

Guide to Refusals and Appeals Under Scientific Animal Protection Legislation



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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 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 legislation. Guidance to applicants on the procedure for refusals is given in section 2.2 of this guide. 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 of the guide.

The various procedures described 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.

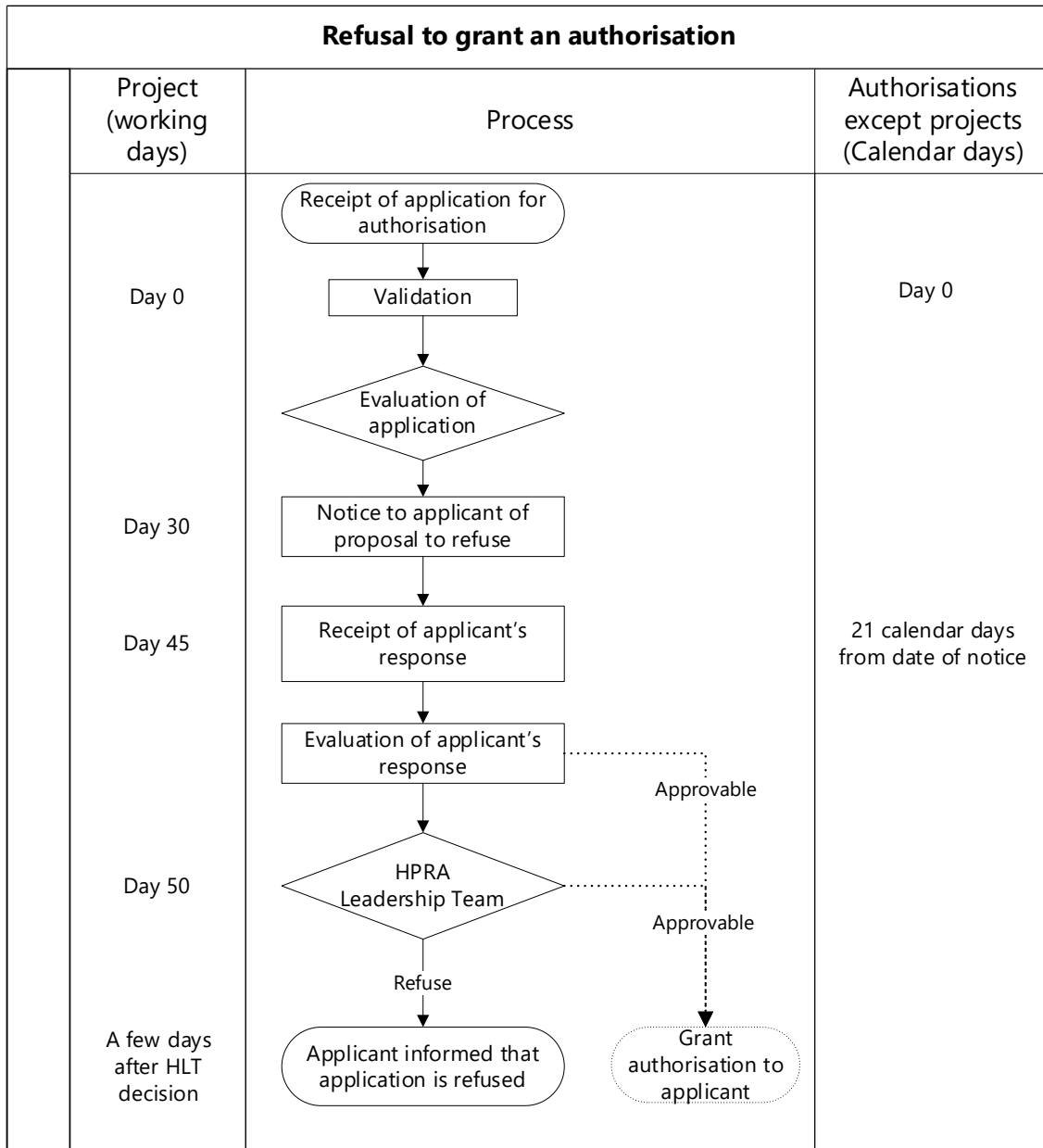
2.2 Refusal procedure

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 Regulation 37(1)(a).
- Refusal to grant an authorisation to an individual under Regulation 54(1)(a).

