

Research on the Chemical Hazard Risk of Toys Exported to EU from China Based on the Analysis of the EU “Safety Gate” Alerts Cases

Weiqliang Huo , Xiaoting Chen, Han Fang, Haijun Guan, Qinglan Li, Minyi Huang

Guangzhou Customs Technology Center, Guangzhou, China

Correspondence to: Weiqliang Huo, huowq@iqtcnet.cn

Keywords: Toy Export, Safety Gate, Technical Trade Measures

Received: March 10, 2023

Accepted: April 23, 2023

Published: April 26, 2023

Copyright © 2023 by author(s) and Scientific Research Publishing Inc.

This work is licensed under the Creative Commons Attribution International License (CC BY 4.0).

<http://creativecommons.org/licenses/by/4.0/>



Open Access

ABSTRACT

Based on the analysis of the 2544 alert cases from “Safety Gate” (the EU rapid alert system for dangerous non-food products) of toys exported to the EU market from China in the past five years (2017-2021), this study focuses on the chemical hazards as the key research object, investigates and identifies categories of toy products and related chemicals with high notification rate. The research results have shown that the most seriously and frequently alerted toy products due to chemical hazards from China exported to the EU are plastic dolls, slimes, rubber toy balloons, toy guns and squeezable toys, while the high failure rate of chemicals in sequence are phthalates, boron element, *N*-Nitrosamines and *N*-Nitrosatable substances, and bis(2-(dimethylamino)ethyl) ether. This study aims to improve the efficiency of inspection and test of export toys, and provide decision-making references for Chinese toy export enterprises to respond to EU technical trade measures.

1. CHEMICAL HAZARDS

China is the largest producer and exporter of toys in the world. According to customs statistics, in 2021, China’s toy exports reached \$46.122 billion, an increase of 37.72% year-on-year, accounting for 70% of the global sales market. Among them, the EU region (including the UK) is the second largest export market for toys in China. In 2020, China exported \$7.241 billion of toys to the EU, accounting for 21.63% of China’s total toy exports (\$33.483 billion) [1] (as shown in [Figure 1](#)). However, at the same time, due to the increasingly stringent technical threshold of the EU, China’s toy exports to Europe continue to notify the high level of non-conformity, especially the standards involving chemical substance limits and regulatory updates more frequently. China’s relevant toy export enterprises have encountered serious trade barriers [2]. In this paper, the EU non-food hazardous products rapid warning system—safety gate (hereinafter referred to as “safety gate”) in the past five years (2017-2021) on China’s toy notification data to

