Questions and Answers on Toy Safety

The below is a compilation of a Q&A-session arranged in Shenzhen, People's Republic of China, by the European Commission (DG Entr) and TIE. The original wording of the questions has been kept.

Soft-filled toys and soft-filled parts of a toy

1. Stuffing--Polyester (see picture) belong to small part? It is failed if material tear and can insert probe A? For some soft-filled toys, we do not have such ability to maintain the toys' shape if add an inside fabric to cover the stuffing foam. So we would like to know whether the tension 70N can change to 45N for soft-filled toy only.

For soft-filled toys filled with fibrous filling material and having no small parts, a 12 mm probe must not be possible to insert more than 6 mm after the seam test (probe A is only used for soft-filled toys containing small parts). The force in the seam test is 70 N.

2. In the previous version of the standard soft filled toys without small parts could be exempted from the seam test. In the new standard it is not exempted.
Most soft filled toys are intended for children below 3, since they are intended to cuddled and held. For some fabric this implies that the final product is finished by hand. Therefore sometimes the strength of the seam will not be that high. We know that EU needs low-cost soft filled toys, but we cannot achieve 70 N if we use the low cost material. As these toys will fail the requirements, we consider that EU will not purchase toys manufactured by hands. This creates a technical barrier to trade for Chinese manufacturers. Please see some examples I brought: can you assess on sight if they comply?

The requirement for seam test has indeed been extended to soft-filled toys with fibrous materials in in EN 71-1:2011 (but assessment is made with a larger probe than for ordinary seam test). The reason was that some European Member States had incident data that they considered showed that there was indeed a risk that children could choke on large clumps of fibrous filling materials. The standard was therefore amended even though there remains some uncertainty about the hazardousness of fibrous filling material. This is explained in A.27 of EN 71-1. In fact, if the member states used their ability to challenge the standard and agree that a change must be made, CEN is obliged to do so and this is what happened in this case. Finally: Only compliant products can be placed on the EU market regardless of cost issues. Testing without tools cannot be made at a Q&A-session - we can only inform about the applicable requirements.

3. The principle of plush toys classification.

All soft-filled toys intended to be held or cuddled are considered to be intended for children under 3 years. See scope of EN 71-1:2011: "....for the purpose of this European Standard, e.g. soft-filled toys with simple features intended for holding and cuddling are considered as toys intended for children under 36 months."

4. The method to identify the different ages of plush toys.

All soft-filled toys intended to be held or cuddled are considered to be intended for children under 3 years. See scope of EN 71-1:2011: "....for the purpose of this European Standard, e.g. soft-filled toys with simple features intended for holding and cuddling are considered as toys intended for children under 36 months."

5. How many items of plush toys fabric should be tested?

The conformity assessment and the internal production control are decided by the manufacturer. Depending on the type of toy the number of items to test and/or inspect has to be determined by the manufacturer.

6. The key ring on the soft plush stuffed toys could be removable after revolved by adult, so the key ring whether complied with removable components or not?

According to EN 71-1 clause 5.1 b), components that are released during the specified tests must not fit in the small parts cylinder. However, if the component is not removed by the tests of clause 5.1 b) (but can only be removed by an adult opening up the coiled ring and rotating), the components are not regarded as "removable" by a child under 3 years of age.

Chemicals

7. The restricted chemical substance category are numerous, our factory how to affectively, simply, and economically distinguish whether our product contain these chemical substances or not?

Within the safety assessment the manufacturer will ideally receive details on the chemical substances that are present in the raw materials or materials. This information should be requested from suppliers. See also guidance document on technical documentation.

8. In the 2009/48/EC, it is added with a new chemical test requirement. What is the difference with the old command in the part of element migration?

Eleven elements have been added and migration limits are specific for three categories of material. The limit values are listed in Annex II, part 3, point 13.

9. About the chemical section, it is added with 19 new types migration, how to test? Especially the Low content, zero of several PPM. Organic tin, trivalent chromium, chromium six. CMR, can it be tested? How to test?

The test methods are under development. The revised version of EN 71-3 is scheduled to be published before 20 July 2013. A draft version is expected to be circulated for CEN Enquiry during 2012.

10. There is no specific rule for chemical methods of testing toys.

In the guidance document for the technical documentation the chapter on chemical safety assessment explains the way to proceed when no standards are available or when such standards do not cover the chemical hazards in question.

