DESIGNING, PROTOTYPING AND MANUFACTURE OF SAFE TOYS MADE OF PLASTICS

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Summary: Toys should guarantee a high level of safety during their use. Children, for whom they are intended, are the group of population particularly vulnerable to risk. Manufacturers should therefore make every effort to put safe toys on the market. Safety actions should cover the basic steps of the manufacture process i.e. designing, prototyping and manufacture of toys. This paper presents a proposal for the procedures including requirements of 2009/48/EC Directive, which are in force, on the example of the manufacture process of plastic toy.

Keywords: production engineering, environment engineering, safety of use, designing and manufacture of toys.

1. Introduction

An orderly sequence of actions aiming to obtain products of quality desired by the clients, meeting their requirements and ensuring satisfaction through their use is called the production process [1].

Production process is of complex nature and it consists of numerous actions, inter alia: analysis of the clients' requirements, specification of the product required parameters, concept development and product design and manufacture process, preparation of production process, product manufacture, including its technical control, product audit and development, as well as manufacture techniques, storage and product distribution. All listed actions have direct impact on the product value.

Features characterizing the product value are as follows: quality level, reliability, modernity and price.

In the case of products intended for children, such as toys, quality of manufacturing is of particular importance. It impacts the basic functional properties of toys and safety of their use which is especially important in case of children.

Improper design solutions, materials and subassemblies, method of surface and edge finish or type of packaging may cause injuries and other negative effects to children [2]. Toxic chemical substances contained in toys are especially hazardous [3][4]. They adversely affect not only the children's health, but also their life environment. Hence, the production process shall include actions resulting from relevant safety requirements, mentioned in the Directive 2009/48/EC – Toys Safety Directive (TSD) [5].

These actions should be initiated already on the toy's design stage. Hazards which may appear while using the toy shall be identified and analysed, and potential users' exposure assessed, basing on the safety requirements. The aforementioned actions, called the toy safety assessment, shall be continued on the prototyping and manufacture stage.

If the safety assessment result is negative, toys designers and manufacturers should take up the measures eliminating hazards or limiting related risks. These may be verification of the toy design, or materials applied and chemical substances, introduction of proper safety

measures, or change of surface and edge finish and protruding components.

In case of the toy manufacture process modification or change of raw materials used for its manufacturing, or change of legal requirements, the assessment of safety shall each time be adequately updated.

Process of continuous monitoring of manufacture process and application of control procedures, especially related to the quality of materials delivered and serial product conformity with the requirement is the necessary condition to introduce safe toys to the market.

In order to document the aforementioned actions, the manufacturers shall make a relevant technical documentation of a toy, conform with the TSD Directive [5].

Toys play important function in intellectual and physical development of children. Thanks to toys, children gain knowledge, develop skills, gain physical fitness and shape imagination. Products intended for this, particularly vulnerable to hazards, group of society population, characterized by high activity and lack of possibility to make self-assessment of dangerous situations shall guarantee high level of their safety use. The fact that safety level is still insufficient is proved by the American Consumer Product Safety Commission (CPSC) data informing that in the period from 2005 to 2009 the toys were reason of 228 000 injuries and accidents, including 60 fatal cases [6].

It shall be also stressed that the value of toys retail sales, despite worsening economic situation in the European Union, has remained on similar level since 2006, i.e. about 14 billion euro. According to data published by the Toy Industries of Europe (TIR), in 2010 in the European Union, the value of sales reached 15.5 billion euro, showing a slight increase (approx. 2%) in comparison to 2009 [7].

The author's experience indicate that toy designers and manufacturers still inadequately interpret safety requirements pertaining to the process of toy designing, manufacture and marketing.

In the literature there is lack of clearly described methods and procedures, which shall be applied on individual stages of toy design and manufacture process.

Hence, this paper is an attempt to systematize the methods and procedures concerning the aforementioned problem.

2. Formal and legal requirements

Toys, as products intended for children under 14 years of age, must be designed and manufactured in compliance with safety requirements mentioned in Annex I to the Directive 2009/48/CE Toys Safety Directive (TSD).