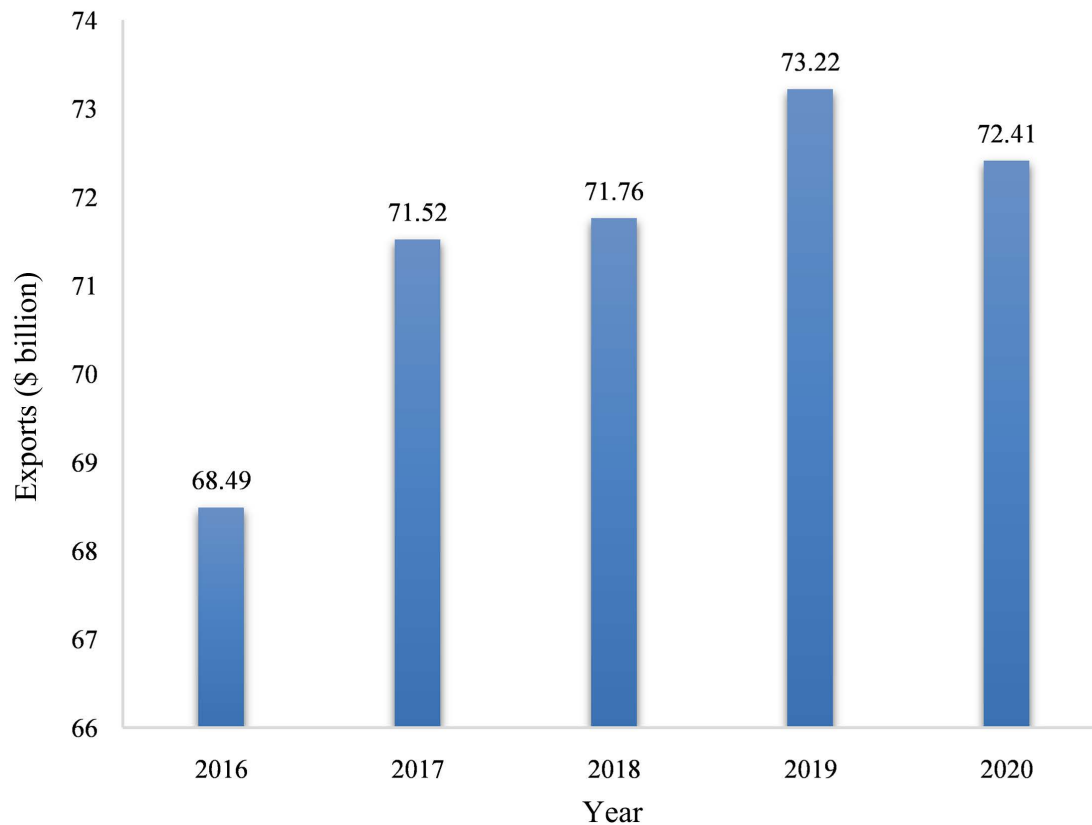


Figure 1. China's toy exports to EU market from 2016 to 2020.

Europe statistical analysis [3], combined with some relevant cases, the type of chemical hazards as the object of analysis, analysis and screening of toys with high chemical hazard risk Product categories and related chemical substances, and the sampling and inspection of export toys and enterprises to respond to the EU technical trade measures to put forward relevant recommendations.

2. EU "SAFETY GATE" ON CHINA'S TOY PRODUCTS CHEMICAL HAZARD TYPE NOTIFICATION ANALYSIS

During the period from 2017 to 2021, the EU "safety gate" system notified China's unqualified toys were 569 cases, 590 cases, 566 cases, 474 cases, 345 cases, respectively, accounting for 89.47%, 83.33%, 86.28%, 78.22%, 80.80% of the total number of toys notified by the EU. 80.80% of the total number of toys notified to the European Union, ranking first in all toy countries.

The risk of chemical hazards of toys refers to toys containing certain specific chemical substances in amounts exceeding the limits set by EU directives or standards, and there is a risk of indirect injury to children when they play with them. In the above-mentioned notification cases, a total of 1327 cases of chemical hazard risk type notification, accounting for 52.16%, that is, an average of every two cases of notification contains a case of chemical hazard risk notification, in the first of the various hazard risk factors (as shown in Table 1). The top five hazard types also include asphyxiation (43.80%), injury (20.09%), electric shock (16.47%) and fire (6.76%). Note: A product notification may contain multiple hazard risk types.

The above notification cases on the one hand reflect the harsh technical barriers to chemical safety of toys in the EU, to the EU Toy Safety Directive (2009/48/EC) and toy standards, for example, the EU in the past three years (2019-2021) proposed to amend the relevant chemical substances or limit amendments to change the directive reached 15 times [4] (as shown in Table 2). On the other hand, the above notification cases also reflect that China's toy industry in the control of raw and auxiliary materials, design and

Table 1. Statistics of cases of toy safety risk types imported from China alerted by EU in 2017-2021.

Hazard risk factors	Notification volume/example by year					Total/ Example	Percentage of China's total toy notification %
	2021	2020	2019	2018	2017		
Chemistry	137	209	271	391	319	1327	52.16
Asphyxiation	137	202	212	282	281	1114	43.79
Injury	37	70	70	158	176	511	20.09
Electric Shock	0	0	2	205	212	419	16.47
Fire	0	1	1	101	69	172	6.76
Burn	15	5	14	58	56	148	5.82
Strangle	12	21	21	33	41	128	5.03
Difficult breathing	20	38	14	19	28	119	4.68
Environment	22	3	3	30	34	92	3.62
Hearing lost	7	8	15	14	31	75	2.95
Visual impairment	2	5	6	26	14	53	2.08
Cut	5	4	2	13	22	46	1.81
Microorganisms	1	5	5	6	8	25	0.98
Drown	0	0	0	3	4	7	0.28
Others	6	2	2	6	7	23	0.90

Table 2. Mainly revised directives/regulations on toy safety issued by EU from 2019 to 2021.