11. Nickel release: Are the standards EN1811-2011 and EN1811-1998+A1-2008 both available at the same time before March 2013? Which one is more important when decide the result? The limit value is lower in 2011.
In 2011, when the result is smaller than 0.35（eg.0.3）, the limit value is 0.2μg/cm2/week, it's fail, but it's pass according to 2011, how to deal with the result?

The date of withdrawal is March 2013, meaning that until then either standard may be used for checking compliance with REACH Annex XVII; entry 27.

12. In EU 494-2011-cadmium limit, it is only mentioned to metal material in jewelry, what about the other materials in jewelry? Whether is available for 91/338/EEC? There is no method for Cd in metal, will it come on recently?

The present restriction is available in 494/2011/EC which repeals 91/338/EEC. 494/2011/EC modifies entry 23, points 1 to 4 and adds points 8-11. Thus, point 1 still applies and regulates cadmium in certain plastic materials (regardless of where they are used). Points 10 and 11 add specific restrictions for cadmium in metal parts of jewelry.
There is presently no method for testing of Cadmium in metals referenced under the REACH regulation.

13. What's the decompose principle for nickel release? Is it up to materials（eg. Iron, zinc copper etc. or parts（eg, chain, drop, pin, buckle etc.）? Does the post part need to be cut when test in EN1811?

Procedures are described in Annex C of EN 1811:2011.

14. Does the Electroplated Metal Coating need to be tested according to EN12472?
If it need to been done, contents of Ni come from Electroplated Metal, if it does note to been done, What's the purpose of corrosion?

The answers below are based on our understanding of the questions which were translated. If you have further questions, please contact the European Chemicals Agency, using the specific information request form; see the web site of the Helpdesk: http://echa.europa.eu/web/guest/support/helpdesks/echa-helpdesk

In the case of children's jewelry having a non-nickel coating, in order to prove the compliance with entry 27, paragraph 1(c), these articles have to be subjected to EN 12472:2005 + A1:2009, which is the method for the simulation of wear and corrosion for the detection of nickel release from coated items followed by the migration test according to EN 1811:2011 (on the worn and abraded article) to prove the compliance with the limit provided in the entry 27, paragraph 1(c).

Would the articles have no non-nickel coating, the release of nickel from articles intended to come into direct contact and prolonged contact with the skin needs to be tested with the standards adopted by the European Committee for Standardization (CEN). EN 1811:2011 was published by CEN on the 9th of March 2011, superseding EN 1811:1988+A1:2008.

Consequently we encourage the exclusive use of EN 1811:2011 to demonstrate compliance with the provisions of paragraphs 1 and 2 of the restrictions on nickel. Notwithstanding the DoW (date of withdrawal) indicated by CEN for the EN 1811:1998+A1:2008 is the 31st of March 2013 and, therefore, in principle, this standard can also be used until this date to demonstrate conformity.

15. Which tests need to been done about CCB beads? Do Ni or Cd need to been done? Or dose the Ni need to been test in electroplated metal, the cd need to been test in inside plastic?

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The entry 23 of the Annex XVII of the REACH regulation (as amended by the regulation 494/2011/EC) states that cadmium and its compounds shall not be used or placed on the market if the concentration is equal to or greater than 0.01 % by weight of the metal in metal beads and other metal components for jewelry making (paragraph 10 (i)). In addition, please note also that articles produced from plastic material referred to in paragraph 1 of the entry shall not be placed on the market if the concentration of cadmium is equal to or greater than 0.01 % by weight of the plastic material. Thus in the case of plastic coated metal beads (CCB beads), both the plastic material and the metallic part of the bead need to comply with the entry 23 (cadmium restriction).

Please note also if the article is painted, then also paragraph 2 shall apply to this article.
The paragraph 1(b) of the entry 27 of the Annex XVII restricts nickel and its compounds in articles intended to come into direct and prolonged contact with the skin and the non-exhaustive list of examples is given. The articles described in the question (CCB beads in children jewelry) need to comply with this restriction entry. The paragraph 1(b) also states that nickel and its compounds shall not be used if the rate of nickel release from the parts of the articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm²/week.

