

# Guide to Refusals and Appeals Under Scientific Animal Protection Legislation

---



## **CONTENTS**

1	SCOPE	3
2	PROCEDURES	3
2.1	Introduction	3
2.2	Refusal procedure	3
2.3	Appeals	5
3	SUBMISSION OF WRITTEN INFORMATION	7
4	ORAL HEARINGS	7
5	CONTACT POINT FOR PROCEDURES	8

## 1 SCOPE

This guide provides information to applicants and appellants on refusals and appeals procedures relating to the grant of authorisations, and the issuing of orders and notices according to the provisions of S.I. No. 543 of 2012 as amended by S.I. No. 434 of 2013 and S.I. No. 174 of 2014 (all hereafter known as the S.I.), and on the procedure for written or oral representations the applicant or appellant may wish to make.

The guide, and the procedures described in it, do not cover:

- Complaints of an administrative procedure (the handling of complaints is described on the HPRA website);
- Urgent suspensions, where the threat to animal welfare or health is such that there is insufficient time to follow the steps in the procedure on refusals;

## 2 PROCEDURES

### 2.1 Introduction

Under the S.I., the HPRA is the competent authority for regulating the use of animals for scientific purposes. We do this in part by authorising breeders, users and suppliers (establishment authorisations); personnel involved (individual authorisations); and projects under which the use of animals for research/regulatory purposes is permitted under specified conditions (project authorisations). Applications for such authorisations may be approved and authorisations granted by the HPRA, or the application may be refused if it does not meet the requirements of the S.I.; guidance to applicants on the procedure for refusals is given in section 2.2 below. An appeal may be made by an applicant when an application is refused, or when certain notices and orders are issued by the HPRA; guidance to applicants on the procedure for appeals is given in section 2.3 below.

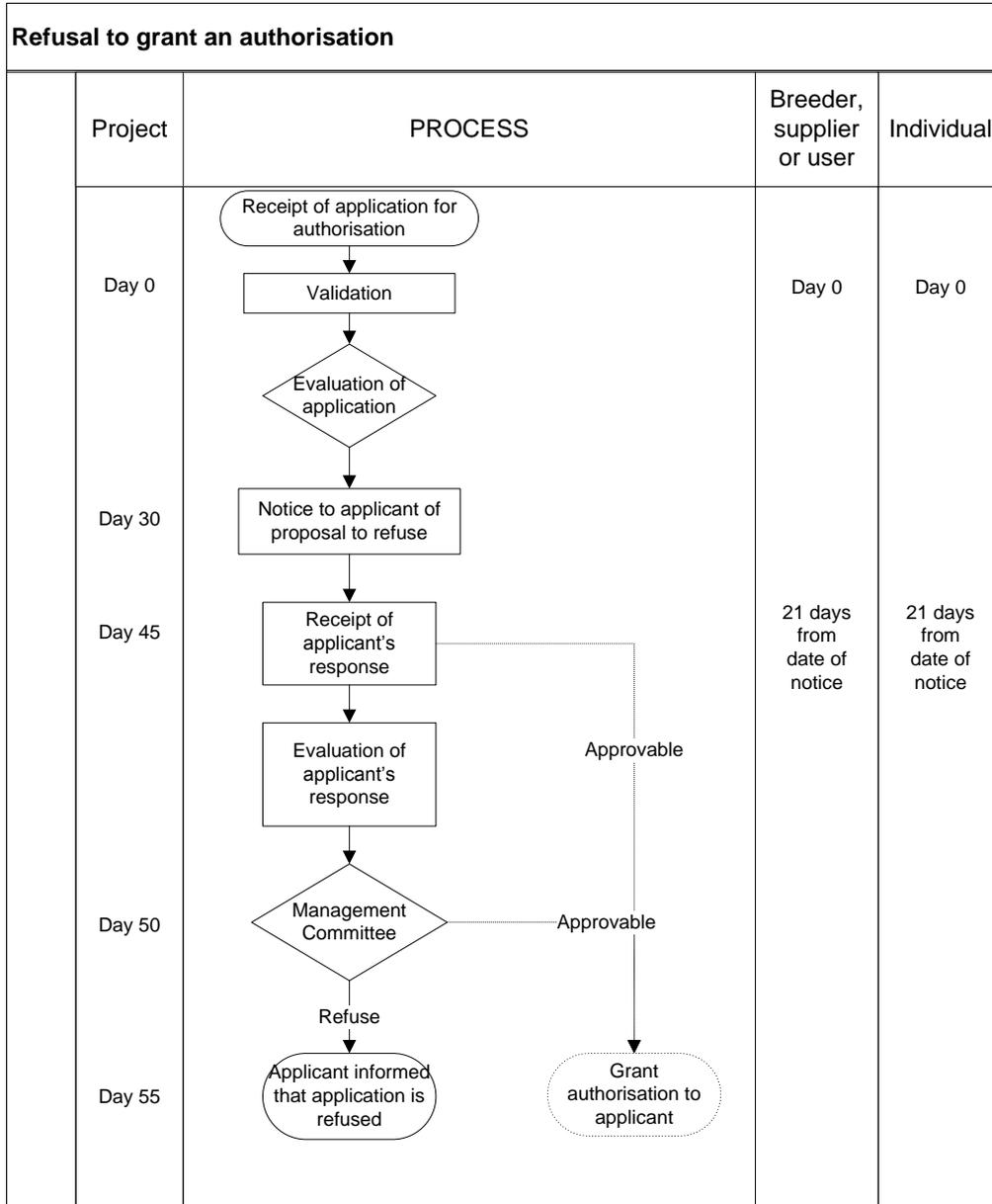
The various procedures described below are designed to comply with the requirements of the S.I. and with the principles of proportionality, fairness, consistency and transparency. At each stage, separate and independent decisions are taken with regard to the proposal to refuse. Applicants will be kept informed at all stages and given copies of all documents presented to the HPRA committees or Authority. Applicants will also be given the opportunity to make written or oral representations.