No.	Release Date	Directive No.	Revision
1	2019-06-11	(EU)2019/957	Revision of REACH Appendix XVII restrictions on (3,3,4,4,5,5,6,6,7,7,8,8,8-Tridecafluorooctyl) silsestradiols and TDFAs, which shall not be placed on the market for supply to the public in spray products at concentrations equal to or greater than 2 ppb weights, alone or in any combination, after January 2, 2021
2	2019-10-15	(EU)2019/1728	Update the harmonized standards referenced in the Toy Safety Directive 2009/48/EC to make EN 71-3: 2019 the harmonized standard for toy safety and EN 71-3: 2013 + A3: 2018 to be withdrawn on April 15, 2020

Continued

3	2019-11-18	(EU)2019/1922	<p>In the Directive 2009/48/EC, tighten the requirements of the migration limit of aluminum in toy materials, adjusted limits: dry, fragile, powder-like or flexible toy materials: 2250 mg/kg; liquid or viscous toy materials: 560 mg/kg; scrapable toy materials: 28,130 mg/kg</p> <p>New formaldehyde limit value requirements for specific materials in toys used by children under 36 months of age or other toys that are attempted to be put in the mouth.</p>
4	2019-11-19	(EU)2019/1929	<p>In polymer toy materials: 1.5 mg/l (migration limit); in resin-bonded wood toy materials: 0.1 ml/m³ (emission limit); in textile toy materials: 30 mg/kg (content limit); in leather toy materials: 30 mg/kg (content limit); in paper toy materials: 30 mg/kg (limit); in water-based toy materials: 10 mg/kg (content limit value)</p>
5	2020-02-06	(EU)2020/171	<p>Revision of REACH Appendix XIV, 10 new substances included:</p> <p>1,2-benzenedicarboxylic acid di-hexyl ester, branched and straight chain, CAS No. 68515-50-4; di-hexyl phthalate, CAS No. 84-75-3; 1,2-benzenedicarboxylic acid di-C6-10-alkyl ester; 1,2-benzenedicarboxylic acid, mixed decyl, hexyl and octyl di-ester ≥ 0.3% Dihexyl phthalate, CAS No. 68515-51-5; 68648-93-1; Alkyl phosphate, CAS No. 25155-23-1, etc.</p> <p>Revision of REACH Appendix XVII, mainly new restrictions on diisocyanate chemicals:</p>
6	2020-08-03	(EU)2020/1149	<p>1) after August 24, 2023, shall not be used as a substance alone, as a component of other substances or in mixtures for industrial and professional use unless: diisocyanate alone and in combination in concentrations of less than 0.1% by weight, or</p> <p>2) the employer or self-employed person ensures that the industrial or professional user has successfully completed training on the safe use of diisocyanate before using the substance or mixture, etc.</p>
7	2020-12-11	(EU)2020/2088	<p>In Directive 2009/48/EC point 11 of Part III of Annex II,</p> <p>1) Citronellol/citronellol (CAS No. 106-22-9), adding two CAS numbers: 1117-61-9 and 7540-51-4;</p> <p>2) 60 new allergenic aromatic substances, the total number of entries in this list after the revision is 72.</p>

Continued

8	2020-12-11	(EU)2020/2089	<p>In Directive 2009/48/EC point 11 of Part III of Annex II, 1) the following three allergenic aromatic substances were added to the “Prohibited List” (56) Atranol (2,6-Dihydroxy-4-methyl-benzaldehyde). CAS No.: 526-37-4; (57) Chloroatranol (3-Chloro-2,6-Dihydroxy-4-methyl-benzaldehyde), CAS No.: 57074-21-2; (58) Methyl heptine carbonate, CAS No.: 111-12-6. 55 to 58 items. 2) Among the substances to be marked out, Methyl heptine carbonate (CAS 111-12-6) of No.10 was deleted.</p>
9	2020-12-16	(EU)2020/2096	<p>Amendment of REACH Annex XVII concerning carcinogenic, mutagenic or reproductive toxicant (CMR) substances, devices covered by Regulation (EU) 2017/745 of the European Parliament and of the Council, test methods for persistent organic pollutants, certain liquid substances or mixtures, nonylphenols and azo colorants</p>
10	2020-12-14	(EU)2020/2081	<p>Revision of REACH Appendix XVII on the restrictions of substances in tattoo inks or permanent cosmetics</p>
11	2021-06-03	(EU)2021/903	<p>Increase aniline requirements for toys used by children under 36 months of age or other toys intended to be placed in the mouth</p>
12	2021-07-17	(EU)2021/979	<p>Revise REACH Appendices VII to XI, which update part of Appendix VII on the standard information requirements for substances manufactured or imported in quantities of 1 ton or more; amend part of Appendix VIII on the standard information requirements for substances manufactured or imported in quantities of 10 tons or more; update part of Appendix IX on the toxicological information in the standard information requirements for substances manufactured or imported in quantities of 100 tons or more; update part of Appendix X on the standard information requirements for substances manufactured or imported in quantities of 1000 tons or more; amend part of Appendix XI on the general rules for the standard test regimes specified in VII to Annex X</p>
13	2021-11-19	(EU)2021/2030	<p>New REACH Appendix XVII on N,N-dimethylformamide restrictions</p>

