

Executive Summary

This is the part of a series of publications that the BTHA is providing for its members on the impact of the revised Toy Safety Directive. It is accompanied by individual guidance documents on specific issues arising from the directive. Currently available on the BTHA webpage are guidance documents on:

- Economic operators
- Technical file
- Warnings and markings
- Bill of materials

Other BTHA documents in the pipeline include:

- Conformity of series production
- Safety assessments
- Revisions to Standards

The BTHA webpage also has links to the EU webpage which has the full text of the directive and EU guidance on the implementation of the directive. The guidance documents will also be accompanied by seminars from the BTHA Technical Team. BTHA Members are advised to use these resources to prepare themselves for this first major change to toy regulations since 1988.

The following table is a brief summary of some of the key changes in the revised Toy Safety Directive. It is a guide and cannot replace analysis of the full text.

2009/48/EC Published 30th June 2009 – Implementation 20th July 2011 for General requirements and 20th July 2013 for Chemical Requirements			
Subject	Summary	Section	Other documents
Economic Operators	Defines the obligations Manufacturers, Importers, Distributors and Authorised Representatives	Section 2.1	BTHA Guidance on <i>Economic operators</i>
Technical Documentation	Revised requirements for technical documentation to support toys which will affect “Technical File” contents.	Section 2.2	BTHA Guidance on <i>Technical file</i>
Conformity assessment procedures	Requirements for on-going evidence of conformity of products. Will require a review with factories and/or the manufacturing sites to assess what conformity assessment procedures are in place and whether they are effective.	Section 2.3	BTHA Guidance on <i>Conformity of series production</i>
Traceability	Requirement for surveillance authorities to trace products placed on the market.	Section 2.4	
Clarifying the Essential Safety Requirements	Various changes to product design criteria, function and chemical contents will lead to updated/new toy standards (EN71 and EN61125 etc). Toys may need to be modified to conform to new standards as they are published.	Section 3.1	New EN 71 (all parts); EN62115 standards BTHA Guidance on <i>Revisions to Standards</i>
Chemicals - Migration of certain elements	The number of restricted elements is increased to 19 and will be incorporated into a standard (probably an updated EN71 Part 3) ready for implementation within 4 years.	Section 3.2 (i)	New chemical standards (EN71-3, EN71-9, EN71-10 and EN71-11)
Chemicals - Carcinogens, Mutagens and Reproductive Toxins (CMR's)	New restrictions for certain categories of CMR's. These requirements are far reaching and will be reviewed by the standards committees within the next few years.	Section 3.2 (ii)	New chemical standards (EN71-3, EN71-9, EN71-10 and EN71-11)
Chemicals – Fragrances	New restrictions on certain fragrance ingredients and labelling requirements for others, where permitted.	Section 3.2 (iii)	New chemical standards
Chemicals - Nitrosamines	New restriction of Nitrosamines and nitrosable substances – often found in rubber or rubberised materials.	Section 3.2 (iv)	New chemical standard EN71-X
Warnings and packaging	Changes to labelling requirements for products and packaging. These are being reviewed by the standards committees.	Section 3.3	BTHA Guidance on <i>Markings and Warnings</i> New EN71-1 standard ¹
Changes concerning choking and suffocation risk	Changes to requirements for detachable components for products and retail packaging. These are being reviewed by the standards committees.	Section 3.4	New EN71-1 standard ¹
Special requirements for toys coupled with food	Additional requirements for toys sold with or attached to foodstuff. These are being reviewed by the standards committees.	Section 3.5	New EN71-1 standard ¹

¹ A draft EN71-1 standard was published for public comment by BSI but, at the time of writing, the draft has been withdrawn. This version contained changes arising from the New Toy Safety Directive but did not include amendments A10-A14 that were in the pipeline when the work on the new directive started. When assessing whether products conform to the new standards, care should be taken to include A10-A14 as well as the new standard.

