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A CRITICAL REVIEW OF BRAZILIAN LEGISLATION ABOUT CHILD-RESISTANT PACKAGING

UMA REVISÃO CRÍTICA DA LEGISLAÇÃO BRASILEIRA ACERCA DE EMBALAGENS ESPECIAIS DE PROTEÇÃO À CRIANÇA

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Design, Ergonomics, Packaging

This article is a literature review regarding the Child Resistant Packaging (CRP), which presents the problems of intoxication, as well as the emergence of those packages. The article also discusses the Brazilian Bill No. 4841/94 compared with the current U.S. testing protocol, in order to make suggestions for improvement to the problems encountered.

Design, Ergonmia, Embalagens

Este artigo é uma revisão bibliográfica em relação às Embalagens Especiais de Proteção à Criança (EEPCs), que apresenta os problemas de intoxicação, bem como o surgimento dessas embalagens. O artigo também aborda o Projeto de Lei nº 4841/94 em comparação com o atual protocolo de teste americano, visando apresentar sugestões de melhoria para os problemas encontrados.

1. Introduction

Child-Resistant Packaging (CRP) became mandatory in the USA in 1970 by the fact that many accidents related to intoxication with children under five years were being reported.

Since then many studies have been conducted to investigate the usability of these packagings. The current American test protocol has 3 different tests: with senior adults, with young adults and with children under 5 years old.

However the CRPs are not mandatory in Brazil, but there is a Bill (No. 4841/94) which is under debate in Congress requiring the use of these packagings, but it was not yet approved.

The aim of this paper was to review the literature regarding poisoning problems, the emergence of CRPs and an assessment of the Brazilian Bill compared with the USA legislation, presenting suggestions for possible problems and unconformities encountered.

2. Poisoning Problems

Poisoning is one of the problems related to the use of packaging. According to SINITOX (Brazilian System of Toxic-Pharmacological Information) in 2003, all the 20,904 reported cases of poisoning in Brazil, a quarter was related to children under 5 y.o. (BOCHNER, 2005) and the United States recorded about one hundred million cases a year involving children of the same age (BEIRENS et al., 2006).

Latest data show that in Brazil, regarding the 23,123 cases of poisoning that occurred with children under 5 y.o., 36.14% are caused by drugs, 23.2% by household cleaning products and 8.63% by industrial chemicals (SINITOX, 2010). And, after falls, poisoning is the leading cause of accidents with children from 0 to 4 y.o. (OZANNE-SMITH, 2001).

According to Bochner (2005), in 2003, the main cases of human poisoning reported by CEATOX/SP (Toxicology Service Center of São Paulo) were medicines, poisonous animals and household cleaning products. Since medicines and household cleaning products are packaged and they go through a design project, this should be a factor that would

minimize such cases.

Warning on labels is a method which seeks to avoid accidents. According to Mont'Alvão (2002), the warning has to draw the user's attention; then the message must be understood and be persuasive for the user to believe the possible incidents that may occur; Finally, the message should motivate the user to obey it, causing him to conduct a proper behavior.

Therefore, for a warning reach its efficiency, it must (Mont'Alvão, 2002):

- Be present how and where it is needed;
- Be easy to see;
- Transmit only the necessary information;
- Be brief, understandable and attractive.

The warnings on labels are the most conventional method to prevent poisoning accidents in Brazil. However, these are hardly evident and are not sufficient to prevent accidents (DAHROUJ, 2009), because children under 5 years old cannot read or understand the messages (BRAZIL, 1999).

3. Child-Resistant Packagings (CRPs)

More than 35,000 children from 0 to 14 y.o. die every year as a result of unintentional poisoning. The use of CRPs for pharmaceutical and household products is one way to limit the children's access to toxic substances (GORDON et al. 2004).

CRPs have become mandatory in the United States in 1970 because of the large number of poisoning accidents with children under 5 y.o. For this reason, it was enacted the Poison Prevention Packaging Act.

As a result of many accidents, Poison Control Centers were established in the United States to provide specialized diagnostics and treatment for poisoning within their communities. The first center was created in Chicago in 1953. Four years later, the National Clearinghouse for Poison Control Centers was established in order to collect data in the centers and provide them therapeutic information and diagnosis regarding a infinity of household products that caused poisoning in children (CPSC, 2005).

After the Second World War, there was a proliferation of chemical products. With the help of the American Medical Association and industry, the Food and Drug Administration developed, which in 1960 became the Hazardous Substances Labeling Act which required certain products, identified as "dangerous substances", to carry on their labels specific warning information (CPSC, 2005).