### 2.2 Refusal procedure

The HPRA may refuse applications for authorisation under the following Regulations in the S.I.:

- Refusal to grant a project authorisation under Regulation 26(1)(a).
- Refusal to grant a breeder, supplier or user authorisation under Regulations 37(1)(a).
- Refusal to grant an authorisation to an individual under Regulation 54(1)(a).

The procedure for refusals is shown in the flowchart below.



When notified by the HPRA of an intention to refuse your application, applicants may wish to consider their response. Applicants will be given the opportunity to make a written representation; if they choose to do so, the response must be received within 15 or 21 days depending on the application type (see flowchart above). Alternatively, applicants may decide to withdraw the application and notify the HPRA of this decision, which will end the refusals procedure.

If applicants do not respond to the notice within the period of time allowed to make a written representation or the representation does not address the issues, the proposal to refuse will be considered by the Management Committee which will decide to either refuse the application or alternatively to grant the authorisation, ensuring in both cases that the decision is based on adequate scientific grounds and that it is proportionate to the risk to animal health or welfare. Applicants will be notified of the Management Committee's decision within five working days of the meeting.

### **2.3 Appeals**

An appeal may be made under Regulation 78 of the S.I. where the HPRA issues:

- a compliance notice,
- a suspension order,
- a revocation order,
- an animal welfare notice,
- a closure order,

or where the HPRA refuses to grant an authorisation.

There are different procedures for appeals depending on the order, notice or refusal which is the subject of appeal, as shown on the following page. The appellant may withdraw the appeal at any time.

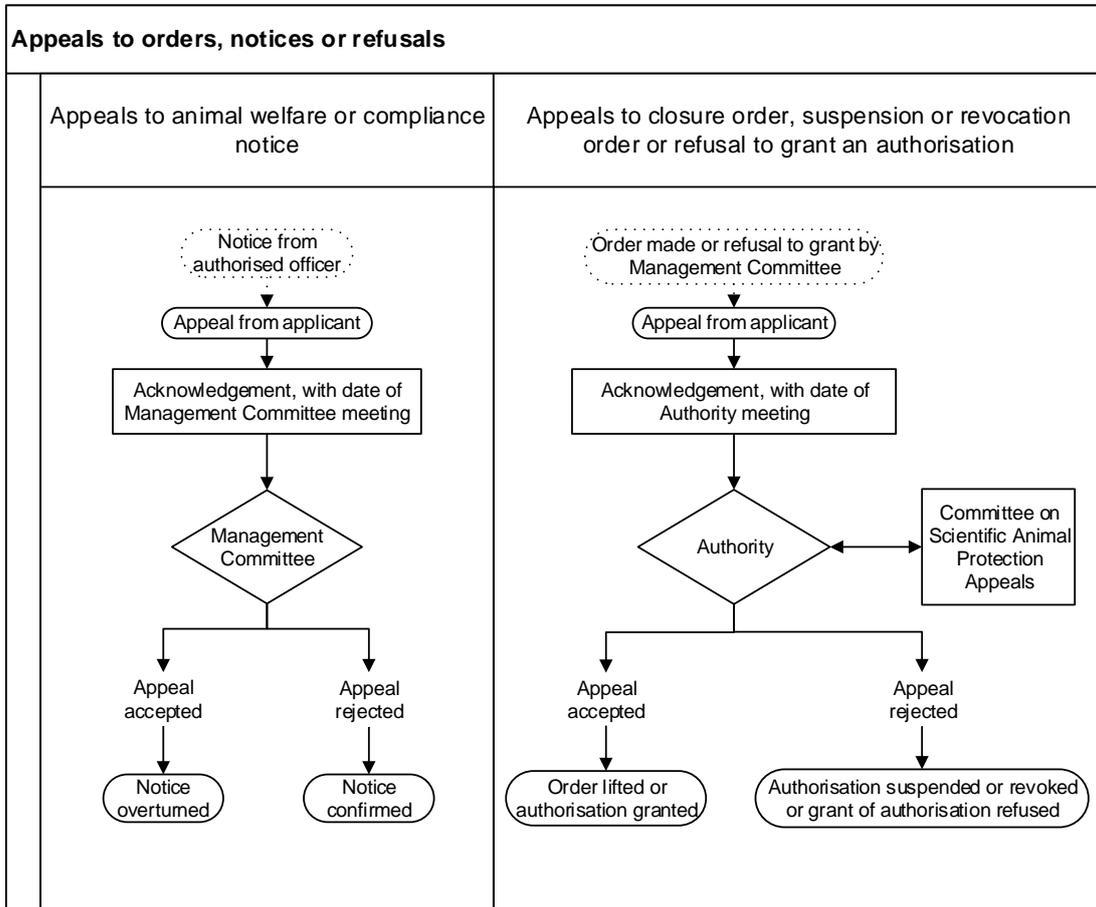
The appeal notification should be accompanied by detailed grounds explaining why an applicant believes the original decision should be overturned. At all stages of the procedure, applicants will be notified of the dates of the meetings at which it will be considered and will be given copies of all documentation to be presented.