Due to general nature of the requirements, not specifying guidelines for design, materials and use of toys, the basis for their design are harmonised standards published in the Official Journal of the European Union [8]:

- EN 71-1:2011. Safety of toys. Part 1. Mechanical and physical properties,
- EN 71-2:2011. Safety of toys. Part 2. Flammability,
- EN 71-8:2011. Safety of toys. Part 8. Activity toys for domestic use,
- EN 62115:2005/A2:2011/AC:2011. Electric toys. Safety.

Due to lack of standards harmonised with the TSD Directive as regards chemical properties of toys, the requirements provided in Annex 3(II) of the Directive 88/378/EEC [9] and standards harmonised with this Directive shall be applicable until 20 July 2013:

- EN 71-3:1998/A1:2001/AC:2004. Migration of certain elements,

- EN 71-4:2009. Safety of toys. Part 4. Experimental sets for chemistry and related activities,
- EN 71-5:1998/A1:2007/A2:2010. Safety of toys. Part 5. Chemical toys (sets) other than experimental sets,
- EN 71-7:2005. Safety of toys. Part 7. Finger paints - Requirements and test methods.

In relation to the requirements pertaining to the content of hazardous chemical substances in toys and materials used for their manufacture affecting children's health and life environment, the manufacturers shall also consider the REACH Regulation requirements [10] and other legal provisions, including:

- Directive 2002/95/CE on the restriction of the use of certain hazardous substances in electrical and electronic equipment [11],
- Directive 2002/96/CE on waste electrical and electronic equipment [12],
- Directive 76/768/EEC on cosmetic products [13],
- Regulation (EC) no 1935/2004, on materials and articles intended to come into contact with food [14],
- Directive 2002/72/CE relating to plastic materials and articles intended to come into contact with foodstuffs [15],
- Regulation (EC) no 850/2004 on persistent organic pollutants [16],
- Directive 84/500/EEC on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs [17].

On the toy design stage, toys designers and manufacturers shall make assessment of their use safety in compliance with the requirements of TSD Directive. Scope of assessment shall include identification and assessment of hazards related to a toy, analysis and assessment of users' exposure to potential hazards and specify actions eliminating or reducing those hazards [18]. An important element of the safety assessment are the tests of physical and mechanical, chemical, electrical, flammability, hygiene and radioactivity properties of a toy. Tests shall be made in laboratories accredited to perform tests on toys safety [22].

According to the requirements of TSD Directive, the toys manufacturers shall use relevant procedures in their manufacture process aiming to ensure compliance of a serial toy with the safety requirements.

A toy manufacture process shall give consideration also to the issues pertaining to reduction of impact of the produced toy and its elements on environment, when toys become a waste. Legal regulations related to waste handling are specified in:

- Directive 2006/12/CE on waste [14],
- Directive 94/62/CE on packaging and packaging waste [15],
- Directive 2006/66/CE, on batteries and accumulators and waste batteries and accumulators [16].

In this respect the manufacturer shall apply relevant procedures pertaining to toys marking and their packaging.

The condition to introduce a toy on the market is to ensure its conformity with the safety requirements. The manufacturers may make self-assessment of toy compliance with the requirements, subject to the internal production control procedure (A module) or they make such assessment in a notified body, through CE audits (B module) in combination with the procedure of assessment with the type, based on internal production control (C module).

The manufacturer's self-assessment of toys compliance, within A module, is possible only if the toy is manufactured in conformity with harmonised standards, including all essential safety requirements. A positive result of the compliance assessment entitles to issuance of the CE conformity declaration which is the manufacturer's statement that the toy is compliant with the TSD Directive requirements. Such declaration is issued on the sole responsibility of the manufacturer.

The results of compliance assessment, including safety assessment shall be properly documented. To achieve this, manufacturers shall develop technical documentation of the toy, in compliance with Annex IV to TSD Directive.