Later, two studies were conducted involving safety packaging. The first occurred in the United States and had as object of study a packaging that contained drugs dispensed to the military, such packaging needed two movements to open: press and turn. The study showed that this type of packaging was more effective to prevent access by children, where only 27 cases of accidents were reported, rather than the previous number that was 210 cases. The second study was carried out in Canada, where a program to use CRPs with all prescribed pills and capsules was brought by pediatricians and pharmacists. The results were very similar to the United States. Through these studies which proved that CRPs were efficient, the Poison Prevention Packaging Act is then enacted in 1970 (CPSC, 2005).

4. Tabelas, gráficos e figuras

In the first 25 years after the establishment of the Poison Prevention Packaging Act, the tests conducted in the United States for approval or rejection of new CRPs were made only with children and adults from 18 to 45 y.o. Elderly and disabled people were excluded from the tests and as a result they ended up having a lot of difficulty to access the safety packaging sold in the market. Therefore, in the early 1990s, the Consumer Product Safety Commission (CPSC) recognized the need to develop a new test protocol in order to make the CRPs more effective to consumers. Then in 1995, the new American test protocol arose (BIX et al., 2009).

The new CPSC protocol is found in the US Code of Federal Regulations (CFR) Title 16, Parts 1700-1750 (CPSC 1995). This protocol describes three tests (with senior adults, young adults and children) that are used to verify the design of new CRPs.

The international standard ISO 8317:2004 "Child-Resistant Packaging. Requirements and testing procedures for reclosable packages", based on the US CPSC protocol, was reference to European standards and it is also followed by Japan, Argentina, Brazil, Paraguay, Uruguay and Venezuela (DE LA FUENTE, 2006). Table 1 shows

the current international standards with respect to CRPs. In the international standard requirements and test methods for CRPs are specified. Such methods provide effective measures for packaging that restrict access of children and ensure accessibility for adults and seniors (ISO 2003).

Country/Region	Local Organization	Standard for	
		Nonreclosable packaging	Reclosable packaging
International	International Standards Organization		ISO 8317:2004
European Union	European Committee for Standardization	CEN EN 14375:2003	CEN EN 8317:2004
United Kingdom	British Standards Institution	BS EN 14375:2003	BS EN ISO 8317:2004
Germany	Deutsches Institut für Normung	DIN EN 14375:2003	DIN EN ISO 8317:2004
Italy	Ente Nazionale Italiano di Unificazione	UNI EN 14375:2004	UNI EN ISO 8317:2005
Spain	Asociación Española de Normalización y Certificación	UNE EN 14375:2004	UNE EN ISO 8317:2005
Australia	Standards Australia	AS 1928:2001	AS 1928:2001
Japan	Japanese Standards Association		ISO 8317:2004
Argentina	Instituto Argentino de Normalización y Certificación		IRAM 3590
Canada	Canadian Standards Association	CSA Z76.2-00 (R2005)	CSA Z76.1-99 (R2003)
United States	Consumer Product Safety Commission	16 CFR 1700-1750	16 CFR 1700-1750

Table 1 - International standards and regulations for Child-Resistant Packaging (DE LA FUENTE, 2006, p. 17).

4.1. Senior-adult test

First, 100 subjects are selected between 50 and 70 y.o. who do not have any physical or mental disability. The age distribution occurs as follows:

- 25% of all subjects must be aged between 50 and 54 y.o., of which 68% to 72% must be female and 28% to 32% should be male;
- 25% of the subjects should be aged between 55 and 59 years, of which 70% are women and 30% must be men;
- 50% of subjects must be aged between 60 and 70 y.o., of which 70% are women and 30% must be men.

The subjects will receive only printed instructions on how to properly open and close the CRP, just as they appear on packaging sold in the market. Then it is given a period of 5 minutes for each subject (individually) attempt to open the CRP. If within this period the person cannot open or close the packaging, it will be granted 2 more minutes (1 minute for each new packaging) as a screening test, so that the individual attempt to open two new packagings that do not have child-protection system: a plastic snap closure and a continuous thread plastic closure. If the person can open and close the two packagings that do not have child-protection system, then it is granted a further 1 minute test with the CRP he/she had tried to open, otherwise the person is eliminated and replaced by another participant . This period of 1 final minute is also mandatory for individuals who managed to open the CRP in the first 5 minutes of testing.