Before any meeting where the appeal will be considered, applicants will be invited to make a written or oral submission for consideration at the meeting. Should applicants wish to do this, they must notify the Secretary to the Committee at least 14 days before the date of the meeting.

In the case of an appeal to an animal welfare notice or compliance notice, the Management Committee will consider the appeal. Applicants will be notified of the meeting date and given the opportunity to make representations. In reaching its decision to either accept or reject the appeal, the committee ensures that due process has been carried out and that its decision is

fair, unbiased and based on the best available information and data. Applicants will be notified of the decision within five working days of the meeting.

In the case of a closure order, suspension or revocation of authorisation orders or a refusal to grant an authorisation, the Committee on scientific animal protection appeals will consider the appeal and advise the Authority. Applicants will be notified of the committee meeting date and given the opportunity to make representations. Having been advised of the merits of the appeal by the Committee, the Authority will decide to either accept or reject the appeal, ensuring that due process has been carried out and that its decision is fair, unbiased and based on the best available information and data. Applicants will be notified of the decision within five working days of the meeting.



Applicants should note that while an appeal to an animal welfare notice is being processed, the terms of the notice remain in force.

### **3 SUBMISSION OF WRITTEN INFORMATION**

Where written information is supplied at any stage, applicants should make sure that the submission addresses the issues raised. Written material should be supplied in both hard copy and electronic format (unless otherwise agreed with the Secretary to the Committee), by the date specified.

Written submissions will be reviewed by the assessor or inspector who was dealing with the case. They will provide a summary of the information and an assessment of it for the meeting; applicants will be provided with copies of these documents before the meeting.

### **4 ORAL HEARINGS**

If applicants wish to make an oral representation at the Management Committee, Committee on scientific animal protection appeals or at the Authority itself, they must submit any presentation and all supporting documentation no later than two weeks before the date of the meeting. The documents should be submitted on CD-ROM, by e-mail and in hard copy (approximately 10 copies, the number to be confirmed with the Secretary to the Authority/Secretary to the Committee).

No later than one week before the meeting, applicants should inform the Secretary to the Authority/Secretary to the Committee of the number of representatives who will attend (usually not more than five) and the name of the chief spokesperson.

The committee or Authority members will have been sent all the material available on the matter (internal assessment reports and procedural documentation, and applicant or appellant data) before the meeting, and will be familiar with the data and the procedure thus far.

After a preliminary discussion among the committee or Authority members, applicants will be invited into the boardroom. Applicant's presentation should take not more than 15 minutes and should specifically and directly address the issues relating to the refusal or appeal. After the presentation, the committee or Authority members or HPRA staff members may ask questions relating to issues raised in the presentation or supporting data or may raise questions of clarification. Applicant representatives should have the technical expertise to address these questions and the managerial authority to take decisions on behalf of the company. They should also be fluent in English.

Following the presentation and questions, applicants will be asked to leave the meeting room. The committee will consider the evidence provided and make its decision. HPRA personnel who may have been present are not entitled to participate in deliberations, but may respond to queries raised by the members.

Applicants will be notified of the outcome within five working days of the meeting.

## **5 CONTACT POINT FOR PROCEDURES**

Secretary to the Committee: Ms Jackie Cottell

or

Secretary to the Authority: Ms. Vanessa Lyons

Tel. +353-1-6764971

Fax: +4353-1-6767836

E-mail: [secretary@hpra.ie](mailto:secretary@hpra.ie)