

**Guide for
Compliance with Directive 2010/63/EU and
S.I. No. 543 of 2012 Scientific Animal
Protection Legislation**

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.



1 INTRODUCTION

The HPRA's aim is to ensure that the requirements of Directive 2010/63/EU ([the Directive](#)) and S.I. No. 543 of 2012, [as amended by S.I. No. 434 of 2013 and S.I. No. 174 of 2014 \(the Regulations\)](#) on the protection of animals used for scientific purposes are met, by implementing a strategy which is effective, proportionate and dissuasive.

The HPRA puts the welfare of animals used for scientific purposes first, and encourages breeder/supplier/user establishments and users to integrate the requirements of the legislation into normal working methods. Breeder/supplier/user establishments and users should seek to proactively identify risks and opportunities for improvement so as to prevent unnecessary pain, suffering or injury to animals before it has had a chance to occur.

The HPRA is empowered to take action in relation to breaches of [S.I. No. 543 of 2012 the Regulations](#). It may address non-compliances by way of advice, administrative actions (e.g. compliance notice, animal welfare notice) as well as judicial actions (e.g. prosecutions). Where necessary following inspection, the HPRA will decide on appropriate action(s). This may include:

- the provision of advice (oral or written),
- administrative action against the breeder/supplier/user establishment, project or individual authorisation, or
- judicial action.

2 PRINCIPLES OF THE HPRA COMPLIANCE POLICY

The HPRA will ensure that the following principles are followed:

- **Fairness:** the HPRA will approach its duties with objectivity and fairness.
- **Proportionality:** the nature of the action ultimately taken will be based on an overall analysis of all of the circumstances of the case.
- **Risk-based:** a risk-based approach will be used to determine the appropriate action and to reduce or, where possible, eliminate the risk of future non-compliances. The HPRA will focus particularly on non-compliances that pose the greatest threats to the safety, health and welfare of the animals involved.
- **Consistency:** the HPRA will implement the compliance policy in a consistent manner for all cases of non-compliance.
- **Prior experience:** non-compliance which previously attracted warnings or remedial actions will be viewed as more severe than first-time non-compliances.
- **Responsibility:** the HPRA will ensure that responsibilities for animal care and welfare are exercised appropriately during the conduct of scientific procedures and general activities. Actions responding to non-compliances will be targeted to ensure that those charged with responsibility under the legislation act accordingly. Both 'top-down' (management) and

'bottom-up' approaches (local staff/researchers) will be applied to ensure that any necessary corrective actions are understood and implemented effectively.

- **Transparency:** formal notification of non-compliances must be communicated to the appropriate animal welfare body within an appropriate timeframe to promote future improvement in animal welfare. Furthermore, any cases of concealment of facts, or of serious animal welfare breaches will be investigated and prosecutions may be initiated.

3 BREEDER/SUPPLIER/USER ESTABLISHMENT INSPECTIONS

The categorisation of non-compliances observed on inspection of [establishments/breeder/supplier/users](#) where animals are bred, kept or used for scientific or educational purposes affects the choice of available regulatory action, which in turn may have significant impact for the [establishment/breeder/supplier/user](#) concerned. Both the natures of the non-compliances observed as well as their quantity need to be fully considered, together with the context and previous inspection history of the [establishment/breeder/supplier/user](#) concerned in making the determination. Failure to remedy previous non-compliances or the occurrence of several non-compliances in one or more areas within [an a breeder/supplier/user establishment](#) may lead to an escalation in the overall classification level to be used.

Given the nature of the area being regulated, the impact of non-compliances on the care and welfare of animals at the [establishment/breeder/supplier/user](#) must be central to the determination of any non-compliance observed.

A large number of non-compliances may potentially fall into several categories, depending on their scale and potential impact on animal health and welfare. The inspector will assess the extent of the non-compliance before classification. An example of a non-compliance which could be categorised as types 1, 2 or 3 depending on its scale and potential impact on animal health is a failure to observe the conditions of the breeder/supplier/user [establishment](#), project or individual authorisations.

The HPRA has developed a system for the categorisation of these non-compliance categories as follows.

3.1 Type 1 non-compliances

A Type 1 non-compliance is one which has produced, or represents a direct, substantial and immediate threat to the health, safety and welfare of the animals, beyond that authorised under a project, individual or establishment authorisation e.g. failure to provide accommodation/ environment/ ~~food~~ ~~water~~ ~~care~~ appropriate to the species of animal kept, which poses a serious risk to the health or welfare of the animal. This may also trigger the need for an additional compliance tool as discussed in point 4 below.