The CRP passes the test if the effectiveness is at least 90%. Effectiveness is the percentage of adults who opened the CRP in the initial period of 5 minutes while appropriately opened and closed the same packaging during the final period of 1 minute. If the CRP has an effectiveness of 90% or more, it passes the test for senior adults and children will then be tested.

4.2. Young-adult test

In 1995, the CPSC concluded that the products packaged in metal containers with metal caps, or aerosols, would not be tested with senior adults, they would be tested only with young adults. The CPSC technical team believed the CRP that was easy to use by the elderly, including metal containers and aerosol, could be produced eventually. At that time, the Commission considered that packages with a metal body and a metal cap, probably would take a long time to develop and implement a child-protection system that is easily accessible to seniors. The test with young adults is to assess metallic packaging and aerosols (CPSC, 2001).

For this test it is selected 100 adults aged between 18 and 45 y.o. who do not have any physical or mental disability. Of this total, 30% must be male and 70% female. All participants (which are individually tested) have only a 5-minute period to open and (when possible) close the package. The subjects receive only printed instructions on how to open and close the CRP, just as they appear on packagings sold in the market. The number of adults who can open the packaging and then close properly (when possible) is the percentage of effectiveness of the CRP.

4.3. Child test

This test is done with a group of children between 42 and 51 months old. It is used 1 to 4 groups of

children according to the criterion of sequential test (Table 2).

Test Panel	Cumulative number of children	Package openings					
		First 5 minutes			Full 10 minutes		
		Pass	Continue	Fail	Pass	Continue	Fail
1	50	0-3	4-10	11+	0-5	6-14	15+
2	100	4-10	11-18	19+	6-15	16-24	25+
3	150	11-18	19-25	26+	16-25	26-34	35+
4	200	19-30		31+	26-40		41+

Table 2 - Test for resistance with children, sequential test panel (DE LA FUENTE, 2006, p. 17).

The age distribution for this test occurs as follows:

- 30% of children in each group must be 42 to 44 months old;
- 40% must be 45 to 48 months old;
- 30% must be 49 to 51 months old;
- The difference between the number of boys and the number of girls in each group cannot exceed 10% of the total number of children in that group.

Children are tested in pairs so that they feel more at ease. The test must occur in a well lit place and familiar to children, isolated from distractions. For each child is granted an initial period of 5 minutes to try to open the packaging. If the child cannot open the packaging after the expiration of the first 5 minutes, the person who is applying the test should demonstrate how to open the packaging and ask for children to try to open it again within a further 5-minute period. It is also said to the children that they can use their teeth if they want.

It is considered fail when certain percentage of children can access the product inside the packaging during one of the two periods of testing, the percentage is determined according to the Table 2, based on the results obtained from the groups of 50 children. For example, a CRP fails if more than 41 children (20%) of the 200 tested could access the content of the packaging. The total number of children can vary from 50 to 200, according to the number of packaging openings obtained in each test phase.

5. The Brazilian Bill

In Brazil, the CRPs are not mandatory, but there is a Bill (No. 4841/94) that determines the use of such packages for medicines and chemical products for domestic use which present a risk to health, however, this Bill is pending in Congress since its inception in 1994 until the present day. This Bill is based on other legislations, particularly the United States and Canada where poisoning levels were reduced by up to 35% from 1969 to 1972 (RAMOS et al., 2005).

The Bill No. 4841/94 (BRAZIL, 1999) defines CRP as every packaging designed with the intention to be difficult for a child under five years old to open it or remove a toxic or dangerous amount of the product contained therein and whereas it is not difficult to open by an adult. It also prohibits price change in the case of product distributed in common packaging and/or CRP.

Brazilian statistics regarding poisoning are incomplete compared to countries like the United States and Canada because, if one takes into account the large size of Brazil, the number of Toxicological Assistance Centers is small and frequently their operation is precarious, not producing regular statistical data. It is known that poisoning accidents involving children occur mostly indoors, because the conditions of poverty of the great majority of Brazilians makes difficult the existence of appropriate places where hazardous materials can be stored. Since these products are of daily use, it is common to be stored in easily accessible places and as a result, children's poisoning accidents cause considerable damage not only to the families but also to the health care system that is overburdened with cases that could be avoided (BRAZIL, 1999).

