

## QUESTIONS TO BE ASKED WHEN ASSESSING A PRODUCT RISK

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### Introduction

The purpose of a technical file is to be able to demonstrate compliance with the requirements. One of the aspects of that file is a risk analysis. It must be clear in the technical file how is being dealt with the identified risks. A common mistake is to say that there is no need for a risk analysis because the product is tested and deemed to comply with the requirements of for example low voltage requirements. Such testing doesn't consider the total scope of risks. For example the product might become child appealing because of adding popular comic figures to the printing on the outside thus changing the risk.

In this document we give you examples of questions that you could ask as part of the risk assessment. Note that this list is not complete and may not cover all questions that should be asked. Products, ideas, technology change everyday. Those aspects that you answer with YES should at least be covered in the technical file! Otherwise you mark them as Not Applicable (N/A). Note that it's about asking questions - that is what you should do too!

Most of these questions find their origin in the continuous flow of product recalls as for example those on [www.rapex.eu](http://www.rapex.eu). We advise you to run over the entire list as you might learn from risks in other categories as well.

### ProductIP

#### note

- It can not be guaranteed that this list is complete and covers all potential risks. You remain responsible for the compliance of your product.
- If you have other examples / risks that we should add then please let us know.
- This is a living document and we advise you to use the latest version as available for download on the download section of [www.ProductIP.com](http://www.ProductIP.com)

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R1 - 2010-07-06 correction of some type errors and added 1.27 1.28. 1.29 1.30 and corrected 4.03 and 4.09

R2 - 2010-07-07 small textual corrections on main page - no changes to questions

To start with the basic risk assessment it is advised to add basic information about the product

-model number

-description

-rating

-intended use (indoor / outdoor / age categories etc.) - note: "use your imagination !" . After you have gone through this document you better check this point again asking yourself, "Have we really considered all possible applications - potential risks?"

-images of product and packaging

- assessment created by who per when and any reference number

The questions are categorised in different sections. We advise you to go over the complete listing even if some sections don't appear to be relevant for the product. Questions might give you an idea!

1	ELECTRICAL PRODUCTS	N/A	HOW IS THIS RISK COVERED?
1.00	In case of class I - is the safety earth wire longer then the L and N wire?		
1.01	In case of class I - are all accessible metal parts connected properly and individually?		
1.02	In case of class I - is the grounding of metal parts made on non painted parts - using a proper washer to create and a proper connection that cannot go loose due to vibrations?		
1.03	in case of class II - is the insulation material used not hydroscopic?		
1.04	Is the IQC sufficient to detect deviations in parts like a thermo fuse or over-current protector that we use to keep our product safe?		
1.05	Is the position of the thermo fuse in the product fixed by design so that it always can act at the right temperature range?		
1.06	Can wear of tools during mass production reduce the contact pressure of internal connections?		
1.07	Can aging of the product in the market reduce the contact pressure of internal connections?		
1.08	Is the IQC sufficient to detect deviations in parts used for internal connections - the right material and material properties!		
1.09	Is the design using any internal connections relying on contact pressure via plastic parts? (as this is not allowed!)		
1.10	In case of socket outlets (how) are you ensuring the right dimensions and contact pressure during mass production? Deviations might cause overheating during usage		

1	ELECTRICAL PRODUCTS	N/A	HOW IS THIS RISK COVERED?
1.11	In case of outdoor application - does the product have the appropriate IP classification?		
1.12	Is the design also water / dust proof after aging? (plastic sealing parts might become brittle during aging / UV light / especially when under pressure!)		
1.13	In case the sealing relies on contact pressure is this contact pressure ensured and locked during mass production and will it stay within acceptable limits during aging and normal usages of the product?		
1.14	In case of an outdoor product is the outside housing UV stable?		
1.15	Is the product child-appealing because of design, shape, colors, function? In that case consider requirements applicable from the toys-directive!		
1.16	Is the product using LED / LASER then how it ensured that this is not harmful to eyes (also consider risk during production!)		
1.17	Could the product be dangerous when it tips over? (Heat on surfaces - then consider it's stability perhaps with a 15 degree stability test)		
1.18	Any risk for an energy shock from short circuit of build in batteries or capacitors?		
1.19	Any risk for injury due to rotating parts?		
1.20	Any risk for injury due to vibration - using the product ?		
1.21	Is the product safe during and again after replacement of spare-parts / batteries?		

1	ELECTRICAL PRODUCTS	N/A	HOW IS THIS RISK COVERED?
1.22	Can the product / parts of the product - be traced back to production sites / moulds / cavities ? This can reduce the burden in case something goes wrong because batches can be identified. Also it helps quality control to trace back the cause of flaws and thus to improve the product / production		
1.23	Is the quality of the product maintained during normal use? Vibrations / dust collection / heat cycles		
1.24	Can insulation of live parts be damaged due to normal use, vibration, movement of parts?		
1.25	Is the cross-section of the conductors used suitable for the currents? Also the earth-wire?		
1.26	Strength of normal flexing parts such as cord anchorages?		
1.27	In normal use are temperatures within the standard table limit		
1.28	Materials that are in direct contact with live parts shall have certain flammability aspects and shall not become weak (ball pressure test). Ensure that materials used during also meet the required properties during mass production !		
1.29	Ensure there are no loose parts in the product during mass production		
1.30	No internal live parts shall be accessible with the test finger		