If the manufacturer applies the internal production control procedure (A module), documentation shall contain the following information [9]:

- detailed description of the design and manufacture process, including the list of used parts, materials and chemical substances, including safety data sheets,
- description of the toy safety assessment,
- copy of the CE conformity declaration,
- address, production site and storage site,
- reports from tests and description of measures by means of which production compliance with harmonised standards is ensured.

The documentation shall be stored by the manufacturer for 10 years after the toy marketing and made available to toy distributors and importers, which are obliged to make sure that the toy meets the safety requirements and to Trade Inspection in the case of control.

3. Process of designing, prototyping and manufacture of toys

The main objective of toy production process is to obtain a product, which meets needs of children to the possibly maximal extent, ensuring safety and environmental protection of their lives.

Production process of toys is carried out mainly by small and medium-sized enterprises (SMEs), which usually have limited technical and organizational infrastructure. They represent approximately 80% of companies in the European Union [7].

High competition of toys, especially those imported from countries outside the European Union, mainly from China, means that toy manufacturers seek to minimize production costs, at the cost of safety of the products manufactured by them. Among others, costs of toys testing as well as the costs of raw materials and components used for their manufacture are limited.

Having in mind minimization of risk of commercialization of the toys which can threaten children health and life, implementation of procedures including the control procedures, which meet requirements of TSD Directive and cited legal acts, in toys designing and manufacture processes, is indispensable.

The presented procedure proposal includes the following stages of toy manufacture process:

- designing of the toys (stage I),
- making the toy prototype (stage II),
- toy manufacture (stage III).

The procedure is discussed on the example of designing, prototyping and manufacture process of the toy made of plastic.

Algorithms of each stage of manufacture process are presented in Fig. 1 and 2.

3.1. Designing of the toy made of plastic (stage I)

In the designing stage, indispensable requirements as regards the toy model should be specified considering results of analysis of clients' previous needs as well as social trends.

The requirements should include technical and functional parameters of the toy, its functions, intention of use and characteristic features as well as appearance and aesthetics of manufacture.

Technical and functional parameters of new plastic toy should be verified as regards requirements of safety use, specified in TSD Directive, harmonised standards and in REACH Regulation.

On the basis of specified requirements the concept of the toy is developed. The concept includes pictorial image of new toy and information concerning the following:

- design, function and way of use,
- intention of use with indication of user age,
- packaging,
- materials of which the toy will be made.

Designing materials make the basis for development design documentation of the toy which should include:

- manufacture drawing of the toy and its components,
- detailed list of materials, including subassemblies, raw materials and chemical substances, including safety data sheets,
- manner of surface and edge and sticking out elements finish,
- list of markings, and use and assembly manual.

Based on the toy manufacturer's construction documentation, a toy model is made which shall further be subject to audit in relation to its compliance with the requirements of EN71-1:2011 standard made in a research laboratory [24] accredited to test physical and mechanical properties of toys.

If the test result is negative, the toy designer shall make modifications in the design documentation.

On the toy design stage, an assessment of the toy use shall be made and its results shall be considered in the toy construction documentation, especially as regards actions eliminating or reducing hazards and type of materials used to manufacture the toy. The assessment shall be continued on the toy prototyping stage (stage II) and every time updated in case of raw materials and chemical substances, or manufacture process change. The scope and methods applied to make toy safety assessment shall be conform with the documented procedure applied in the company. An example of the safety assessment procedure is presented in the paper (Grynkiewicz-Bylina B, 2011) [18].

3.2. Prototyping of a plastic toy (Stage II)

Design of injection mould and its further building shall be made on the basis of the toy design documentation and its model. After building a mould, a prototype of new toy is made, such prototype shall further be tested on its compliance with the requirements of the following standards: EN 71-1:2011, EN 71-2:2011 and EN 71-3:1998/A1:2001/AC:2004 and REACH Regulation.

The scope of toy prototype test shall include the assessment of physical, mechanical, and chemical properties as well as flammability and hygiene properties of the toy, which may have impact on safety use of the toy[19].