However, if the articles referred to in the paragraph 1(b) have a non-nickel coating, they can be placed on the market if they conform to the requirements in the paragraph 1(c) which states that nickel and its compounds shall not be used in the referred articles unless the non-nickel coating is sufficient to ensure that the rate of nickel release from the parts of articles coming into direct and prolonged contact with the skin does not exceed 0.5 µg/cm²/week for a period of at least 2 years of normal use of the article.

16. What are the EU's new requests about lead and other compounds in jewelry?

The answers below are based on our understanding of the questions which were translated. If you have further questions, please contact the European Chemicals Agency, using the specific information request form; see the web site of the Helpdesk: http://echa.europa.eu/web/guest/support/helpdesks/echa-helpdesk.

You will find below an update of the situation regarding the restriction proposed by France about the use of lead in jewelry.

On 15 April 2010, France submitted an Annex XV dossier for restriction to the European Chemicals Agency with the aim of prohibiting the use of lead and its compounds in jewelry. Following the REACH restriction process laid down in Articles 69 to 72 of the REACH regulation (EC) N°1907/2006, ECHA's Committees for Risk assessment ("RAC") and Socio-economic Analysis ("SEAC") adopted their respective opinions in March and September 2011, and subsequently a draft Regulation has been prepared by the

European Commission proposing to prohibit the placing on the market and use of jewelry containing lead or lead compounds, when the concentration of lead is equal or greater than 0.05% by weight of any individual part of jewelry and imitation jewelry and hair accessories.

This draft has been submitted to the World Trade Organization under the TBT Agreement on 17 January 2012 (G/TBT/EN/EU/12).
This draft Regulation is envisaged to be adopted in the second half of 2012.

17. What chemical requirements apply?

The new chemical requirements apply as from 20 July 2013 and can be found in 2009/48/EC. Until then, the chemical requirements in 88/378/EEC apply. For the purpose of the present requirements, the present version of the chemical standards can be used to show compliance.

18. For the prohibition of 66 allergenic fragrances: we want to know what kind of products will fall into this scope? All toys? or only the olfactory toys, gustative toys and cosmetic toys？ Because many toys or their parts almost no probability contain these allergenic fragrances, e.g. Ride-On Toys, Electric Toy. If all toys or their parts need to be tested these allergenic fragrances. It will be a needless huge burden to manufacturer.

All toys are a subject to the requirements. The intention of the safety assessment is partly to determine whether further information or testing is needed. If the safety assessment shows that there is no likelihood of fragrances being present in the toy, this is documented and nothing further is required

19. Follow-up questions:
- Does the testing need to be 3rd party testing or can it be done by ourselves? Most manufacturers do not have the testing tools and therefore most of the testing will be done by the supplier; do they need to submit the test report? This is a burden to the supplier and will increase the cost and transfer the cost.
- What is the progress of the standard for fragrance-testing in the EU?
- Most Chinese manufacturers will purchased from outside China so they might not know if the fragrances is added. If there is no standard for fragrance-testing in EU, what about enforcement - how can it be verified that the toy complies? In China there are a many manufacturers dedicated to make toys and books with fragrances. Can we ask for the test methods used by enforcement authorities?
- Fragrance toys might have metal parts and plastic parts free of fragrances; will an exemption list be available.
- What kind of documents do we need to provide?

There is no general requirement to have 3rd party testing - In-house testing is permitted. You need documentation to show compliance with the Toy Safety Directive. If your safety assessment shows that there is a very low likelihood of restricted fragrances being present, there is no need to perform testing.

If you add a fragrance intentionally, it must not be one of the 66 restricted. We do not expect any harmonized standard to be developed by CEN. It has not been considered necessary to develop a harmonized standard for fragrance testing since fragrances are normally intentionally added in known amounts. Although there is no harmonized method, there are testing methods available and enforcement authorities can/will use these to verify compliance when needed and will need to inform economic operators what methods they have used. There will be no list of exemptions – If the SA shows that there is low likelihood of presence there is no need to test. In your SA you should file documents stating/proving that restricted fragrances have not been used - if necessary that could include test reports.

20. In 2009/48/EC, the limit of some 19 heavy metals is very low, is it based on the science basis? And is it from a biological test results? If it is, how the amount of intake of the test is responded to the Soluble.

The requirements are based on a report from RIVM and the opinion of the SCHER-committee. The report and the opinion are available on the European Commission's website.

21. If has it been investigated what proportion of the toys exported to the EU meet the new heavy metals limits (2009/48/EC) requirements? In the commonly used materials in toys, which are the most at risk?