2	TOYS - CHILD APPEALING PRODUCTS	N/A	HOW IS THIS RISK COVERED?
2.00	Is the product suitable for the intended age category?		
2.01	Is the product strong enough / are parts attached strong enough - to not create hazardous loose small parts?		
2.02	Are the intended small parts correct in size?		
2.03	Are the materials used clear of hazardous chemicals? (Additional requirements when the toy or childcare article can be placed in the mouth of children)		
2.04	Is the paint used clear of hazardous chemicals?		
2.05	Any possible sharp parts / points?		
2.06	Any parts that be ejected - shot - from the product that can be hazardous on impact?		
2.07	Any (laser) light that could be hazardous for eyes?		
2.08	Any sound level that could be hazardous for ears? (80 dB)		
2.09	Is the packaging intended to be used to play with? Then the packaging is also a toy!		
2.10	In case of socket outlets (how) are you ensuring the right dimensions and contact pressure during mass production? Deviations might cause overheating during usage		
2.11	Any use of battery cells? Note that these are very dangerous when swallowed so ensure there is no access to these without a tool - two independent simultaneously movements		
2.12	Any small parts / sharp parts when other parts detach (to) easy during normal usages?		

2	TOYS - CHILD APPEALING PRODUCTS	N/A	HOW IS THIS RISK COVERED?
2.13	Any magnet on the product? Any risk of it coming loose and then can be swallowed?		

3	CLOTHES / TEXTILE / SHOES	N/A	HOW IS THIS RISK COVERED?
3.00	Children clothes - any cords/drawstrings? (Neck, Waist, other area)		
3.01	Children clothes - any non-continues shoulder strap or free-end halter neck functional cords?		
3.02	Children clothes - nightwear - no fire hazard?		
3.03	Children clothes - no decoration or other small parts that can be detached to easy and can thus become a hazardous small parts (toys directive)		
3.04	Are the materials used clear of hazardous chemicals?		
3.05	Masks / carnival clothes / party clothes - often impose an additional fire hazard.		
3.06	Any skin contact risk related to chemicals (DMF and the like)		

4	ISSUES GENERIC	N/A	HOW IS THIS RISK COVERED?
4.00	Any liquids or other substances used that can become a bacterial risk during aging / transport ? Microbiological risk.		
4.01	Is the packaging method / instructions sufficient to keep the product safe?		
4.02	Is the instruction / manual up to date to the product version?		
4.03	Are the warning labels attached on the right place and in the right language and are the fonts used in the right size?		
4.04	Are labels of sufficient quality - both glue and ink - not easy to remove - rub out - UV stable in case required		
4.05	Is it required for the consumer to clean the product and if so can it withstand the required cleaning method? Dishwasher?		
4.06	Is the product likely to be subjected to temperature shocks?		
4.07	Is the product likely to be subjected to high temperatures?		
4.08	Is the product likely to be subjected to low temperatures		
4.09	Is it likely that the product is in direct or indirect contact with food?		
4.10	Is it likely that the product is in contact with human skin?		
4.11	No sharp edges on packaging materials?		

4	ISSUES GENERIC	N/A	HOW IS THIS RISK COVERED?
4.12	Packaging not hazardous for children - suffocate?		
4.13	Does the product look like food or does the product have parts that look like food and can be detached easily and become a risk when swallowed?		
4.14	Small battery cells can be extremely dangerous when swallowed?		
4.15	Have you considered maximum temperatures for different materials of areas to be touched by the user during normal use and repair?		
4.16	Can the product be damaging to hearing? (dB)		
4.17	Can the product be damaging to sight? (LED / Laser)		
4.18	Any risks for injuries during, unintended, folding / dismantling?		
4.19	Is the product child appealing then it must comply with requirements of toys directive as well !		
4.20	Does the product contain any liquids hazardous when swallowed then ensure that		
4.21	Does the packaging or coloring of the product lead to unintended use and or additional requirements to be imposed. (for example a normal extension cord with a packaging saying garden extension cord makes that outdoor and waterproof requirements become relevant)		
4.22	Does the product what it has to do in order to protect the user! (Personal Protective Equipment, Smoke alarms, etc)		
4.23	Any grip parts that can come loose due to normal use / aging? (consider handle bars)		

4	ISSUES GENERIC	N/A	HOW IS THIS RISK COVERED?
4.24	Is insulations of hot liquids an issue? Consider aging of seal as well?		
4.25	In case the product is intended to be fixed to a wall are surface temperatures within limits? Have you considered different wall materials?		
4.26	In case the product is intended to be fixed to the wall or otherwise be assembled by the user are screws and other fitting materials supplied of sufficient strength for this purpose?		
4.27	Have you considered that the product might be used in a completely different way as intended in the market of sales.		

5	GAS APPLIANCES	N/A	HOW IS THIS RISK COVERED?
5.00	Have you considered the fact that GAS is not the same everywhere? Different GAS with different caloric values require different burners in order to prevent incomplete burning - production of CO and other hazardous gases.		
5.01	Are tubes, valves and so on suitable for the right GAS?		
5.02	Are tubes, valves and so on suitable for the right PRESSURES?		
5.03	Is the product portable and if so it is stable enough?		
5.04	In case the product is portable what will happen when it tips over, even when it's stable enough?		
5.05	Are tubes / hose and other parts subjected to aging provided with a production date / end of live date ?		

6	BUSINESS OPERATION RISKS	N/A	HOW IS THIS RISK COVERED?
6.00	Can the product / batch be traced back? Also on inner / outer cartons? Also on the product without packaging		
6.01	Packaging and packaging materials also in compliance with requirements / REACH?		
6.02	Barcodes can be scanned also after packaging / shrink wrap		
6.03	Are you using any technologies or brand-names that could require a license?		