[F1SCHEDULE 6

CONFORMITY ASSESSMENT PROCEDURES (Annex II to Decision No 768/2008/EC)

Textual Amendments

F1 Schs. 1-7 inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 15 para. 43** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 9(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

MODULE B

Type examination

1. Type examination is the part of a conformity assessment procedure in which an approved body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of these Regulations.

2. Type examination may be carried out in either of the following manners:

— examination of a specimen, representative of the production envisaged, of the complete product (production type),

— assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type),

— assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

3. The manufacturer must lodge an application for Type examination with a single approved body of the manufacturer's choice.

The application must include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative as well,

— a written declaration that the same application has not been lodged with any other approved body,

— the technical documentation. The technical documentation must make it possible to assess the product's conformity with the applicable requirements of these Regulations and must include an adequate analysis and assessment of the risk(s). The technical documentation must specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation must contain, wherever applicable, at least the following elements:

— a general description of the product,

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

— a list of the designated standards and/or other relevant technical specifications applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements where those designated standards have not been applied. In the event of partly applied designated standards, the technical documentation must specify the parts which have been applied,

— results of design calculations made, examinations carried out, etc., and

— test reports,

— the specimens representative of the production envisaged. The approved body may request further specimens if needed for carrying out the test programme,

— the supporting evidence for the adequacy of the technical design solution. This supporting evidence must mention any documents that have been used, in particular where the relevant designated standards and/or technical specifications have not been applied in full. The supporting evidence must include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on the manufacturer's behalf and under the manufacturer's responsibility.

4. The approved body must:

For the product:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product;

For the specimen(s):

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant designated standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant designated standards and/or technical specifications, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant designated standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of the legislative instrument;

4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The approved body must draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations set out in paragraph 8, the approved body must release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of the specific legislative instrument that apply to the product concerned, the approved body must issue a Type examination certificate to the manufacturer. The certificate must contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes must contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of these Regulations, the approved body must refuse to issue a Type examination certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.

7. The approved body must keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument, and must determine whether such changes require further investigation. If so, the approved body must inform the manufacturer accordingly.

The manufacturer must inform the approved body that holds the technical documentation relating to the Type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential safety requirements or the conditions for validity of the certificate. Such modifications must require additional approval in the form of an addition to the original Type examination certificate.

8. Each approved body must inform the Secretary of State concerning the Type examination certificates and/or any additions thereto which it has issued or withdrawn, and must, periodically or upon request, make available to the Secretary of State the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each approved body must inform the other approved bodies concerning the Type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The authorised body must keep a copy of the Type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer must keep a copy of the Type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.**]**

Changes to legislation:
There are currently no known outstanding effects for the The Toys (Safety) Regulations 2011, MODULE B.