Cassociados DVOGADOS

BRIEFING

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approved by Decree-Law no. 43/2011, of 24 March, which transposed Directive 2009/48/EC, of the European Parliament and the Council, of 18 June 2009, into Portuguese law, thereby expanding the previous toy safety rules, approved by Decree-Law no. 237/92, of 27 October.

In fact:

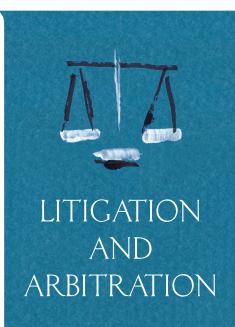
The new statute extends the former **definition of toy**, which now includes all products designed or intended, whether or not exclusively, for use in play by children under 14 years of age, and introduces new safety rules applicable to toys made available on the Community market, for distribution, consumption or use, in the course of a commercial activity, whether in return for payment or free of charge.

As previously occurred, excluded from the said definition will remain playground equipment intended for public use and all products listed in Annex I of the new statute (namely, babies' soothers, decorative objects for festivities and celebrations, products for collectors of 14 years of age and above, sports equipment intended for children with a body mass of more than 20 kg, bicycles with a maximum saddle height of more than 435 mm, puzzles with more than 500 pieces, functional educational sold exclusively for teaching purposes under adult supervision, and electrical transformers for toys).

Besides establishing new essential safety requirements (article 13), Decree-Law 43/2011 revises several others (Annex II), namely related to the toys' physical properties, mechanical properties (impact, noise, movement, speed limits and asphyxiation hazards), electrical properties and chemical properties (such as substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) and allergenic fragrances).

In addition, this Decree-Law also intensifies the information provided to final consumers regarding packaging or specific warnings. In certain cases, the statute actually requires a separate packaging and a specific warning that alerts for the need of adult supervision.

Furthermore, the new set of rules finally clarifies the obligations of each and all economic operators involved in this distribution business, according to the definitions of manufacturer, authorized representative, importer and distributor set out in EC Regulation no. 765/2008.



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The new toy safety rules extends the former definition of toy and introduces new essential safety requirements

In brief, regarding this final aspect, in addition to a general obligation to cooperate with ASAE, which is the relevant Portuguese market surveillance authority (article 4), Decree-Law 43/2011 imposes several specific obligations on each group of economic operators.

In light of the abovementioned, please find below some of the most significant specific obligations imposed on:

(i) MANUFACTURERS (articles 5 and 6):

- ensure that the toys they place on the market were designed and manufactured in accordance with the requirements set out in article 13 and Annex II of the Decree-Law (understanding *placing on the market* as the first making available of a toy on the Community market);
- draw up the technical documentation required in article 24 and keep it for a period of at least 10 years after the toy has been placed on the market;
- carry out or have carried out the applicable conformity assessment procedure, to demonstrate the compliance of a toy with the applicable requirements, under article 22;
- draw up an EC declaration of conformity and affix the CE marking, where compliance
 of a toy with the applicable requirements has been demonstrated by the said conformity
 assessment procedure;
- ensure that procedures are in place for series production to remain in conformity;
- carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and keep distributors informed of any such monitoring, when deemed appropriate with regard to the risks presented by a toy that endanger the health and safety of consumers;
- ensure that their toys bear a type, batch, serial or model number or other element allowing their identification, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy;
- indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy;
- ensure that the toy is accompanied by instructions and safety information in Portuguese;
- immediately take the corrective measures necessary to bring into conformity a toy they placed on the market, to withdraw it or recall it, if they consider or have reason to believe that such toy is not in conformity with the relevant Community harmonization legislation:
- immediately inform the authority of non-conforming toys and any corrective measures taken, where the toy presents a risk.

Increase of information provided to final consumers regarding packaging or specific warnings

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In addition to a general obligation to cooperate with ASAE, the statute imposes several specific obligations on each group of economic operators

(ii) IMPORTERS (articles 8 and 9):

- place only on the Community market compliant toys, under article 13;
- before placing a toy on the market, ensure that the manufacturer has drawn up the technical documentation and has complied with the requirements set out in article 5(8) and (9), that the toy bears the required conformity marking and is accompanied by the required documents;
- not to place on the market toys that they consider or have reason to believe to be nonconforming with the requirements set out in article 13 and Annex II, until they are brought into conformity;
- inform the manufacturer and ASAE where the toy presents a risk;
- indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy;
- ensure that the toy is accompanied by instructions and safety information in Portuguese;
- ensure that the storage or transport conditions of a toy do not jeopardize its compliance with the requirements set out in article 13 and Annex II, while it is under their responsibility;
- carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of
 complaints, of non-conforming toys and toy recalls, and/or keep distributors informed
 of such monitoring, when deemed appropriate with regard to the risks presented by the
 toy;
- immediately take the corrective measures necessary to bring a toy into conformity, to
 withdraw it or recall it, when they consider or have reason to believe that it is not in
 conformity with the relevant Community harmonization legislation;
- immediately inform the competent national authority of non-conforming toys and any corrective measures taken, where the toy presents a risk;
- keep a copy of the EC declaration of conformity at the disposal of ASAE and ensure
 that the technical documentation can be made available to that authority, upon request,
 for a period of 10 years after the toy has been placed on the market.

(iii) DISTRIBUTORS (article 10):

- act with due care in relation to the applicable requirements when making a toy available on the market;
- before making a toy available on the market, verify that it bears the required conformity marking, that it is accompanied by the required documents and by instructions and safety information in Portuguese, and that the manufacturer and the importer have complied with the requirements set out in article 5(8) and (9) and article 8(5);
- not to make available on the market toys that they consider or have reason to believe to be non-conforming with the requirements set out in article 13 and Annex II, until they are brought into conformity;

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A stricter set of rules that requires more attention and law awareness from all economic operators involved.

- inform the manufacturer or the importer, as well as ASAE, where the toy presents a risk, providing them information regarding its non-conformity and on any corrective measures taken;
- ensure that the storage or transport conditions of a toy do not jeopardize its compliance with the requirements set out in article 13 and Annex II, while it is under their responsibility;
- make sure that the corrective measures necessary to bring a toy into conformity, to withdraw it or recall it, are taken, when they consider or have reason to believe that it is not in conformity with the relevant Community harmonization legislation.

Finally, it should also be noted that, for the purposes of this Decree-Law, importers or distributors shall be considered manufacturers and shall be subject to obligations set forth in articles 5 and 6, where they place a toy on the market under their name or trademark or modify a toy already placed on the market in such a way that compliance with the applicable requirements may be affected.

This is stricter set of rules imposes a wider participation in the established toy safety procedures and, thus, requires more attention and law awareness from all economic operators involved.

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