The specifications of effectiveness, in the Brazilian Bill, are given as follows:

- The CRP should have an opening resistance effectiveness per child not less than 85% without a demonstration and not less than 80%, after a demonstration of the proper way of opening. In the case of individual packaging the resistance effectiveness should be not less than 80%.
- The opening effectiveness for the use by adults should not be less than 90%.
- In the case of CRPs containing liquid, the flow should not exceed 2 ml of the content when the container, open and inverted, shaken or compressed at a time or when the container is activated

by any other way.

Therefore, the products defined to be distributed in CRPs in Brazil are (BRAZIL, 1999):

- All medicines for internal, topical or inhaled use in solid, powder or liquid;
- sodium or potassium hydroxide for domestic use, in dry form with granules, powders or flakes containing 10% or more by weight of sodium or potassium hydroxide not chemically neutralized and any other product containing 2% or more of sodium or potassium hydroxide not chemically neutralized;
- All domissanitary products and household products containing muriatic acid or ammonia;
- All household products containing 10% or more by weight of turpentine;
- Products for ignition or lighting containing 10% or more of petroleum distillates and a viscosity less than 100 Saybolt at 37,7ºC;
- Household products in liquid form containing 4% or more of methanol, except those in pressurized aerosol containers;
- All flammable products for domestic use.

5.1. Problems encountered

The lack of mandatory use of CRPs in Brazil generates a lack of standards in products, where the use of safety caps, is up to the producing company. And often when they are used, the opening instructions are in English, and so many Brazilian users do not understand the opening procedures. An example is the multivitamins packaging sold in Brazil with the push-down-and-turn cap, which opening instructions are illustrated in Figure 1.

Another very common product that is also sold in Brazil in CRP is the mouthwash, such packagings have safety caps depending on the brand and even within the same company it can be found packages of the same size that have the security system and others do not, however, these products do not fit into any of obligations cited in the Bill 4841/94, unlike the legislation of the United States that contains a specific topic for such products, determining that mouthwashes that contain 3 grams or more of alcohol must be distributed in CRPs (CPSC 2001).

Figure 1 - Opening instructions of a multivitamin sold in Brazil.

Other products that must be distributed in CRPs that are present in the United States legislation and are not contained in the Brazilian Bill are (CPSC, 2001):

- Products containing 10% or more by weight of sulfuric acid;
- Liquid products containing 10% of more by weight of ethylene glycol;
- Liquid home permanent wave neutralizers that contain more that 600 mg of sodium bromate or more than 50 mg of potassium bromate;
- Liquid glue removers containing more than 500 mg of acetonitrile;
- Liquid products containing more than 5% methacrylic acid on a weight to volume basis;
- Products containing more than 50 mg of elemental fluoride in a concentration that is more than 0.5% on a weight-to-volume basis for liquids and a weight-to-weight basis for solid products.

In addition, the Brazilian Bill only uses the tests with children and young adults to ascertain the effectiveness of CRPs, that is, it does not consider the elderly as a test group. It can be seen that Brazil follows the former American test protocol. This can be explained by the fact that the Brazilian Bill have emerged in 1994, while the reformulation of the

American test protocol occurred only in 1995. However, many changes have been made in the Brazilian Bill, and the introduction of a test with the elderly should have been considered.

Another unconformity found in the Brazilian Bill is the assertion about the CRPs, where it is said that such packages are simple devices. However, studies show that these devices become complex for many users.

Lane et al. (1971) conducted a study with 134 ambulatory patients aged between 22 to 87 y.o. divided into two groups: one group would be tested with a packaging without child-resistant cap and the other group would be tested with the palm-n'-turn cap. For this study, there was no significant difference between people who managed to open the CRP (87%) and people who managed to open the conventional packaging (95%). However, 44 people said they had difficulty to open the CRP and as a result, many of them put the package contents into another easier to open container.

In a telephone survey conducted in 1976 with 636 people in the city of Omaha (United States), it was asked some questions related to CRPs. The results show that 92% of families with children under 6 y.o. and 82% of childless families approve of the idea of CRPs; 92% of respondents under 30 y.o. and 75% of those over 60 also approved the idea. Eighty-nine percent of the families interviewed had CRPs at home. The difficulty of use or misuse of the packagings was 14% for subjects younger than 30 y.o. and 33% for those over 60 y.o. The consequences for the difficulty of use were: put the product into another container (41%), leave the child-resistant cap open (25%) and stop using the product (3%). Regarding the changes, 8% of the families with children, 17% of those without young children, 29% of individuals over 60 y.o. and 8% of those under 30 think the CRPs should be more difficult for children to open. While 9% of families with children and 3% of those without young children suggested that more products should be child proof (MCINTIRE et al., 1977).