Continued

14	2021-11-23	(EU)2021/2045	Update REACH Appendix XIV table entries 4 to 7 for plasticizers such as DEHP (listed in Article 57 for reasons) and the transition period
15	2021-12-13	(EU)2021/2204	Revision of REACH Appendix XVII, concerning carcinogenic, mutagenic or reproductive toxicity substances (CMR), adding a variety of substances to Appendices 2, 4 and 6

manufacturing and other aspects of the industry still exists a large short board [5]. At the same time, due to the lack of professional technical support and access to information on technical trade measures, the ability of domestic enterprises to deal with technical barriers is very lacking, which led to the continued high notification of China's toy exports to Europe.

3. HIGH CHEMICAL HAZARD RISK TOY PRODUCT TYPES AND THEIR CHEMICAL ANALYSIS

According to the 2017-2021 chemical hazard risk type case analysis found that the most serious notification of toy product categories (the top five): plastic dolls, crystal clay, rubber toys balloons, toy guns, and squeezable toys, the number of notifications were 471 cases, 115 cases, 25 cases, 24 cases and 21 cases, respectively, accounting for 35.49%, 8.67%, 1.88%, 1.81% and 1.58% of chemical risk type cases. 1.88%, 1.81% and 1.58% (as shown in [Figure 2](#)).

3.1. Plastic Dolls and Toy Guns

Plastic doll's head, hands, torso and other 95% parts are made of plastic (PVC, PET, etc.), in order to enhance its softness and increase the plasticity of polymer resin, some companies usually add phthalate plasticizers (hereinafter referred to as plasticizers) in the product. However, plasticizers are highly migratory and can enter the body through the respiratory tract, digestive tract and skin, and can damage the reproductive system and health of children in the case of exceeding the limit value [6]. In 471 cases of plastic doll notification cases, there are 469 cases containing one or more plasticizer content that exceeds the limit value. Among them, di(2-ethylhexyl) phthalate (DEHP) exceeded the limit in the most serious cases, accounting for more than 95% of the notified amount (as shown in [Table 3](#)).

Take the plastic doll with notification number A12/01629/21 as an example (as shown in [Figure 3](#)). The main raw material of this product is PVC; its head and legs were detected to contain plasticizers DEHP, DINP, DBP, DIBP and SCCPs (measured values of 25.2%, 1.4%, 4.3%, 0.17% and 0.24% by weight, respectively) exceeding the limit values, which do not comply with the EU REACH regulation and POPs regulation. After the notification was issued, the importer withdrew the products from the EU market and removed them from the shelves.

Toy guns are mainly raw materials for plastic, there are also plasticizer safety risks. In 24 cases of toy gun notification cases, there are 23 cases containing one or more plasticizer content that exceeds the limit value (as shown in [Table 4](#)).

Taking the notification number A12/00122/21 as an example (shown in [Figure 4](#)), the projectile head (suction cup) of the toy gun set was found to contain plasticizers DEHP and DBP (measured at 6.6% and 10% by weight, respectively) that exceeded the limit values and did not meet the requirements of the EU REACH regulation. After the notification was issued, the Hungarian government ordered that the product be banned from the country.