See above. The methods are still under elaboration and no exact figures are available either for toys produced in the EU or toys imported to the EU.

Cords, chains, strap, and electrical cables in toys

22. Under 36 months toy, If there is requirement for length of USB cable and microphone cable?

If such a toy includes an electrical cable longer than 300 mm it needs to carry a warning (see EN 71-1:2011)

23. The reason of modification of welds tension from new 2009/48/EC.

A new test has been added in EN 71-1:2011 for soft-filled toys that have no small parts inside but is filled with fibrous filling. A.29 in EN 71-1 states: "Despite uncertainty as to the hazard presented by fibrous filling, it has been deemed prudent to require that the seams of soft-filled toys undergo a tension test. The requirements in 5.2 c) are therefore intended to ensure that the seams of such soft-filled toys do not come apart in a way that enables a child to insert two fingers through a seam to pull out clumps of filling (simulated by a 12 mm probe inserted to a depth of more than 6 mm)."

24. The determination of plush toys string.

Question not understood. "Cord" is defined in 3.11 of EN 71-1:2011

25. The toys that be used in the book for 36 months following, must be designed or made into cleaning, In addition to containing mechanical device cause damage, are there any special requirements?

Toys intended for children under 36 months shall be possible to clean. If they are 100 % textile toys they must be possible to soak wash and still fulfill safety requirements. If the textile toy intended for children under 36 months contains an electronic device or other devices that can be damaged in soak washing, the toy must be possible to clean.

26. Do the request of cords' thickness from EN71-1 2011 clause 5.4 only indicate the self-retracting cords and the cords of the pull-along toys? Should we think about the thickness of the beard on animal toys or the thread on the toys' mouth?

The requirement in 5.4. a (1,5 mm minimum thickness) applies only to cords connected to a self-retraction mechanism and to cords in pull-along toys.
As part of the safety assessment, any laceration hazard presented by a toy but not covered by the standard, should be assessed.

27. The soft plush stuffed toys contains button cell batteries which could emit simple sound whether should be tested according to EN62115?

Yes. The toy would be covered by EN 62115 "electrical toys"

28. The soft plush stuffed toys which could emit sound by batteries whether complied with the sound-producing toys or not? The toys whether should be tested according to EN71 Part 1 Clause 4.20?

Yes, all toys of this type that are clearly designed to emit sound are subject to the requirements in clause 4.20.

29. When measuring the length of an electrical cable, shall the USB contact be included in the measurement.

If the fixing point has the same shape or form as the cord or chain, this part is measured as part of the entire cord or chain (see Figure 48 in EN 71-1). Toys intended for children under 36 months, with electrical cables longer than 300 mm and their packaging shall carry the following warning: “Warning. Long cable. Strangulation hazard.”

30. You mentioned that if the length of a cable is more than 300 mm a warning is needed?

Yes, if the toy is intended for children under 3 and contains an electrical cable longer than 300 mm the toy shall carry a warning (se 7.21 in EN 71-1:2011).

31. There are requirements that e.g. spaces between the wheels and the body or parts of the body (e.g. mudguards) shall also allow a 12 mm diameter rod to be inserted if they allow a 5 mm diameter rod can be inserted. What force shall be used when trying to insert the rod? We have a toy with 4.6 mm opening but an authority in Europe applied a high force to the 5 mm rod and managed to insert it and failed the toy.

There is no specification of the actual force in the standard. This should be taken to mean "freely inserted" i.e. with no force.

32. When does the requirement apply that spaces between the wheels and the body or parts of the body (e.g. mudguards) shall also allow a 12 mm diameter rod to be inserted if they allow a 5 mm diameter rod to be inserted?

According to A.20, the requirements are intended to address the hazards associated with chain transmissions and wheel arrangements capable of crushing fingers and other parts of the body, if entrapped. They would therefore not apply if it is obvious that there is no such hazard.

33. For toy umbrellas, the spokes must have a 2 mm diameter. Does this requirement apply also to other toys?

Tubes and rigid components in the form of projections which constitute a puncture hazard to a child shall be protected.

Toys intended for children under 3 shall not present hazardous sharp points after foreseeable use test. In toys for children under 3, any metal point or wire with a cross section of less than 2 mm shall be assessed as a potential hazardous sharp point (also if it passes the sharp point test).