LEGAL NOTICE

This document contains guidance only.
It is intended to explain obligations and how to fulfil them. However readers are reminded that the text of the original regulation, directive or standard is the only authentic legal reference and that the information in this document does not constitute legal advice.
The British Toy and Hobby Association does not accept any liability with regard to the contents of this document.

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1. Introduction

This document describes the major changes that will be introduced by the revised Toy Safety Directive (2009/48/EC) that was adopted by the European Parliament on 18 December 2008 and published in the *Official Journal of the European Union (OJ)* on 30 June 2009.

The revised directive strengthens the rules laid out by the 1988 Toy Safety Directive. The revised legislation will require adaptations by manufacturers and procedural changes in the supply chain. The extent of these changes is still being determined and will require changes to toy standards and other procedures. This document outlines the expected impact on manufacturers, importers and other actors in the supply chain resulting from the current understanding of the revised directive.

This is the first of a series of guidance documents and seminars that the BTHA will provide for its members. Members are advised to use this information to prepare themselves for this first major change to toy regulations since 1988.

1.1 History

The original Toy Safety Directive (88/378/EEC) was introduced as a New Approach Directive in 1988 in an attempt to harmonise the proliferation of national safety regimes in the EU at that time. It was the first EC Directive that applied the New Approach method. The key concept of New Approach was that the legislation laid down the essential safety requirements, leaving the technical specifications of products meeting these essential safety requirements to be defined in harmonised standards.

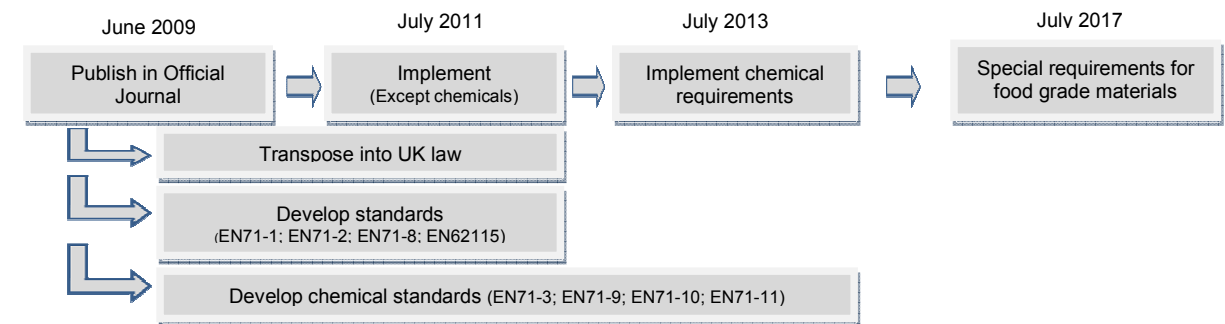
Whilst the TSD has, in general terms, been successful in providing safe products and removing trade barriers, the Commission felt that there were a number of deficiencies that needed to be strengthened:

- To improve the enforcement and efficiency of the directive:
 - a) Clarity of the responsibilities of Economic Operators
 - b) Changes to the Technical File contents, especially as regards to information on chemicals
 - c) Changes to CE marking and traceability requirements
 - d) Changes to the conformity assessment procedures.
- To enhance safety requirements of toys:
 - a) Clarifying the criteria of essential safety requirements
 - b) New provisions on the chemical requirements
 - c) More stringent requirements on warnings
 - d) Changes to the requirements concerning choking risk
 - e) Clarifying the suffocation risk
 - f) Special requirements for toys in food

These requirements have, by and large, been incorporated in the revised directive and these are outlined in subsequent sections of this document.

1.2 Timelines of Implementation

The final text was formally adopted and published in the OJ on 30 June 2009. From this date, the overall timetable for implementation is shown schematically below.



2. Changes to improve the enforcement and efficiency of the directive

These changes affect how the directive is enforced. An important change to the directive is the definition of the role of different stakeholders in the supply chain. These are now known as Economic Operators and the directive specifically defines the obligations of each.