3.2 Type 2 non-compliances

A Type 2 non-compliance is defined as a non-critical failure, which may or may not pose a threat to an animal's health, safety or welfare e.g. failure to have a functional animal welfare body in place.

3.3 Type 3 non-compliances

Type 3 non-compliances are defined as variances which require correction but which are not serious breaches of legislation or do not endanger the health, safety and welfare of the animals, beyond those procedures that have been authorised under a project or [establishment/breeder/supplier/user](#) authorisation. These refer to a problem for which an immediate solution is not necessary to protect life or prevent distress e.g. deficiencies in animal records which have not negatively impacted on animal welfare.

Note: the classification of all non-compliances may be escalated if they are not addressed in a timely manner.

4 ADDITIONAL COMPLIANCE TOOLS

Advice and guidance will be provided as a constructive measure to help address and resolve non-compliances. The HPRA will apply formal actions as needed in order to secure compliance. These include administrative and judicial compliance tools. Emergency measures may apply to cases with serious animal welfare implications. The compliance tools are outlined in Regulations 74-81 of [S.I. No. 543 of 2012](#) [the Regulations](#).

The HPRA action will be determined based on case-by-case analysis of the severity of non-compliance.

a) Compliance notice

A compliance notice may be served by an authorised officer when a person has failed to comply with the requirements of [S.I. No. 543 of 2012](#) [the Regulations](#), but the failure is not sufficiently serious to warrant suspension or revocation of the relevant authorisation. The notice must identify the requirements of the legislation with which the person has failed to comply, the action the person is required to take, and the timescale in which they must take action.

Failure to comply with the requirements set out in the notice within the specified timescale will ordinarily lead, by a further notice (Regulation 74(3)) served on the person concerned, to suspension or revocation of the authorisation concerned.

Where the HPRA issues a compliance notice to a project manager (Regulation 47) in respect of a project authorisation or to an individual authorisation holder in respect of the conduct of a procedure or euthanasia, the HPRA will copy that notice to the compliance officer (Regulation 44) of the user establishment. The user establishment is expected to bring such matters to the attention of the animal welfare body and designated veterinarian or suitably qualified expert so that they can consider the matter and take appropriate actions.

A repeat transgression of the same nature in relation to the conduct of another project or different personnel within the time period given in the notice or within a short period of time thereafter will be investigated by the HPRA for evidence of a more widespread system failure. Such evidence may lead directly to further actions being directed against both the user establishment and the persons involved.

b) Suspension order

A suspension order may be served on an authorisation holder on one or more of the grounds set out in Regulation 75 of ~~S.I. No. 543 of 2012~~the Regulations, which includes failure to comply with the requirements of ~~S.I. No. 543 of 2012~~the Regulations, failure to comply with the conditions of authorisation, failure to comply with a compliance notice, or not having the resources necessary to carry out properly the activities to which the authorisation relates.

It is not necessary for the HPRA to issue a compliance notice before it issues a suspension (or revocation) order. In accordance with Regulation 75(5), the suspension (or revocation) of an authorisation may be limited to a particular activity or to one or more activities carried out at a particular ~~establishment~~breeder/supplier/user.

Where the HPRA issues a suspension (or revocation) order to a project manager (Regulation 47) in respect of a project authorisation or to an individual authorisation holder in respect to the conduct of a procedure or euthanasia, the HPRA will copy that notice to the compliance officer of the user establishment (Regulation 44). The user establishment is expected to bring such matters to the attention of the animal welfare body and designated veterinarian or suitably qualified expert so that they can consider the matter and take appropriate actions.

A further transgression of the same nature in relation to the conduct of another project or different personnel within a short period of time following the making of the order will be investigated by the HPRA for evidence of a more widespread system failure. Such evidence may lead directly to further actions being directed against both the establishment and the persons directly involved.

It should be noted that the suspension (or revocation) of a breeder/supplier/user ~~establishment~~ authorisation will have direct effects insofar as all linked authorisations for projects and individuals would also ~~have to~~ be suspended.

c) **Revocation order**

A revocation order may be served on an authorisation holder to revoke an authorisation on the same grounds as for the suspension order, but when the failure(s) to comply is more serious in nature or cannot be remedied.

Ordinarily, the HPRA will move to revoke an authorisation only after it has suspended it and considered any representations made.

d) **Animal welfare notice**

An animal welfare notice may be served when an animal is being caused, or is at risk of being caused, unnecessary pain, suffering or injury or where there is a serious risk to the welfare of the animal. Such notice may also be served where the conditions under which an animal is being bred or kept contravene [S.I. No. 543 of 2012](#); ~~the Regulations~~. The notice will specify the measures to be taken and may state a time limit within which the notice is to be complied.