In toys for children over three, points that fail the sharp point test shall be assessed to determine whether they are hazardous. Also, for certain types of toys intended for children over 3, tests shall be performed to check if sharp points are exposed after testing.

Magnets and electrical functions

34. After abuse test, when the magnet in the toys was not accessible, whether the flux of the magnet should continue to be test?

If the magnet is inside a magnetic component and that component is released and fits entirely in the small parts cylinder, the flux index shall be below 50 kG2mm2. See also reply to the question below.

35. After abuse test, when the magnet in the toys was accessible, but which could not be fit within the cylinder, then can we ignore the flux of the small magnet?

The flux index requirement applies only if the magnet or magnetic component fits entirely in the small parts cylinder.

36. A toy without electronic function that is sold together with a toy that has an electronic function - does the non-electronic toy also need to comply with the RoHS-directive?

In practical terms, a co-dependency criteria is applied to non-electrical parts of a product supplied in the same box. For example a special adjusting spanner for a chainsaw designed to fit the chainsaw it is supplied with would be in scope but if the 'box' contained a simple screwdriver that could be used generally it would not. The same approach has been applied to toys. What is the co-dependence? Are they a set or just two different toys bundled together.

There is a FAQ (DG ENV draft RoHS 2 FAQ) on this: Components, accessories, RFID chips and security tags…

Under the current implemented RoHS Regulations, whether a part sold as part of the finished product is considered to be within scope, depends on such considerations as interdependence, expected inclusion in WEEE and product description. This may include items such as cases supplied with the product. It does not include packaging, instruction manuals or consumables such as printer cartridges, jigsaw blades or LEDs when sold separately. Non electrical accessories which are supplied separately such as mobile phone covers are not considered within scope. Chips and tags used for stock control and retail security are considered electrical and electronic equipment products in themselves and therefore considered to be within scope.

Pull Tension test and seam test

37. In the requirement of the EN71-1：2011 section 8.3/8.4, if the pull test is required to be done for the injection which can be grasped by the thumb and index finger, how to define whether it can be seized ? Is the following exemption and immunities cases correctly?

It is correct that the tension test should be applied if it is possible to insert the feeler gauge more than 2 mm (with a force of 10 N and an angle of between 0 and 10 degrees) between the component and the underlying body.

There is no specific measurement to use in order to determine whether or not the component is graspable between the thumb and forefinger. This is an assessment that has to be made on a case to case basis. The indications in the attached picture seem reasonable (the four upper examples above would be exempted and the four lower would be subjected to the test if the feeler gauge can be inserted at least 2 mm).

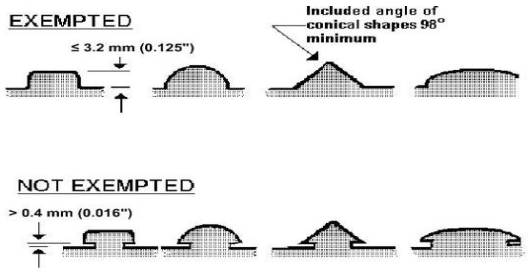

FIGURE 1

38. Follow-up questions:
- The example shows 1 piece but what if the toy is assembled; is the requirement the same for assembled toys?
- If the toy is intended for children under 3, we need to conduct tension test on all parts but if it is intended for children over 3 years we only need to conduct the tests on certain parts. Is this correct?
- If the height is smaller than 3.2 mm is the part then exempted from the test?
- For packaging for the toys made in PVC and intended for children under 3: what tension force should be applied in the test for the seam of a PVC bag?

- There is no difference if the toy is assembled or not. The test would apply even if it is a fully moulded toy.
- Toys for children under 3 are not permitted to release small parts (if they do the toy is banned). Toys intended for children over 3 need to carry a warning if they release small parts (unless they are clearly unsuitable for children under 36 months) since they could then be dangerous for children under 3.
A spontaneous reply is that a part less than 3.2 mm would be very difficult to grip but there is no general exemption based on dimensions.
PVC-bag - The question is not understood. There is, however, no requirement for a seam strength test for packaging of toys.

39. According to EN71-1 clause 8.4, "When the largest accessible dimension of the component to be gripped and tested is greater than 6 mm. Apply the force (90 ± 2) N gradually within a period of 5 s. Maintain the force for 10 s, then make sure whether the component has become detached." But the test report attached to a case (1293/11) indicate that they didn't apply the force (90 ± 2) N gradually within a period of 5 s, and the test time was more than 20s. Can we test according to the latter test method? Which is the right method?