2.1 Economic Operators

The revised Toy Safety Directive defines the new obligations of four economic operators:

- Manufacturers
- Importers
- Distributors
- Authorised Representatives (formally appointed by manufacturers only)

These roles are adopted by companies based on criteria laid down in the directive. The criteria depends, for example, on how toys are purchased, who designed (or modified) the toy, the brand of the toy and the stage in the product cycle at which an operator becomes involved.

The operator roles, as defined in the new directive, may be different to what a company would consider to be their “normal trading role”. For example, there are times when an importer must adopt the role of a “manufacturer” furthermore depending on the mode of supply; companies may even adopt different operator roles when selling the same toy into different retailers.

It is therefore important to note that the role adopted needs to be assessed on a case by case basis. For each operator type there are a series of obligations that they are legally required to meet when supplying or purchasing toys. In general terms the obligations are more onerous when companies adopt the role of “manufacturer” and less onerous when adopting the role of “importer” and even less onerous when adopting the role of “distributor”. A Manufacturer can appoint by a written mandate, an “Authorised Representative”. The authorised representative shall perform all the tasks in the mandate.

What do you do now?

Members should familiarise themselves with the requirements of the Economic Operators and the obligation this imposes on them. The BTHA has produced guidance and this is available at: <http://www.btha.co.uk/work/template.php?id=207>.

Members should determine what role of Economic Operator they adopt and ensure that they meet the appropriate obligations.

2.2 Technical Documentation

The revised directive is more specific on the contents of the *Technical Documentation* than its predecessor and these include:

- A detailed description of the design and manufacture, including a list of components and materials used in toys as well as the safety data sheets on chemicals used, to be obtained from chemical suppliers
- A safety (risk) assessment for each toy placed before it is placed on the market. This should include an analysis of the chemical, physical, mechanical, electrical, flammability and other hazards that the toy may present to a child. The EU, along with industry representatives, is working on a risk assessment guideline.
- A description of the conformity assessment procedure followed. In other words, how the manufacturer ensures that all toys are manufactured to the required standards.
- A copy of the EC declaration of conformity. In other words, a formal certificate signed by a senior officer of the company, confirming that the toys is designed *and manufactured* to the appropriate legislation and standards.

These requirements mean that, for the first time, manufacturers of toys will need to know *exactly* what materials and substances go into making the toy.

An important change in the revised directive gives the enforcement authorities (TSO) the opportunity to make an enforcement notice for not keeping *Technical Documentation*. Up to now, the technical file has been used to support a challenge about a product. In future, a challenge can be brought if a

company fails to keep the *Technical Documentation* or it is not up-to-date, even if the product meets legal and safety requirements.

What do you do now?

Members should familiarise themselves with the content of the Technical Documentation. The BTHA has produced guidance and this is available at: <http://www.btha.co.uk/work/template.php?id=207>.

If the member has the Economic Operator status as a *Manufacturer*, it should review the content of this documentation, specifically for the new requirements e.g:

- Safety (or risk assessment)
- Conformity assessment procedures
- Declaration of conformity

2.3 Conformity assessment procedures

This relates to the way manufacturers ensure that all products they place on the market meet the legal requirements.

In the process of preparing the directive, the Commission examined the need for mandatory third party certification to ensure that the toys meet the requirements of the directive. This would have meant that every toy had to be examined by a notified body before it could be put on the market. The final directive text did not include this proposal as the Commission determined that the current approach was adequate.

Therefore the revised directive requires that manufacturers take appropriate steps to ensure that their products are manufactured to the required legal requirements and standards and keep these details in the *Technical Documentation*.

What do you do now?

The BTHA is currently producing guidance on *Conformity of Series Production*. These will be available at: <http://www.btha.co.uk/work/template.php?id=207>.

BTHA members should review with the factories and/or the manufacturers what conformity assessment procedures are currently in place.

When the requirements are known, these should be compared with the current procedures and enhanced (if necessary) to meet the new requirements.