The animal welfare notice is expected to be used mainly in the face of serious risk or harm to an individual animal or a group of animals at an establishment. The notice is expected to be served on the animal care and welfare officer (Regulation 45) of the ~~establishment~~ [breeder/supplier/user](#) and/or to the person responsible for the animal(s) concerned. The notice may direct the treatment or remedy to be put in place (or euthanasia of the animal(s) concerned) or the alteration to the facilities or premises concerned or other measures necessary to safeguard animal welfare. The notice is binding in full on the person on whom it is served, unless a new animal welfare notice is issued by the HPRA that replaces the previous one.

The issue of an animal welfare notice does not preclude the HPRA using another regulatory tool e.g. compliance notice at the same time, where justified by the findings.

Where the HPRA issues an animal welfare notice to a project manager (Regulation 47) in respect of a project authorisation or to an individual authorisation holder in respect of the conduct of a procedure or euthanasia, the HPRA will copy that notice to the compliance officer of the breeder/supplier/user ~~establishment~~ (Regulation 45). The ~~establishment~~ [breeder/supplier/user](#) is expected to bring such matters to the attention of the animal welfare body and designated veterinarian or suitably qualified expert so that they can consider the matter and take appropriate actions.

A further transgression of the same nature in relation to the conduct of another project or different personnel within the time period given in the notice or within a short period of time thereafter will be investigated by the HPRA for evidence of a more widespread system failure. Such evidence may lead directly to further actions being directed against both the ~~breeder/supplier/user establishment~~ and the persons directly involved.

e) Closure order

An authorised officer, following consultations with the chief executive of the HPRA, may issue a closure order to close an establishment (or part thereof) when there is, or is likely to be, a grave and immediate danger to animal welfare.

Ordinarily, the use of this tool is expected only where critical (Type 1) non-compliances have been identified at the establishment and such action is needed to prevent further grave risks to animal welfare.

Where a closure order has been served and activities are carried on in contravention of the order, an application may be made to the High Court to prohibit the continuance of activities and to order closure of the premises.

f) Fixed penalty notice

Provision is made in ~~S.I. No. 543 of 2012~~[the Regulations](#) for fixed penalty notices. Payment of a €250 penalty for an offence under ~~S.I. No. 543 of 2012~~[the Regulations](#) must be made to the HPRA within 28 days. If a fixed penalty is not settled within that timeframe, prosecution in respect of the alleged offence may be instituted.

The range of offences which relate to a fixed penalty notice is set out in Regulation 84 ~~of S.I. 543 of 2012~~.

It should be noted that the penalty applies for each contravention identified, so the financial penalty is cumulative.

The HPRA will ordinarily consider the use of fixed penalty notices in situations where:

- the person(s) concerned have failed to act, or to act effectively, in relation to actions set out in a compliance notice or animal welfare notice, or
- there has been an attempt to mislead or interfere with an HPRA officer conducting an inspection, or
- an individual has acted outside the conditions of their individual, project or [establishment breeder/supplier/user authorisation](#) or has failed to carry out their responsibilities.

Where the HPRA has reason to believe that the person concerned has been acting with the consent, collusion or approval of the [establishment breeder/supplier/user](#), the HPRA expects also to use the fixed penalty notice against the relevant responsible or designated persons (i.e. the compliance officer, the animal care and welfare officer, the training officer or the designated veterinarian or suitably qualified expert).

Where fines are unpaid within the time period specified, the HPRA will ordinarily move to prosecute such cases.

g) Power to seize and dispose of an animal

An authorised officer has the authority to seize an animal at [an establishment](#) [breeder/supplier/user](#) when a person has failed to comply with the terms of a notice or order, or the officer believes they will not comply with a notice or order. The officer also has the authority to euthanise and dispose of the seized animal as appropriate.

The HPRA expects to use this authority in exceptional circumstances. It should be noted that the costs involved in the seizure, maintenance, disposal and destruction of a seized animal will be levied on the owner of the animal in accordance with Regulation 79(4).

h) Emergency measures

Emergency measures may be taken immediately by an authorised officer in order to relieve pain, suffering, injury, or risk of pain, suffering or injury to an animal in breach of the relevant project or breeder/supplier/user [establishment](#) authorisation.

The HPRA expects that recourse to the use of the emergency measures provisions will rarely arise.

i) Judicial action

If administrative actions do not fully address serious offences, judicial proceedings will be considered. The factors involved in considering prosecution include the effects of the offence, the foreseeability of the offence or the circumstances leading to it, the intent of the offender, the history of offending and the level of cooperation provided to investigating authorities.