An important issue in the plastic toys tests is determination of toxic chemical substances content. Among these substances we find phthalates, commonly used as plasticizers, so called plastics softeners [25]. Due to their impact on health, they are one of the serious contaminations of children's life environment. Phthalates do not form covalent bonds with polymers with which they are mixed. This results in their migration to the products surface, and further to the environment [4].

The toy prototype safety tests should be carried out in the laboratory [24] accredited to make safety tests of toys.

If the test and safety assessment result is negative, the toy design documentation shall be verified. A positive toy safety assessment, certified by documented tests results enables to start development of the manufacture system design which includes selection of the following [1]:

- surface of production halls and warehouses of raw materials, subassemblies and finished products,
- power supply parameters and requirements, and water and sewage installations capacity,
- manufacturing machines and equipment, tools, control systems, control and measuring instruments, means of transport,
- raw materials and subassemblies used for toy manufacturing and operating of manufacturing machines and equipment,
- people employed in production system.

The manufacturing points, which must be monitored as regards quality of manufactured toy and its safety use, should be pointed out in the design system.

Subsequently to manufacture process, development and selection of all its subsystems, technical documentation of the toy should be developed, containing all information and data related to measures applied by the manufacturer in the process of toy design and manufacture in order to ensure toy conformity with the requirements of TSD Directive.