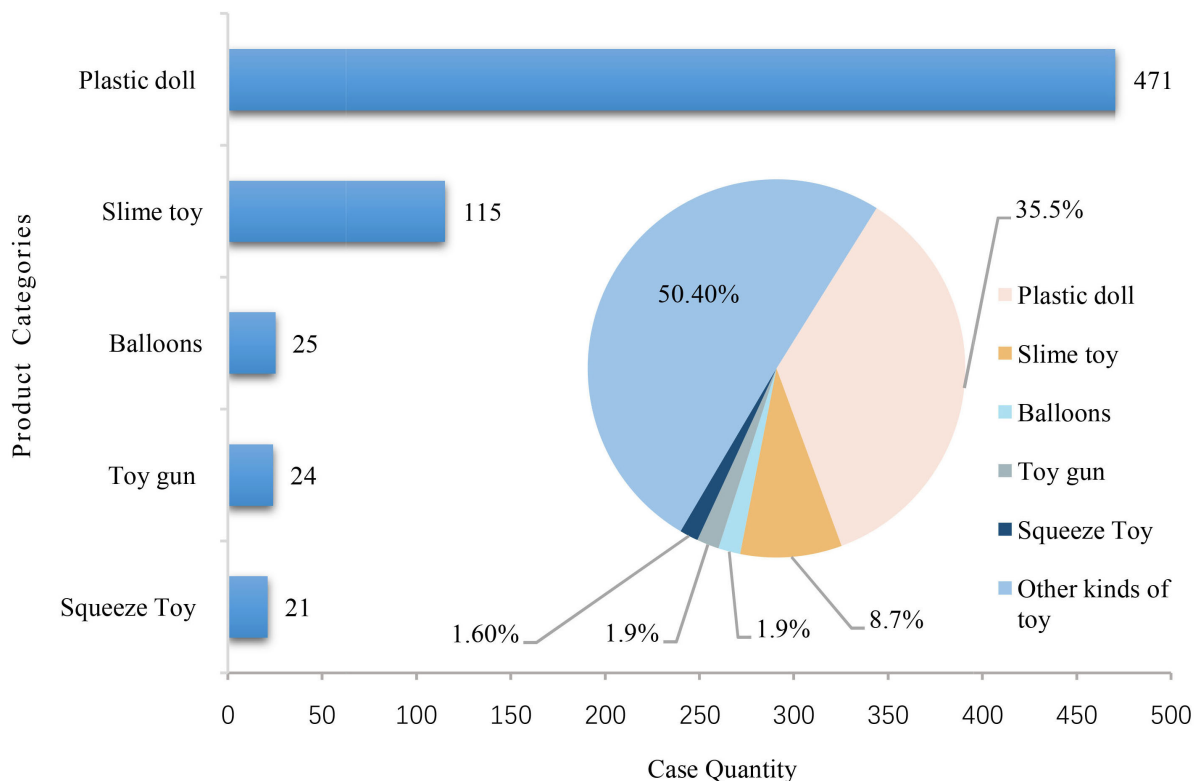


Figure 2. EU alerted the toys (chemical hazard types) products imported from China in 2017-2021.



Figure 3. The plastic doll with accessories in alert No. A12/01629/21.

Table 3. Prohibited/restricted chemical substances in plastic dolls from China exported to EU in 2017-2021.

No.	Chemical substances with excessive amounts	Case quantity
1	Plasticizers (DEHP, DBP, DINP, DIBP, etc.)	469
2	Heavy metals (lead, cadmium)	1
3	Short-chained chlorinated paraffins (SCCPs)	2

Note: The above notified cases of a product may contain one or more ultra-limited chemical substances.



Figure 4. The toy guns set in alert No. A12/00122/21.

Table 4. Prohibited/restricted chemical substances in toy guns from China exported to EU in 2017-2021.

No.	Chemical substances with excessive amounts	Case quantity
1	Plasticizers (DEHP, DBP, DINP)	23
2	Coin cell batteries (risk of battery fluid leakage)	1

3.2. Crystal Clay

Crystal clay is a plastic and repeatedly shaped jelly-like toy, which is very popular among younger children and elementary school students because of its colorless and malleable raw materials [7]. The boron element in borax, the main raw material in crystal slime, is toxic to many human organs, endangers the action of digestive tract enzymes, reduces appetite, inhibits the absorption of various nutrients, and thus accelerates fat decomposition and weight loss [8]. Among the 115 cases of crystal clay notification cases, there are 109 cases of excessive content of boron elements (as shown in Table 5), which do not comply with the EU Toy Safety Directive, EN 71-3 and REACH regulations.

