

Guide to Appeals under Cosmetic Product Legislation

1 SCOPE

This guide provides information on the procedure for appealing the issue of notices or measures according to the provisions of Regulation 12 and 17 of S.I. No. 440 of 2013, European Union (Cosmetic Products) Regulations 2013, (hereafter known as 'the S.I.'), and on the procedure for written or oral representations the appellant may wish to make.

The guide, and the procedures described in it, do not cover prohibition orders. Appeals against prohibition orders can be made to a judge of the District Court in the district in which the prohibition order was served.

2 PROCEDURES

The procedure described below is designed to comply with the requirements of the S.I. and with the principles of proportionality, fairness, consistency and transparency. Independent decisions are taken with regard to the appeal. Appellants will be kept informed at all stages and given copies of all documents that will be evaluated as part of the appeal. Appellants will also be given the opportunity to make written or oral representations. An appeal can be withdrawn at any stage.

An appeal may be made under Regulation 17 of the S.I. where a person is aggrieved by:

- a compliance notice,
- measures taken by an authorised officer pursuant to Regulation 12(9) to ensure compliance with a compliance notice,
- emergency measures taken by the HPRA [Board] pursuant to Regulation 14, or
- provisional measures taken by the HPRA [Board] pursuant to Regulation 15.

Following issuance of a compliance notice (or measures taken pursuant to Regulations 12(9), 14 and 15 of the S.I.), the person on whom it is served has 20 days to put forward his or her viewpoint or to appeal the notice or measures.

Where the aggrieved person appeals the notice or measures, the appeal should be accompanied by detailed grounds explaining why the appellant believes the notice or measures should be overturned. At all stages of the appeal (see flowchart below), the appellant will be notified of the date(s) on which the appeal will be considered and will be given copies of all documentation that will be reviewed.

Before the appeal is considered, appellants will be notified of the meeting date and will be invited to make a written or oral submission for consideration. Should an appellant wish to do this, they must notify the Secretary to the Committees at least 14 days before the date of the meeting.

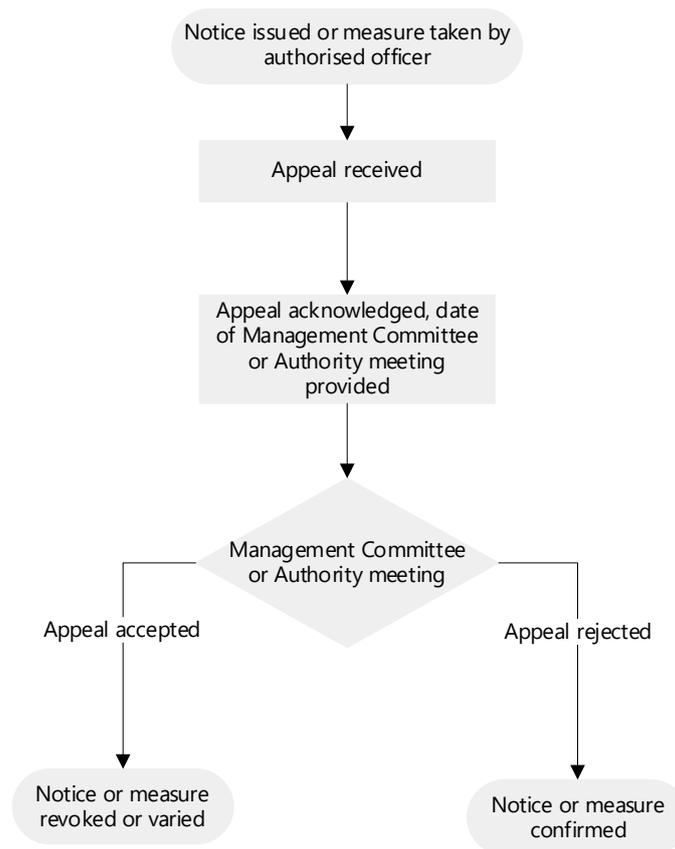
Consideration of and decisions regarding appeals submitted in relation to a compliance notice and/or measures taken to ensure compliance with a compliance notice, are taken by the Management Committee of the HPRA.

Consideration of and decisions regarding appeals submitted in relation to emergency measures and/or provisional measures, are taken by the Authority of the HPRA.

In reaching its decision to either accept or reject the appeal, the Committee or Authority ensures that due process has been carried out and that its decision is fair, unbiased and based on the best available information and data. The appellant will be notified of the decision within seven working days of the meeting.

The appellant should note that the terms of the compliance notice take effect on the day following the day on which the notice is confirmed on appeal, or the appeal is withdrawn. If the compliance notice is overturned the terms of the notice will not take effect.

Flowchart of appeals procedure:



3 SUBMISSION OF WRITTEN INFORMATION

Where written information is supplied at any stage, appellants 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 Committees), by the date specified.

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

4 ORAL HEARINGS

If appellants wish to make an oral representation, they must submit any presentation and all supporting documentation to the Secretary to the Committees no later than two weeks before the date of the meeting. The documents should be submitted in electronic format or as otherwise discussed with the Secretary to the Committees.

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

The Committee or Authority will have been sent all the material available on the matter (internal assessment reports and procedural documentation, and 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, appellants will be invited into the meeting room. The appellant's presentation should take not more than 15 minutes and should specifically and directly address the issues relating to the compliance notice or measures. After the presentation, the Committee or Authority as appropriate, or HPRA staff members, may ask questions relating to issues raised in the presentation or supporting data or may raise questions of clarification. Appellant representatives should be fluent in English and 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, appellants will be asked to leave the meeting room. The Committee or Authority 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 of the committee or of the Authority as appropriate.

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

5 CONTACT POINT FOR APPEALS

Secretary to the Committees,
Telephone: +353-1-6764971
Email: secretary@hpra.ie

HPRA
4 November 2022