2.4 Traceability

The revised directive specifically recognises the need to for surveillance authorities (TSO's in the UK) to trace toys back through the supply chain. This is defined in two ways:

- Include in the *Technical Documentation* or on the *Declaration of Conformity* a colour image of sufficient clarity to enable the identification of the toy.
- Ensuring traceability of a toy throughout the whole supply chain to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant toys available on the market.

What do you do now?

BTHA members should review traceability of their products and ensure that:

- Enforcement authorities can identify products and trace the Manufacturer or Importer who placed the product on the market (as defined in the required by Economic Operators guide, available at: <http://www.btha.co.uk/work/template.php?id=207>)
- The products have identification appropriate to its type and which allows non-compliant toys to be identified in the market and traced.

3 Changes to enhance the safety of toys

This section deals with the main changes that will directly affect the design and content of toys and shows which categories might be affected. The table points readers to the paragraph number that addresses each issue.

	Essential Safety	Chemicals				Warnings and packaging	Choking and suffocation	Toys with food
		Heavy elements	CMRs	Fragrances	Nitro-samines			
All toys	3.1	3.2 i)	3.2 ii)			3.3	3.4	
Packaging for all toys	3.1	3.2 i)	3.2 ii)			3.3	3.4	
Fragrance toys	3.1	3.2 i)	3.2 ii)	3.2 iii)		3.3	3.4	
Sound toys	3.1	3.2 i)	3.2 ii)			3.3	3.4	
Electrical toys	3.1	3.2 i)	3.2 ii)			3.3	3.4	
Rubber (e.g. Balloons)	3.1				3.2 iv)	3.3	3.4	
Toys with food	3.1	3.2 i)	3.2 ii)			3.3	3.4	3.5

3.1 Clarifying the Essential Safety Requirements

The revised directive updates the Essential Safety Requirements to take account of technical progress since the original directive.

These include:

- Complete and update the provisions of chemical requirements in toys to cover CMRs and allergenic substances. These should take account of other legislation, including REACH, and be adapted to take account of the particular needs of children.
- Update the limits for the heavy elements allowed for the original 8 elements and bring 11 further elements into the restricted list.
- Impose stronger limits of noise levels emitted from toys, from both impulse and prolonged noise.
- Allow toys to exceed the current limit of 24 volts in electrical toys, without reducing safety.

What do you do now?

These will be incorporated in new standards.

Some draft EN71 standards have been published for public comment by BSI but, at the time of writing, the drafts had been withdrawn. However, BTHA Guidance on the *Revisions to Standards* is being developed and this will outline the new requirements of the revised standards.

Members are advised to keep abreast of the BTHA *Revisions to Standards* and the standards as they are published to ensure that toys are manufactured to the new requirements.

It is likely that the new standards will be published just before the implementation dates of the Directive (July 2011 and July 2013).

3.2 Chemical Requirements (implementation July 2013)

i) Migration of certain elements

The current directive has 8 elements that have restricted migration levels (that is levels that are released from a toy). The revised directive reviews the migration levels for these and other elements from July 2013. The objective is to ensure that only unavoidable traces of heavy elements are contained in materials (as the general rule is to ban heavy elements but this is unachievable).

The result is that the restricted elements are now increased to 19 at levels that are considered safe according to the criteria used by the Commission. The tables below show the new and existing requirements.

<i>Element</i>	<i>Revised Toy Safety Directive</i>			<i>Existing EN 71 Standard</i>
	<i>mg/kg</i> <i>in dry, brittle, powder-like or pliable toy material</i>	<i>mg/kg</i> <i>in liquid or sticky toy material</i>	<i>mg/kg</i> <i>in scraped-off toy material</i>	<i>mg/kg</i>
Aluminium	5,625	1,406	70,000	
Antimony	45	11.3	560	60
Arsenic	3.8	0.9	47	25
Barium	4,500	1,125	56,000	1,100
Boron	1,200	300	15,000	
Cadmium	1.9	0.5	23	75
Chromium (III)	37.5	9.4	460	60
Chromium (VI)	0.02	0.005	0.2	
Cobalt	10.5	2.6	130	
Copper	622.5	156	7,700	
Lead	13.5	3.4	160	90
Manganese	1,200	300	15,000	
Mercury	7.5	1.9	94	60
Nickel	75	18.8	930	
Selenium	37.5	9.4	460	500
Strontium	4,500	1,125	56,000	
Tin	15,000	3,750	180,000	
Organic tin	0.9	0.2	12	
Zinc	3,750	938	46,000	
	<i>These limits apply to accessible toys or accessible components of toys</i>			