Take the crystal slime with notification number A12/00847/20 as an example (Figure 5). The product was found to contain boron (measured value: 1700 mg/kg), which did not meet the requirements of the EU Toy Safety Directive and its harmonized standard EN 71-3. After the notification was issued, the Finnish government ordered a ban on the sale of the product in the country and a mandatory withdrawal from the market.

3.3. Rubber Toy Balloons

In 25 cases of rubber toy balloon notification cases, there are 16 cases of N-nitrosamines and nitroso compounds that exceed the limit value (as shown in Table 6). In the production of rubber toy balloons vulcanization process will be used in the vulcanization accelerator, containing secondary amine group of the vulcanization accelerator will decompose to produce secondary amines, and with the atmosphere or with the nitrogen oxides in the compound to generate stable N-nitrosamines. Therefore, the raw materials, compatibility agents, vulcanization agents and other factors of the manufacturing process may produce or leave residual N-nitrosamines in the manufacturing process if they are not selected properly [9]. This substance is a genotoxic carcinogen [10], which will pose a serious risk to health safety when inhaled or ingested by children (toy balloons are usually inflated directly through the mouth) into the body.

Take the rubber balloon toy with notification number A12/00631/21 as an example (as shown in Figure 6). The product was detected to contain dimethylnitrosamine (NDEA), N-nitrosomorpholine (NMOR) and N-nitrosodiethanolamine (NDELA) (measured values: 0.08 mg/kg, 0.060 mg/kg and 0.050 mg/kg



Figure 5. The toy slime in alert No. A12/00847/20.



Figure 6. The balloons in alert No. A12/00631/21.

Table 5. Prohibited/restricted chemical substances in slimes from China exported to EU in 2017-2021.

No.	Chemical substances with excessive amounts	Number of cases
1	Boron element	109
2	Heavy metals (lead, barium)	4
3	Preservatives (MI, CMI)	2
4	N-Nitrosodiethanolamine (NEDLA)	1

Note: The above notified cases of a product may contain one or more ultra-limited chemical substances.

Table 6. Prohibited/restricted chemical substances in rubber toy balloons from China exported to EU in 2017-2021.

No.	Chemical substances with excessive amounts	Number of cases
1	N-nitrosamines and nitroso compounds	16
2	Coin cell batteries (risk of battery fluid leakage)	7
3	Plasticizers (DINP)	1

Note: The above notified cases of a product may contain one or more ultra-limited chemical substances.

respectively) in excess of the limit values, which did not meet the requirements of the EU Toy Safety Directive and its harmonized standard EN 71-12. After the notification was issued, the distributors of the product took off the shelves and recalled the relevant products in the EU market.

3.4. Squeezable Toys

Squeezable toys have a certain degree of stress relief effect, by achieving a sense of control of the squeeze, drop, knead, rotate, etc., children's attention to stress is diverted, gaining a temporary sense of control. However, in 21 cases of squeezable toys notify the case, involving up to six kinds of harmful chemical risks. Among them, 10 case products were detected with bis(N,N-dimethylaminoethyl) ether exceeding the limit value (as shown in Table 7). Bis(N,N-dimethylaminoethyl) ether is a commonly used polyurethane catalyst, and cyclohexanone, N,N-dimethylformamide and triethylenediamine are common industrial organic solvents, mainly used in the production of flexible foam products [11]. Children are prone to eye and mucous membrane irritation when exposed to toys with residues of these substances.

Take the squeezable toy with notification number A12/1083/19 as an example (as shown in Figure 7). The product was detected to contain N,N-dimethylformamide, bis(N,N-dimethylaminoethyl) ether, triethylenediamine and cyclohexanone respectively, which did not meet the requirements of the EU Toy Safety Directive. After the notification was issued, the importer withdrew the products from the EU market and removed them from the shelves.



Figure 7. The squeezable toy in alert No. A12/1083/19.

Table 7. Prohibited/restricted chemical substances in squeezable toys from China exported to EU in 2017-2021.