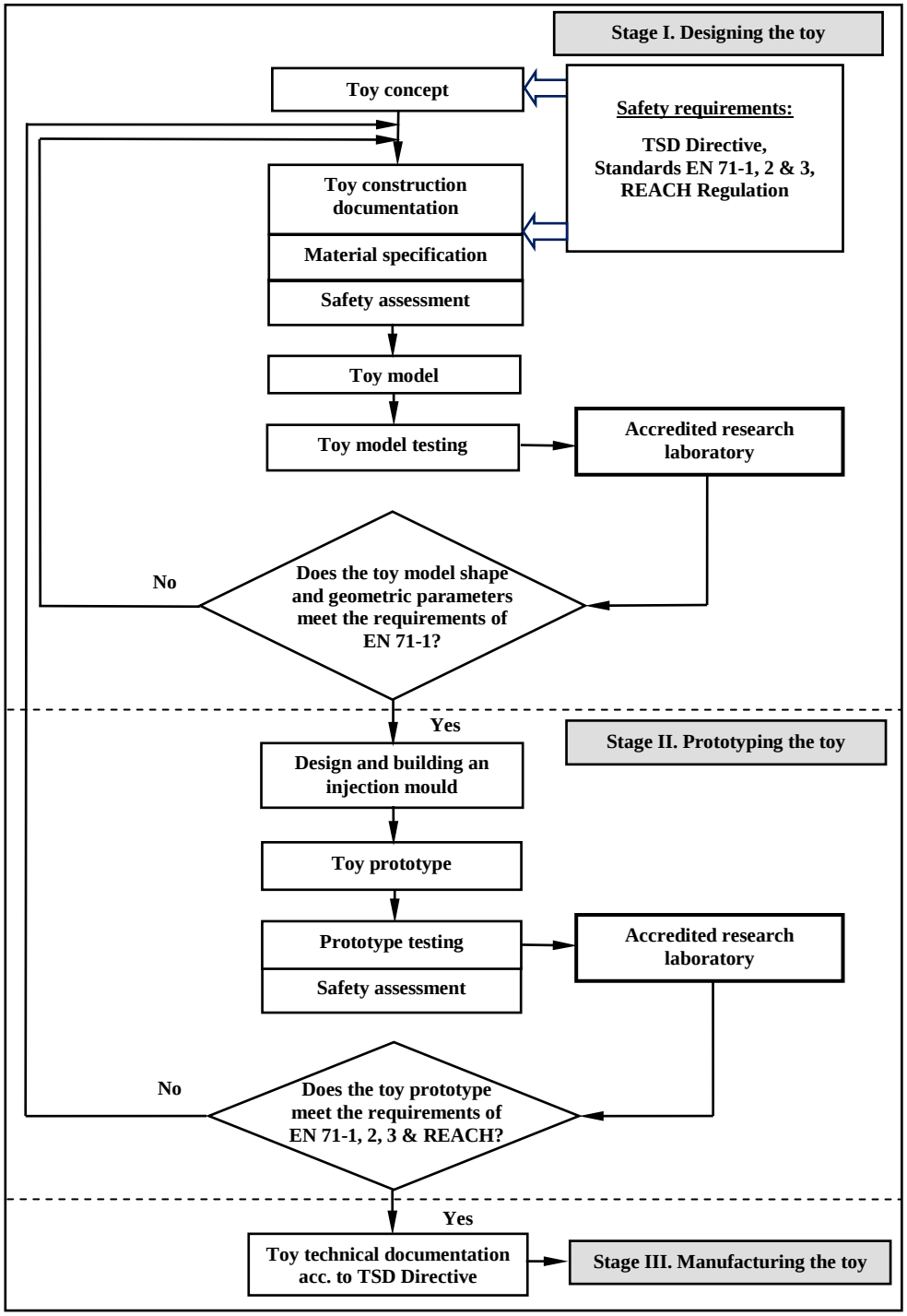

Fig. 1. Algorithm of plastic toy designing and prototyping stage [source: own study]

3.3. Manufacturing of a plastic toy (Stage III)

Process of a plastic toy manufacture starts with raw materials delivery, e.g. in the form of transparent granules of polypropylene, polyethylene, and polystyrene and a dye. Granules are usually delivered in bags placed on pallets.

Raw materials shall be subject to quality control in relation to their conformity with the material specification.

The quality control procedure shall include periodical raw materials testing in an accredited laboratory for migration of hazardous elements acc. to EN 71-3:1998/A1:2001/AC:2004 and hazardous substances content acc. to REACH Regulation. Negative result of chemical analyses may result in return of raw materials to the suppliers.

The raw materials tested are poured to properly marked storage containers. Plastic is transported by means of a pneumatic system, through a switcher, to the injection mould dosing unit. Individual raw materials transport routes are marked with relevant number, depending on type of the machine to which they are sent. Dosage of plastics is made simultaneously with dosage of dye. After mixing and heating the plastics and dye to the temperature of 200°C, plastic mass is injected into a mould. After cooling, the form is dropped into a container from which it is transported to the moulded pieces warehouse or it is further processed. During treatment, sprues and blurs on a moulded piece edges are removed.

After the treatment, moulded pieces are subject to technical control in relation to their conformity with the pattern. The reference pattern of a specific mould piece should be periodically checked on its compliance with technical parameters of the design documentation.

In the case of moulded pieces transported from the warehouse, they shall also be subject to control procedures due to the possibility of their deformation during storage. Moulded pieces not compliant with the pattern are reground and then the material returns to the technological process.

After the quality control, moulded pieces are sent to the assembly line, where other components of toys also come (e.g. metal axes, wheels, labels) and a complete toy is assembled, e.g. a plastic car.

The final form of a toy shall be subject to technical control which verifies its conformity with the construction documentation.

The technical control procedure shall include periodical inspection of manufactured toy samples in an accredited laboratory. Scope of the test pertains to the assessment of compliance with the requirements of TSD Directive and EN 71-1:2011.

Controlled toys, after packing and labeling, including placement of a CE mark and accompanied with the information about name and address of the manufacturer and distributor may, with the manufacturer’s CE declaration of conformity, be marketed.