The procedure for refusals is shown in Flowchart 1. Note that project evaluation timelines are in working days as per legislation, while other authorisations are assessed in calendar days.

Flowchart 1. Refusal to grant an authorisation.



[Click here for accessible alternative description for this flowchart available in Appendix 1.](#)

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 working days or 21 calendar days depending on the application type (Flowchart 1). 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 HPRA leadership team (HLT), which will decide to either refuse the application or alternatively to grant the authorisation, ensuring in both cases that the decision is based on the legislative framework, adequate scientific grounds and that it is proportionate to the risk to animal health or welfare. Applicants will be notified of the HLT's decision within a few 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 timelines and considerations for appeals depending on the order, notice or refusal which is the subject of appeal, as per the sections 2.3.1 and 2.3.2 of this guide. The appeal notification should be accompanied by detailed written grounds explaining why the applicant believes the original decision was incorrect.

2.3.1 Appeals to an animal welfare notice or compliance notice

Appeals to an animal welfare notice or compliance notice are considered by the HLT within a period of seven days of receipt. However, in the case of the animal welfare appeal, the effect of the appeal will not have a material effect on the action required by the notice, as, in accordance with the legislation, the direction given under the notice is binding. The effect of the appeal will be to address any observations or grievances by the appellant, but the actions open to the HLT must relate to improving the process for the future. In the case of a compliance notice, the HLT will consider the merits of the arguments and it is open to the HLT to instruct its officers to issue an amended notice or to withdraw the compliance notice that has already been issued. Appeals to animal welfare or compliance notices shall be in writing only.

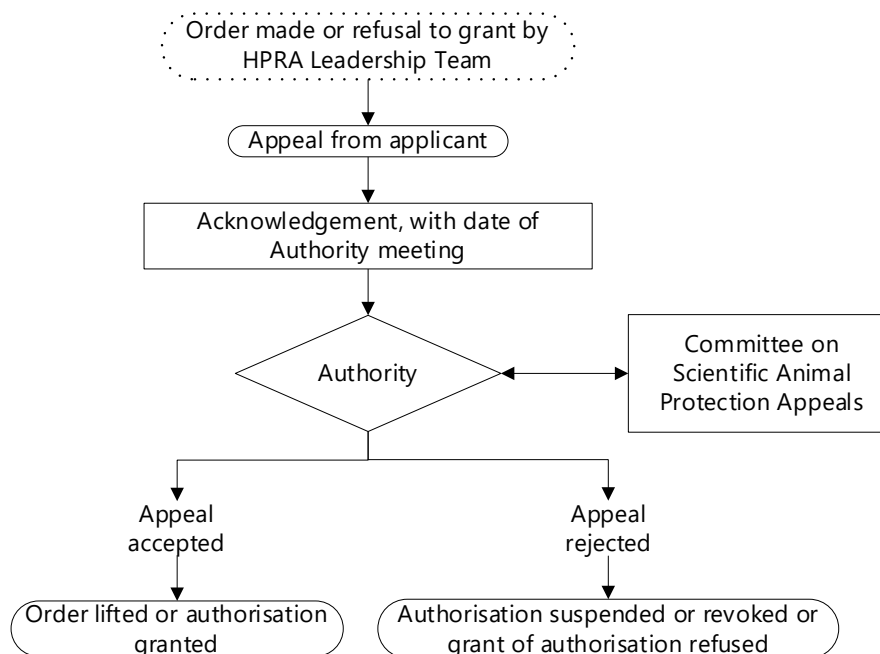
In reaching its decision to either accept or reject the appeal, the HLT ensures that due process has been carried out and that its decision is fair, unbiased and based on the best available

information and data. Applicants will be notified of the decision within a few working days of the meeting.

2.3.2 Appeal to a suspension, revocation or closure order

In the case of an appeal to a suspension, revocation or closure order, the appeal will be considered by a specially appointed expert scientific committee which will advise the Authority. As this committee will need to be constituted to consider the appeal, the appeal process is expected to take a number of months before it can be concluded. The time needed for the committee to decide their position will depend on the complexity of the appeal. In any event, applicants will be notified of the committee meeting date and given the opportunity to make an oral representation (probably by telephone or video call) before the committee reaches a decision in the matter. The committee will ensure that its decision is fair, unbiased and based on the best available information and data. The committee will provide its advice to the Authority and inform the applicant at the same time. 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. Applicants will be notified of the decision within a few working days of the meeting. It should be noted that the appellant may withdraw the appeal at any time, thus ending the process.