What do you do now?

These new requirements will be incorporated into a new standard (probably EN71 part 3) within the next few years.

In the meantime, you could review the content of the materials used and phase out any materials that use any of the new restricted elements over the next 3 years to be compliant by the time the revised directive is enforced.

ii) Carcinogens, Mutagens and Reproductive Toxins (CMRs)

Chemical substances or mixtures that may present diverse harmful effects for human health are categorised as CMRs. These can be defined as follows:

- Carcinogens (C): substances that causes or tends to cause cancer;
- Mutagen (M): chemical or physical agent that induces permanent, transmissible genetic change;
- Reproductive toxins (R): substances that may damage reproductive capacities or functions.

The revised directive adopts latest terminology for CMR categories. Instead of CMR categories 1, 2 or 3 the following categories apply:

- Category 1A CMRs (previously CMRs 1)
- Category 1B CMRs (previously CMRs 2)
- Category 2 CMRs (previously CMRs 3)

Any substance that is CMR category 1A, 1B or 2 are prohibited for use in toys unless they meet at least one of a number of defined exemptions set out in the table below:

<i>CMR categories 1A and 1B</i>	<i>CMR category 2</i>
The substance is below the total concentration limit set in the Regulation on classification, labelling and packaging of substances and mixtures..... <i>or</i>	The substance is below the total concentration limit set in the Regulation on classification, labelling and packaging of substances and mixtures..... <i>or</i>
The substance is inaccessible to children in any form, including inhalation..... <i>or</i>	The substance is inaccessible to children in any form, including inhalation..... <i>or</i>
The substance has been exempted by the Scientific Committee who has published a <i>positive list</i> set out in appendix A. The exemption can be granted if: <ul style="list-style-type: none"> ○ It has been evaluated by the Scientific Committee and been found to be safe.....<i>and</i> ○ There are no alternatives available.....<i>and</i> ○ They are not prohibited under REACH 	The substance has been exempted by the Scientific Committee in the context of the <i>positive list</i> . This exemption can be granted provided that: <ul style="list-style-type: none"> ○ It has been evaluated by the Scientific Committee and been found to be safe.....<i>and</i> ○ They are not prohibited under REACH
The directive has already placed one substance on the <i>positive list</i> ; namely nickel in stainless steel.	

In addition to these exemptions, the directive allows materials that comply with the food contact legislation. However, the Commission shall review the limit values for food contact materials and make them applicable to toys. This will form the basis of Appendix C if this is considered a suitable solution.

What do you do now?

These requirements are far reaching and will be reviewed by the standards committees within the next few years.

In the meantime, BTHA members should ensure that their products conform to REACH and encourage the use of food grade plastics for products for under threes and mouth contact products. BTHA Guidance for REACH is available on the website.

iii) Fragrances

The revised directive specifically bans 55 fragrances (subject to trace levels up to 100 ppm when their presence is unavoidable under good manufacturing practices). More fragrances are banned than are currently banned under the cosmetics requirements, so care will have to be taken when sourcing fragrances for toys.

The table below shows all 55 fragrances banned by the revised directive. Those in bold show the fragrances banned in toys but not in cosmetics.

