

SCHEDULE 3

Regulation 49

Operational obligations of notified bodies

1. A notified body must carry out conformity assessments in accordance with the relevant conformity assessment procedures.
2. A notified body must carry out conformity assessments in a proportionate manner, avoiding unnecessary burdens on economic operators.
3. A notified body must perform its activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.
4. A notified body must respect the degree of rigour and the level of protection required to ensure that the product is in conformity with the requirements of these Regulations.
5. Where a notified body finds that essential health and safety requirements or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it must require the manufacturer to take appropriate corrective measures and must not issue a certificate of conformity or grant an approval.
6. Where, in the course of the monitoring of conformity following the issue of a certificate or grant of an approval, a notified body finds that a product is no longer in conformity with the essential health and safety requirements, it must require the manufacturer to take appropriate corrective measures and must suspend or withdraw the certificate of conformity or approval (if necessary).
7. Where the notified body has required a manufacturer to take corrective measures and the manufacturer has failed to take such measures, or those measures have not had the required effect, the notified body must restrict, suspend or withdraw any certificate of conformity or approval.
8. Paragraph 9 applies where a notified body is minded to—
 - (a) refuse to issue a certificate of conformity or grant an approval;
 - (b) restrict, suspend or withdraw a certificate of conformity or approval.
9. Where this paragraph applies, the notified body must—
 - (a) give the person applying for the certificate or approval, or the person to whom the certificate or approval was given, a notice in writing giving reasons and specifying the date on which the refusal, restriction, suspension or withdrawal is intended to take effect;
 - (b) give the person applying for the certificate or approval, or the person to whom the certificate or approval was given, an opportunity to make representations within a reasonable period from the date of the notice; and
 - (c) take account of any such representations before taking its decision.
10. A notified body must inform the Secretary of State of—
 - (a) any refusal, restriction, suspension or withdrawal of a certificate of conformity or approval;
 - (b) any circumstances affecting the scope of, or conditions for, notification under regulation 44 (notification);
 - (c) any request for information which it has received from the market surveillance authority regarding conformity assessment activities; and
 - (d) on request, any conformity assessment activities performed within the scope of its notification under regulation 44 and any other activity performed, including cross-border activities and subcontracting.

Status: This is the original version (as it was originally made).

11. A notified body must make provision in its contracts with its clients enabling such clients to appeal against a decision—

- (a) to refuse to issue a certificate of conformity or grant an approval; or
- (b) to restrict, suspend or withdraw a certificate of conformity or approval.

12. A notified body must provide other bodies notified under the ATEX Directive carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

13. A notified body must participate in the work of any notified body coordination group established under the ATEX Directive, directly or by means of its designated representatives.

14. A notified body must—

- (a) acknowledge receipt of the technical documentation provided by the manufacturer in accordance with regulation 39(1)(b)(ii)(bb) (conformity assessment procedures) as soon as possible; and
- (b) retain the technical documentation referred to in sub-paragraph (a).