- the evaluation and authorization of projects involving the use of animals for procedures defined by the lawmaker as any form of use, invasive or not, of an animal, for experimental or scientific purposes, with known or unknown results or for educational purposes, which can cause to the animal in question a certain level of pain, sufferance, stress or lengthy damage, equivalent or even stronger than those generated by introducing a needle for good veterinarian practices; it is included any action which pursues or could result into an animal being born or hatching or which aims to create and maintain a line of animals genetically modified in any of these conditions, but is excluded killing animals for the exclusive purpose of using their organs or tissues [article 2 letter a)].

[5] Published in the Official Gazette No. 326 from 6th May 2014. When Law No. 43/2014 entered in force, it was abrogated the G.O. No. 37/2002 on the protection of animals used for scientific purposes or other experimental purposes, published in the Official Gazette No. 95 from February 2nd 2002.

In the general provisions, the Romanian law establishes in details the categories of animals concerned and the procedures, as well as the activities which are not under the incidence of the normative act. Regarding the procedures, just like the directive, the Romanian law refers to a broader area comprising procedures performed for the purposes of basic research, transferrable or applied research, procedures concerning the protection of natural environment on behalf of health or animal and people welfare, research on behalf of the species protection, high education or professional training and medico-legal investigations.

3.2. The 3R principle

Just like the directive, the Romanian law asserts too the 3R principle, pursuing to facilitate and to promote the progress of alternative methods. For this matter, its provisions impose the condition of authorising the use of animals for scientific purposes, if there is no satisfactory alternative method, in accordance with the norm on the replacement, reduction or refinement of the procedures carried out on animals. All the projects involving experiments on animals are evaluated by the competent authorities and no project can start before receiving a favourable evaluation from them. This evaluation must prove that the use of animals is justified and that the expected benefits overcome the eventual damage caused to animals. The same principle demands for the reduction at minimum of the number of animals used inside a project, but without compromising the objective of that project. Moreover, the living conditions and the methods used within procedures must avoid, as much as possible, to cause pain, sufferance or stress to animals.

3.3. The use of certain animals within scientific procedures

In a special chapter the law makes reference to the use of certain animals for scientific procedures, being concerned the animals on the verge of extinction, non-human primates, animals captured from the wild, animals grown for being used within scientific procedures, lost animals and half-savage animals belonging to domestic species. As a rule, the law clearly forbids the use of animals captured from the wild, lost animals and half-savage animals belonging to domestic species, within scientific procedures. As an exception, the competent authority can grant derogations on the basis of a scientific justification, according to which the purpose of a procedure cannot be achieved with the use of an animal bred for scientific procedures. At the same time, the law also forbids the use of non-human primates for scientific procedures, except for the case in which the procedures meet altogether the following conditions:

- the aim of the procedure is the transferrable or applied research for the development, production and testing of the capacity, efficacy and safety of medicines, food products, animal food or other substances and products; the aim of the procedure is to prevent, diagnose or treat diseases, precarious health states or other anomalies, as well as their effects on humans, animals or plants and it is performed with the purpose of avoiding, preventing, diagnosing and treating some affections potentially deadly or causing invalidity, appearing in humans or animals.

- there is a scientific justification, according to which the aim of the procedure cannot be reached by the use of other species than non-human primates.

At the same time, the animals belonging to the species on the verge of extinction listed in Annex A of the EC Regulation No. 338/97 of the Council from 9th December 1996 on the protection of the fauna and flora species through the control of their commerce, which does not enter under the incidence of article 7 paragraph (1) of the regulation, are used only for procedures complying with the requirements clearly provided for by law.

3.4. Procedures

According to article 11 of law, procedures are usually carried out only at the headquarters of the user, the latter being any physical or legal person who uses animals for procedures, with lucrative or not lucrative purposes. Any derogation is allowed on the basis of a scientific justification. Are concerned here only the procedures taking place inside a project, as the latter is defined by law[6]. Moreover, according to article 12 paragraph (1) of Law No. 43/2014, a procedure is allowed to take place only if within the European Union there is no other acknowledged testing method or strategy for obtaining the result desired and which does not involve the use of living animals. When procedures are chosen, there must be selected those with the highest probability of offering satisfactory results and meeting most of the following requirements:

- they use a minimum number of animals;
- they involve animals with the lowest capacity of feeling pain, sufferance, stress or undergoing lengthy damages;
- they provoke the lowest level of pain, sufferance, stress or lengthy damages.

With the exceptions provided for by law, are forbidden those procedures involving severe pain, sufferance or stress, which can last for a long time and which cannot be relieved.

The law also provides for the conditions in which it is possible to reuse animals for procedures, to set them free or to relocate them.

3.5. Authorisation

The legal text dedicates a generous space to the use of animals for scientific purposes, if no alternative method is identified.

The category of legal norms includes:

- sanitary-veterinary authorization of animal breeders, providers and users;
- projects authorization.

A. The activity of breeders, providers and users of animals used for scientific purposes is carried out only on the basis of the sanitary-veterinary authorization issued by the competent authority. The sanitary-veterinary authorization is granted for 5 years, with the possibility to be renewed. According to law, if the requirements provided for by the authorization are not observed, them it can be suspended or withdrew by the competent authority, case in which the welfare of sheltered animals must not be adversely affected (article 20).

Just like the directive, the Romanian law provides for the units belonging to animal breeders, providers or users several requirements regarding their installations and equipment,

[6] According to law, the term project signifies a working program with defined scientific objectives, which presupposes the use of one or several procedures [article 2 letter b)].

the competence of the staff who needs the have the necessary education and preparation, as well as for some specific requirements regarding their staff.