No	Name of the allergenic fragrance	CAS number	No	Name of the allergenic fragrance	CAS number
1	Alanroot oil (Inula helenium)	97676-35-2	29	6-Methylcoumarin	92-48-8
2	Allylthiocyanate	57-06-7	30	7-Methylcoumarin	2445-83-2
3	Benzyl cyanide	140-29-4	31	5-Methyl-2,3-hexanedione	13706-86-0
4	4 tert-Butylphenol	98-54-4	32	Costus root oil (Saussurea lappa Clarke)	8023-88-9
5	Chenopodium oil	8006-99-3	33	7-Ethoxy-4-methylcoumarin	87-05-8
6	Cyclamen alcohol	4756-19-8	34	Hexahydrocoumarin	700-82-3
7	Diethyl maleate	141-05-9	35	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
8	Dihydrocoumarin	119-84-6	36	2-Pentylidene-cyclohexanone	25677-40-1
9	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0	37	3,6,10-Trimethyl-3,5,9-undecatrien-2-one	1117-41-5
10	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5	38	Verbena oil (Lippia citriodora Kunth)	8024-12-2
11	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9	39	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
12	Dimethyl citraconate	617-54-9	40	4-Phenyl-3-buten-2-one	122-57-6
13	7,11-Dimethyl-4,6,10-dodecatrien-3-one	26651-96-7	41	Amyl cinnamal	122-40-7
14	6,10-Dimethyl-3,5,9-undecatrien-2-one	141-10-6	42	Amylcinnamyl alcohol	101-85-9
15	Diphenylamine	122-39-4	43	Benzyl alcohol	100-51-6
16	Ethyl acrylate	140-88-5	44	Benzyl salicylate	118-58-1
17	Fig leaf, fresh and preparations	68916-52-9	45	Cinnamyl alcohol	104-54-1
18	trans-2-Heptenal	18829-55-5	46	Cinnamal	104-55-2
19	trans-2-Hexenal diethyl acetal	67746-30-9	47	Citral	5392-40-5
20	trans-2-Hexenal dimethyl acetal	18318-83-7	48	Coumarin	91-64-5
21	Hydroabietyl alcohol	13393-93-6	49	Eugenol	97-53-0
22	4-Ethoxy-phenol	622-62-8	50	Geraniol	106-24-1
23	6-Isopropyl-2-decahydronaphthalenol	34131-99-2	51	Hydroxy-citronellal	107-75-5
24	7-Methoxycoumarin	531-59-9	52	Hydroxy-methylpentylcyclohexene-carboxaldehyde	31906-04-4
25	4-Methoxyphenol	150-76-5	53	Isoeugenol	97-54-1
26	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4	54	Oakmoss extracts	90028-68-5
27	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8	55	Treemoss extracts	90028-67-4
28	Methyl trans-2-butenate	623-43-8			

11 other potentially allergenic substances are permitted but must be labelled if their concentration level is above 0.01% by weight. These are shown in the next table.

No	Name of the allergenic fragrance	CAS number	No	Name of the allergenic fragrance	CAS number
1	Anisyl alcohol	105-13-5	7	Lilial	80-54-6
2	Benzyl benzoate	120-51-4	8	d-Limonene	5989-27-5
3	Benzyl cinnamate	103-41-3	9	Linalool	78-70-6
4	Citronellol	106-22-9	10	Methyl heptine carbonate	111-12-6
5	Farnesol	4602-84-0	11	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5
6	Hexyl cinnamaldehyde	101-86-0			

Exemptions apply for certain games and cosmetic kits that use smell as a part of its function.

What do you do now?

These requirements are far reaching and will be reviewed by the standards committees within the next few years.

In the meantime, BTHA members should ensure that their products meet the current cosmetic requirements and consider phase out plans for fragrances banned by the revised directive.

iv) Nitrosamines

Nitrosamines and nitrosable substances are banned in toys for children under three and for toys that can be mouthed unless the migration levels are:

- Below 0.05 mg/kg for nitrosamines
- Below 1 mg/kg for nitrosable substances

What do you do now?

These requirements are far reaching and will be reviewed by the standards committees within the next few years.

BTHA members should ensure that their products do not contain nitrosamines or nitrosable substances for products for under threes and mouth contact products.