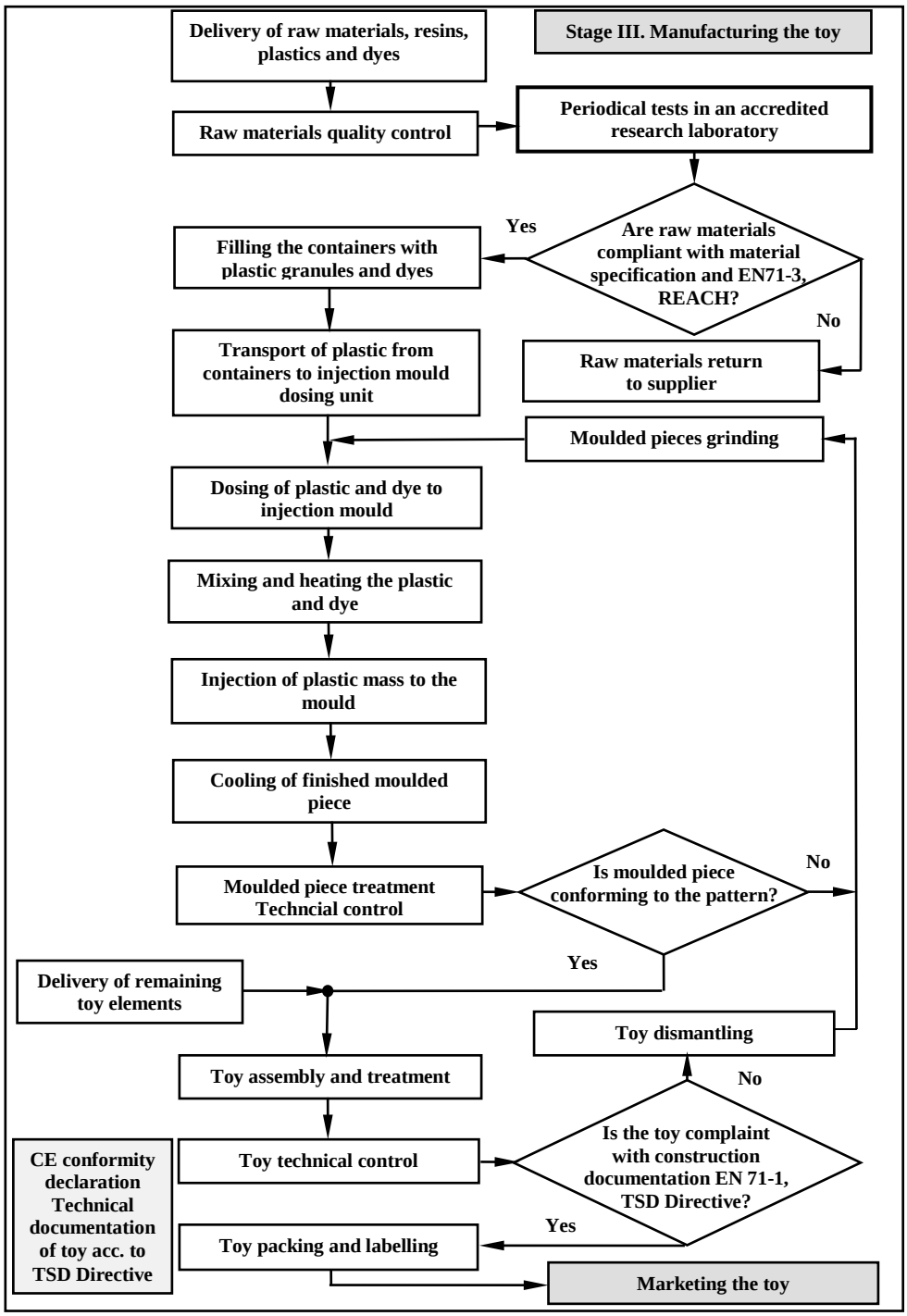

Fig. 2. Algorithm of plastic toy manufacture stage
[source: own study]

4. Summary

Toys, as the products intended for children must meet the safety requirements specified in the TSD Directive, harmonised standards and other legal acts.

Hazards related to the use of toys often result from improper design parameters, function, intended use and manner of use, and also poor quality of manufacture and materials applied which contain chemical substances toxic to humans and environment.

Toys design and manufacture process is hence especially important and should include actions mentioned as mandatory in the TSD Directive.

A significant element of the conducted actions shall be tests made in the laboratories accredited to perform tests pertaining to safety of toys. The tests constitute a basic tool in the manufactured toys quality control process, in relation to their use parameters and raw materials applied.

The actions presented in the paper should be realized according to the documented procedures implemented by the company. The suggested procedures given on the example of plastic toy designing, prototyping and manufacture process may be the basis for their development.

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