No.	Chemical substances with excessive amounts	Number of cases
1	Bis(N,N-dimethylaminoethyl) ether	10
2	Cyclohexanone	9
3	N,N-dimethylformamide	8
4	Triethylene diamine	7
5	Plasticizers (DINP)	6
6	Coin cell batteries (risk of battery fluid leakage)	4

Note: The above-mentioned notification cases in a product may contain one or more ultra-limited chemical substances.

4. SUMMARY

From 2017-2021, EU “safety gate” notification toy product data analysis can be seen, the risk of chemical hazards for China’s exports to Europe products notified the highest rate of risk types. Among them, the most serious notification of the top five types of toys—plastic dolls, crystal clay, rubber toys balloons, toy guns and squeezable (soft) toys—contain a high failure rate of prohibited/restricted chemical substances which are plasticizers, boron, N-nitrosamines and nitroso compounds, bis(N,N-dimethylaminoethyl) ether. It is recommended that in the export of toys sampling inspection and product risk monitoring, the above products and chemical substances should be considered as key monitoring objects. This is conducive to improving the detection rate of unqualified products, thereby improving the accuracy of supervision and enforcement, controlling and enhancing the quality of China’s export toys.

On the other hand, due to the EU’s strict control of chemical and hazardous substances, China’s toy manufacturers exported to Europe should enhance product compliance awareness. Those especially involved in the production of the aforementioned products should strengthen control over key manufacturing processes, as well as enhance the inspection of raw and auxiliary materials during incoming and finished product stages. In order to improve the ability to deal with technical trade measures and reduce the economic loss caused by the notification of recalls, manufacturers should look for suitable alternative technologies, such as the use of citric acid esters, epoxy acid esters and other safe and environmentally friendly plasticizers [12].

CONFLICTS OF INTEREST

The authors declare no conflicts of interest regarding the publication of this paper.

REFERENCES

1. General Administration of Customs. China. <http://stats.customs.gov.cn>
2. Wen, F. (2021) Research on Legislative Trend and Future Development Direction of EU Toy Product Technical Regulations. *Standard Science*, No. 2, 41-48.
3. Europenn Commission (2022) Safety Gate: The EU Rapid Alert System for Dangerous Non-Food Products. <https://ec.europa.eu/safety-gate-alerts/screen/web>
4. European Commission (2022) EUR-LEX. <https://eur-lex.europa.eu/>
5. Liu, H.-Z., Dong, L. and Wang, C. (2020) Toys Exported to Europe Frequently Hampered by Technical Barriers Highlighting the Shortcomings of China’s Industry. *China Customs*, No. 10, 88.
6. Wilkinson, C.F. and Lamb, J.C. (1999) The Potential Health Effects of Phthalate Esters in Children’s Toys: A Review and Risk Assessment. *Regulatory Toxicology and Pharmacology*, **30**, 140-155. <https://doi.org/10.1006/rtp.1999.1338>
7. Liu, C.-M., Zhang, P., Wu, X.-Y., *et al.* (2018) Quality and Safety Risk Monitoring Analysis of Slime. *China Quality Supervision*, No. 8, 52-54.
8. den Braver, M.W., Schakel, D.J., Hendriks, H.S., *et al.* (2021) Monitoring and Risk Assessment of Hazardous Chemicals in Toy-Slime and Putty in the Netherlands. *Regulatory Toxicology and Pharmacology*, **125**, Article ID: 105000. <https://doi.org/10.1016/j.yrtph.2021.105000>
9. Xie, Y.-P., Lan, H.-X., Li, H.-Y., *et al.* (2018) Risk Analysis of Harmful Substances in the Rubber Balloon. *Contemporary Chemical Industry*, **47**, 2309-2312.
10. Liu, Y.-H., Yuan, W.-F., Wang, Z.-J., *et al.* (2019) Determination of 15 Kinds of N-Nitrosamines Residues in Plastic Children’s Toys by GC-MS/MS. *Journal of Chinese Mass Spectrometry Society*, **40**, 549-557.
11. Li, X.-D., Yin, Y.-B., *et al.* (2017) Progress of Synthesis Process for PU Catalyst Bis(N,N-Dimethyl-aminoethyl)

Ether. *Plastics Additives*, No. 1, 13-17.

12. Wang, Y.-D., Li, L.-P., Cao, C.-H., *et al.* (2019) Environment-Friendly Plasticizer Design under Green Chemistry Principles. *Engineering Plastics Application*, **47**, 135-139.