For the enforcement of the directive provisions, the law establishes for each breeder, provider or user of animals used for scientific purposes or other experimental ones that he has to create a structure responsible for the animal welfare. This structure has attributions such as counselling the staff taking care of the animals, evaluating internal operational and identification processes, in accordance with the results of the projects and of the elements contributing even more to the replacement, reduction and refining of the methods for breeding, sheltering, taking care and using animals within procedures.

Moreover, all animal breeders, providers and users are bound to keep animal records, with a minimum content established by law, but also records with information on dogs, cats and non-human primates. According to article 30 paragraph (2), each dog, cat and non-human primate must have an individual file, which accompanies it, as long as it is grown in the conditions provided for by law.

Law also regulates the care and sheltering of animals, establishing the principle that all animals must benefit from shelter, environment, food, water and adequate care for their health and welfare. At the same time, a particular attention is paid to the controls performed by the competent authority periodically, at all animal breeders, providers and users, including their units.

B. According to law, the projects involving the use of animals for scientific procedures are implemented only with a previous authorization from the competent authority and only after it has been received from the latter a positive evaluation. The authorisation is done on the demand of the animal user or of the person in charge with the project. After filing the authorization application in the form provided for by law, the evaluation of the project takes place. This is an ethical evaluation, on the occasion of which the competent authority checks if the projects meet the following criteria:

- the project is justified from the scientific or educational perspective, or demanded, according to law;
- the objectives of the project justify the use of animals;
- the project is conceived in such way that it allows for performing the procedures in a manner as human as possible and respecting the environment;

When evaluating the projects involving the use of animals for procedures, law imposes the following objectives:

- evaluating the objectives of the project, of its potential benefits or educational value;
- evaluating the project conformity with the requirements on the replacement, reduction and improvement of the use of animals used in procedures;
- evaluating the classification of the severity of procedures and the assignment of the corresponding classification;
- analysing the prejudice-benefice of the project, in order to evaluate if the harm caused to animals is justified by the expected result, taking into account ethical arguments and if that project could be after all in the benefit of people, animals or environment;
- analysing any justification triggering derogations;

- specifying the circumstances and the moment when the project should be retroactively evaluated.

Thus, law also provides for a specific evaluation called *retrospective evaluation*, which the competent authority carries out in order to determine if the objectives of the project have been met, the harm caused to animals, including their number and species, the severity of procedures, but also any other element which could contribute to consolidating the enforcement of the requirement regarding replacement, reduction and refinement of animal use within scientific procedures. According to law, all projects using non-human primates and those involving procedures classified as severe are subject to a retrospective evaluation. The competent authority can exempt from the duty of retrospective evaluation the projects including only procedures classified as moderate or without recovery[7].

The authorization for the project is granted for a period of at maximum 5 years.

Law also provides for a simplified administrative procedure for the authorization of projects containing procedures classified as "without recovery", "superficial" or "moderate" and which do not use non-human primates, which are necessary for the observance of normative requirements or which use animals for production or diagnosis purposes, with the use of the methods established.

In agreement with the objectives of the directive, the Romanian lawmaker aims to improve transparency in the field of the projects authorization, reason for which article 42 refers to the summaries with a non-technical character of the projects involving the use of animals within procedures. These summaries comprising information on the objectives of the project, including the harm produced to animals and the benefits expected, the number and types of animals which are to be used, but also a proof of the conformity of the project with the requirements on the replacement, reduction and refinement of animals used within procedures, are published on the website of the competent authority, with all their updates.

Law institutes the obligation of notification if some significant changes of the project take place and have a negative effect on animal welfare, within 30 days, with the consequence of granting a new authorization for the project, if a favourable result is obtained after the project evaluation. If the project is not implemented by observing the authorization prescriptions, then the authorization can be withdrawn by the competent authority.

3.6. Alternative methods

As already underlined, the European Union aims to end the experiments carried out on animals, by replacing them with alternative methods. In the spirit of this preoccupation, also reflected by the text of the directive discussed, the Romanian law clearly states that the National Sanitary Veterinary and Food Safety Authority contributes to the development and validation of alternative methods which could insure at least the same level of information with the one obtained by means of the procedures carried out on animals, but which does not involve the use of animals, uses less animals or involves procedures which are less painful.

[7] Procedures are included into one of the categories provided for by annex 7 of law, that is "without recovery", "superficial", "moderate" or "severe", according to each case and using the assignment criteria provided for by the annex under scrutiny.

4. Conclusions

Out of ethical reasons, the use of animals for scientific purposes must be limited, but without preventing the research in the field of severe diseases. Naturally, the most pragmatic approach consists in the use of alternative methods, as the actual technical knowledge does not allow yet for the complete exclusion of the experiments carried out on animals. It therefore emerges that it is absolutely necessary for the animals which are still being used for well-grounded reasons to benefit from the highest level of protection and welfare, in accordance to the purposes of the experiment. From this point of view, the Directive 2010/63/EU represents an important step towards accomplishing the final objective of replacing completely the procedures involving living animals, implemented for scientific or educative purposes, as soon as this is possible from a scientific point of view.

In its turn, the Romanian law for the transposition of the directive creates an ethical background meant to prevent intense sufferance of animals used for scientific purposes.

It can be identified here a normative background modernizing the current legislation in the field and insuring an equilibrium between the protection of animals and the freedom of research.

5. Bibliography

Mihai Decun, Alina Bodnariu, *Experimentarea pe animale în România, analizată din perspectivă europeană,* in Revista Română de Bioetică, Volume 7, No. 3, July-September 2009.