In order to check compliance with the requirement in the standard, the method in the standard should be used (application of the force during approx. 5 s and maintain the force for 10 seconds).

40. When testing to the requirement in 4.15.5.4 c) (insert probe between 5 and 12 mm), what force should be applied?

There is no force specified in the standard EN 71-1, and this should be taken to mean "freely inserted" (i.e., with no force).

Marking

41. Does the age warning must update as below?
Current:WARNING! Not suitable for children under 3 years of age. Choking Hazard.
Updated:WARNING! Not suitable for children under 3 years of age. Small Part. Choking Hazard

Yes, due to new requirements in the TSD, the standard EN 71-1:2011 has been updated to clarify that the hazard has to be indicated (e.g. small parts, long cord, etc).

42. Some toys without packing, without age identification, in the seventh part asks judge, is it right there must be the manufacturer or importer and other information in the toy or packing, or toy must bear the CE marking.

If the toy has no packaging, the necessary information (e.g. addresses, identification, warnings and CE-mark) needs to be on the toy or an attached leaflet. See the explanatory guidance document for details.

43. If we have "Made in China" on the toy, do we need to specify the country of origin further?

All the goods that are classified in the Combined Nomenclature are subject to EU non preferential rules of origin. The rules define the non-preferential origin of goods for the purpose of applying the Customs Tariff of the EU with the exception of preferential tariff measures, measures other than tariff measures (safeguards, origin marking requirements, quantitative restrictions, trade statistics or government procurement).

Release for free circulation in the EU entails the charging of duties legally due to goods (toys) and also application of other measures depending on the country of their origin. All goods intended to be placed under a release for free circulation customs procedure shall be covered by a declaration for that customs procedure. The country of origin shall be entered as all other required data into the declaration.

Generally speaking, there is no EU law requiring industrial goods (toys) to bear marks indicating their origin (for example, an Origin marking law for consumer goods exist in Italy), nor is there a law preventing voluntary origin marking where traders wish to do so. However, in the event that such marks are applied to goods, the competent authorities of the Member States require these marks to be accurate. This meaning that goods (toys) do not need to be labeled with ''made in...''.

Flammability

44. Flammability: the combustion performance test of molded masks requirements or details which should be paid attention to.

The test in EN 71-2:2011 is the same as in the previous version of EN 71-2 except that the flame is applied between 20 and 30 mm above the lower edge (previously "at least 20 mm above")

45. Does a diaper need to be tested for flammability?

Diapers for new born babies are not toys. If the diaper is e.g. for a doll, you will need to apply at least clause 4.1 of EN 71-2.

Any other business

46. When the revised harmonized standard (EN 71-3) will be published by European Union? Which can provide a presumption of conformity with the requirements of 19 migration elements in Directive 2009/48/EC.

The test methods are under development. The revised version of EN 71-3 is scheduled to be published before 20 July 2013. A draft version is expected to be circulated for CEN Enquiry during 2012.

47. Which date does the 20 July refer to - manufacturing date or import date?

The date refers to when the toy is placed on the market. For products imported to EU, this would be the date when they are cleared in EU-customs.

48. Where can the guidance document be downloaded?

http://ec.europa.eu/enterprise/sectors/toys/documents/guidance/

49. What should the technical documentation include? Is there an example somewhere?

The Commission's guidance document on the technical documentation (published on the Commission's website) lists details about all parts of the technical documentation.

50. If we have several kinds of toys, can we only provide one copies of the technical document? Is the 10 years keeping duration too long for the manufacturers?

Some parts of the technical documentation can be generic (the same for several products) but for other parts individual documentation may be needed. It is up to the manufacturer to decide how to store and compile the necessary data. See also guidance document on technical documentation.

51. From RAPEX: The product poses a risk of choking as small parts may easily become detached and be placed in the mouth by young children.
Description: Plastic, pull toy plane on 2 wheels, decorated with stickers. There is a tag with CE mark, name and address of the distributors, "Made in China", EAN number & the pictogram concerning "0-3" age restriction. There are also warnings about the risk of swallowing small parts and about necessity of storing the packaging due to useful information, but not within the reach of children, as the packaging is not a toy.
This product is not intended for use by child under 3 years old, and also the package has shown the age restriction "0-3", so the adults must supervise it, but not to just recall this product, EU should give the chance to the manufacturer can improve their design.