3.3 Warnings and Markings that accompany toys

The revised directive is more explicit on the requirements of warnings and markings for toys including the CE mark. There are more requirements for markings on the actual product. These are primarily obligations of the *Manufacturer* but an *Importer* has to show the name and address on the product. Other Economic Operators have a responsibility to ensure that the marking has been done.

The directive specifically states:

- The CE marking shall be affixed visibly, legibly and indelibly to the toy, or to an affixed label, or to the packaging. In the case of small toys and toys consisting of small parts the CE marking may alternatively be affixed on a label or an accompanying leaflet. If that is not technically possible in the case of toys sold in counter displays, and on the condition that the counter display was originally used as packaging for the toys, the CE marking shall be affixed to the counter display.
- If the CE marking is not visible from outside the packaging, if any, it shall at least be affixed on the packaging.

The revised directive is also more explicit on the warning statements that accompany toys:

- The word “Warning” or “Warnings” need to precede the statement. The revised EN71- 1 standard¹ (which is currently in draft form) will have a comprehensive list of warnings that must accompany toys.
- Warnings that determine the decision to purchase, including specifying the intended age groups, should be clearly visible at point of sale and on the webpage if the product is sold online.
- Toys contained in foods must have their own packaging with appropriate warnings, including the warning “Contains a toy. Adult supervision recommended”. The packaging must not be a small part choking hazard.
- Warnings and safety instructions should be in one or more languages to ensure that they are understood by the consumer as required by the appropriate Member State.

What do you do now?

Members should familiarise themselves with the requirements of Markings and Warnings. The BTHA has produced guidance and this is available at:
<http://www.btha.co.uk/work/template.php?id=207>.

Draft EN71-1 standard has been published for public comment by BSI but, at the time of writing, the drafts had been withdrawn. However, BTHA Guidance on the *Revisions to Standards* is being developed and this will outline the new requirements of the revised standards.

Members are advised to keep abreast of the BTHA *Revisions to Standards* and the standards as they are published to ensure that toys are manufactured to these new requirements.

3.4 Changes concerning choking and suffocation risk

Toys and their detachable parts must not present a risk of asphyxiation by externally blocking mouth and nose; nor must they block off airways if wedged in the mouth lodged over the entrance to lower airways if swallowed.

Toys that are designed for children under 36 months, or those designed to be placed in the mouth, must not be a small part that can be swallowed or inhaled. This also applies to components and detachable parts of these toys.

Retail packaging must not present a risk of strangulation or asphyxiation by external blockage to mouth and nose.

Special attention must be paid to spherical, egg shaped or ellipsoidal packaging.

The revised EN71-1 standard¹ (which is currently in draft form) will incorporate these requirements. .

What do you do now?

Draft EN71-1 standard has been published for public comment by BSI but, at the time of writing, the drafts had been withdrawn. However, BTHA Guidance on the *Revisions to Standards* is being developed and this will outline the new requirements of the revised standards.

Members are advised to keep abreast of the BTHA *Revisions to Standards* and the standards as they are published to ensure that toys are manufactured to these new requirements.

3.5 Special requirements for toys coupled with food

For the first time the revised directive seeks to include the requirements of toys sold with foodstuffs. These include:

- Prohibiting toys that are firmly coupled with foodstuffs in such a way that prior consumption of the food item is necessary to access to the toy itself.
- Introducing the new requirement that:
 - i) Toys within food or co-mingled with food must have their own packaging and
 - ii) The packaging itself should not present any choking hazard (namely that it passes the safety 'small parts cylinder test')

What do you do now?

Draft EN71-1 standard has been published for public comment by BSI but, at the time of writing, the drafts had been withdrawn. However, BTHA Guidance on the *Revisions to Standards* is being developed and this will outline the new requirements of the revised standards.

Members are advised to keep abreast of the BTHA *Revisions to Standards* and the standards as they are published to ensure that toys are manufactured to these new requirements.