Flowchart 2. Appeals to suspension, revocation, or closure order, or refusal to grant an authorisation



[Click here for the accessible alternative description for this flowchart available in Appendix 2.](#)

Note:

Applicants should note that while an appeal to an animal welfare notice is being processed, the terms of the notice remain in force. This means that the actions required by an animal welfare notice must be complied within those timebound cases where the appeal to the HLT cannot take place within the time of the notice. If that is the case, the HLT action in respect of the animal concerned is moot, but the HLT will consider the applicant's case and implement any changes needed for future such cases.

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 electronic format (unless otherwise agreed with the Secretary to the HLT), by the date specified.

Written submissions will be reviewed by a HPRA evaluator/assessor or inspector. 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 HLT, or the committee on scientific animal protection appeals, 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 electronically.

No later than one week before the meeting, applicants should inform the Secretary to the Authority / Secretary to the HLT of the number of representatives who will attend (usually not more than five) and the name of the chief spokesperson. The oral representation may be held virtually, by teleconference.

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 meeting. The 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. 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 a few working days of the meeting.

5 CONTACT POINT FOR PROCEDURES

Secretary to the HLT / Secretary to the Authority:

Tel. +353-1-6764971

Fax: +4353-1-6767836

Email: secretary@hpra.ie

APPENDIX 1 ACCESSIBLE ALTERNATIVE DESCRIPTION OF FLOWCHART 1

This flowchart provides a high-level overview for the process to refuse granting authorisation. For project authorisation, working days are considered. For authorisations of applications other than projects, calendar days are considered.

Overview of the refusal process for projects authorisation applications:

1. The application for authorisation is received from the applicant.
2. The Day 0 of the timeline starts when the application is validated.
3. The application is evaluated.
4. If the proposal is to refuse the application, a notice with the proposal to refuse is sent to the applicant by Day 30.
5. Applicants are given the opportunity to make a written representation; if they choose to do so, the response must be received within 15 working days after the notice with proposal to refuse.
6. The applicant's response is evaluated.
7. The HPRA Leadership Team makes a decision on whether to approve or refuse the application by Day 50.
8. If the decision is to approve the application based on applicant's response, the applicant is granted authorisation.
9. If the decision is to refuse, the applicant is informed that the application is refused within a few working days after the HPRA Leadership Team meeting.

Overview of the refusal process for applications other than projects:

1. The application for authorisation is received from the applicant.
2. The Day 0 of the timeline starts when the application is validated.
3. The application is evaluated.
4. If the proposal is to refuse the application, a notice with the proposal to refuse is sent to the applicant.
5. Applicants are given the opportunity to make a written representation; if they choose to do so, the response must be received within 21 calendar days after the notice with proposal to refuse.
6. The applicant's response is evaluated.
7. The HPRA Leadership Team makes a decision on whether to approve or refuse the application.
8. If the decision is to approve the application based on applicant's response, the applicant is granted authorisation.
9. If the decision is to refuse, the applicant is informed that the application is refused.

The flowchart and the appendix provide an overview of the refusals processes. Please refer to the rest of the guide for other details related to this.

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APPENDIX 2 ACCESSIBLE ALTERNATIVE DESCRIPTION OF FLOWCHART 2

This flowchart provides a high-level overview of the process for appeals to closure order or suspension or revocation order or refusal to grant an authorisation.

1. The appeal is made by the applicant against an order or refusal to grant authorisation by the HPRA Leadership Team.
2. The appeal is acknowledged with the date of the Authority meeting.
3. A decision is made by the Authority in consultation with the special committee on scientific animal protection appeals.
4. If the appeal is accepted, the order is lifted, or authorisation is granted.
5. If the appeal is rejected, the authorisation is suspended or revoked or grant of authorisation is refused.

The flowcharts and the appendix provide only a high-level overview of the appeals processes. Please refer to the rest of the guide for details related to these.

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