The toy is not compliant because it is considered to be intended for children under three years according to e.g. CEN TR 14379, table 16 (according to Directive 2009/48/EC "intended for use by" means that a parent or supervisor shall reasonably be able to assume by virtue of the functions, dimensions and characteristics of a toy that it is intended for use by children of the stated age group"). A toy intended for children under three cannot carry an age warning "not suitable for children under 3". Since a warning must not be in conflict with the "intended use" of the toy.

52. According to EN71 Part 1 Clause 5.4, the toys intended for children under 36 months were divided two testing age grading: under 18months & between 18 and 36 months, how to distinguish it please?

According to EN 71-1:2011:References regarding age grading of toys e.g. "intended for children under 18 months" can be found in the CPSC Age Determination Guidelines and in CR 14379 (see Bibliography)."

53. Is there any specific guideline to define "children's product" and "toy" in EU, e.g. 3D-stickers, stationary, keychain, magnet sets with figures?

1. The definition of "Toy" is in the TSD. There is no definition of "children's product" (this is however an important definition in CPSIA in the USA). "Child care articles" are defined in EU. These are not toys, but covered by GPSD.

2. Classification can be difficult and therefore COM has published guidance documents on their website to assist

54. Can a raw material manufacturer issue an (M) SDS for their own made material. If No, how can they get a valid SDS?

The answer is available in the Guidance document on the Technical documentation. It should be noted that classifications should be in line either with the Regulation on Classification, Labeling and Packaging (CLP) in the case of substances or the Dangerous Preparations Directive (DPD) in the case of mixtures. Classification for the same substance can be different e.g. due to different impurity profiles or lack of information, however the hazardous substances listed in annex VI of the CLP regulation have to be classified accordingly as this classification has been established at Community level. If no classification is present, the manufacturer can self-classify but the SDS must comply with the requirements for drafting of SDS according to the REACH-regulation.

55. How shall manufacturers comply with the TSD?

The requirements are available in the TSD and the guidance documents explain details and the harmonized standards support the particular safety requirements.

56. The washing cycles and washing machine of under 3 year toy if required? The standard describe that 'removing the impurities and dirt from the toy in general' is ok, but the real user would wash the toy for such a lot of times, should the toy need to be wash for more cycles to ensure the safety?

It is up to the manufacturer to assess this in the safety assessment. The horizontal committee for the Notified Bodies under the TSD have elaborated a protocol that NBs can apply when undertaking an EC type examination. This protocol will be published on http://ec.europa.eu/enterprise/sectors/toys/documents/recommendations/index_en.htm provided that it is approved by the European Commission and Member States.

57. The standard describes that 'changes in toy design or characteristics shall be adequately taken into account'. How long will be testing by each material?
Proposed advice: Advise that perform test at the third party lab once the material changed, and one time each year for inside laboratory test.

If a product is changed in a manner that can affect the safety of the product, new tests may be needed of the finished product in the conformity assessment procedure. There is no obligation to use third party testing. It is up to the manufacturer to decide how to ensure that the product complies with the appropriate standards and the frequency of testing. Test reports shall be part of the technical documentation.

58. The conformity assessment procedure (conformity assessment/safety assessment) may be performed by factory or third-party outside lab and what is the details?

1. Conformity assessment procedure is normally self-certification which can be based on in-house testing or third party testing verifying that requirements in relevant harmonized and referenced standards are fulfilled. On rare occasions, EC Type examination is needed which for a compliant toy will result in a EC Type examination certificate.

2. The safety assessment is drawn up by the manufacturer who may use third party consultancy. If the toy is going to be submitted to EC-type examination, the same NB must not have been involved in the safety assessment for that toy.

59. How to perform the EC type-examination certificate?

This is described in article 20 of the TSD. The NB shall not only test to standards but shall assess the toy against the requirements in the TSD. Only NBs can carry out EC Type examination.

60. It is difficult that the product archives and EC declaration of conformity are in good kept for10 years at factory.

It is permitted to keep the documentation in electronic format in different systems and to compile it on request.

61. When does it come into force? Is the execution date clear?

TSD is applicable from 20 July 2011 except for chemical requirements that are applicable from 20 July 2013.