Thien and Rogmans (1984) evaluated four types of CRPs: two were the push-and-turn type and two the squeeze-and-turn type. Subjects were divided into 5 groups by age: 24-41 months old, 42-51 months old, 18-45 years old, 60-75 years old and over 75 years old. The results show that the push-and-turn packaging with the smaller diameter cap, failed the test with the children, because 27% of the younger ones and 77% of the older ones managed to open the packaging, besides, this packaging lost its child-resistant property after some opening attempts. With the adults and the elderly, the effect of age was statistically significant for all packagings, however, the results suggest that none of the containers is accessible for senior adults.

Ward et al. (2010) observed the use of CRPs of different types: the turn-down-and-push, the squeeze-and-turn, and blisters, which is the order of the most difficult to easiest to open, with almost 50% frustrated opening attempts for the first two. The most common expressions that were recorded during the interface were "Quite a struggle", "There's not enough power in my hands", "It hurts my fingers", " No I can't do it". As a result of the difficulty of opening, the individuals: used scissors or other tool to cut the packaging, transferred the product to another container or have not closed the packaging. The authors also comment that 1 every 5 individuals older than 75 y.o. cannot open the press-and-turn packaging type.

Another study which used a press-and-turn CRP, was performed by Nayak (2002). Participated in this study 103 people from 60 to 80 y.o., 37 males and 66 females. Considering the total of participants, 80% were able to open the packaging without instructions within the first 3 minutes of test, 17% needed verbal instructions and managed to accomplish the task within 6 minutes. Verbal instructions were needed for 1% of participants; and the number of individuals who failed to open the CRP (even after the demonstration) was 2%. Grip strength was also collected, showing a significantly higher result of strength for men.

Bix and de la Fuente (2012) conducted a research with a group of individuals over 70 y.o. and with a group of people with cognitive, physical and perceptual disabilities. Eight CRPs were evaluated with different opening systems, which were rated by the participants on a scale from 0 to 4 (0 the most difficult to open and 4 the easiest one). Overall, the packagings received negative scores, but individuals with disabilities qualified packaging with fewer points than the elderly. Sentences like "I have a horrible time to get them off", "Old people should not get child-proof containers", "Once I get the package open, I never close it again" was also common among participants. In his masters, de la Fuente (2006) also included people with disabilities and seniors over 70 y.o. to perform the tests with different types of CRP, as they are often those users

who have more difficulties with the packaging.

Observing this inclusion of individuals with perceptual disabilities in some studies, there is another problem with the Brazilian Bill. To participate in the tests with the CRPs, individuals need to be "normal", that is, without evident physical or mental disability. However, a fact that has been noted by Bix et al. (2009) is that a wheelchair user has an evident physical disability, but at the same time he/she has the movements of the upper limbs and this person could participate in tests with CRPs.

6. Conclusions

For the Brazilian Bill achieve a good quality in its content, it is very important to consider the seven principles of Universal Design: Equitable Use, Flexibility in Use, Simple and Intuitive Use, Perceptible Information, Tolerance for Error, Low Physical Effort, Size and Space for Approach and Use; besides the ergonomic requirements as efficiency, safety and satisfaction.

With respect to CRPs, ergonomic mechanisms used in the opening ensure that the rest of the packaging remains undamaged during the process of opening and closing. And this has been a great challenge for packaging designers, as these products must prevent the access of children, while providing ease of use to other users, mostly the elderly. However, studies show that CRPs end up becoming an embarrassment to the elderly population, mainly because individuals over 70 y.o. are not considered in the new CRP test.

In response to the problems presented in this review, it is suggested that the Brazilian Bill obliges that the opening instructions of CRPs to be written in the vernacular language, and preferably with illustrations.

Furthermore, products containing substantial quantities of alcohol, as is the case of mouthwashes and alcoholic beverages, should be distributed in CRPs. However there would be a lot of complaint from consumers of alcohol, but the main objective is the safety of children.

Tests with elderly over 70 y.o. should replace the tests with adults, because that age group is the one that often uses large amounts of drugs, which will be required to be sold in CRPs, and it is also the age group that most shows difficulties in opening these packagings. However, the possibility of requesting drugs in normal packaging should also be mentioned in the Brazilian Bill, as it is in the legislation of the United States.

Finally, it is suggested that the criterion for exclusion of individuals in participating in the tests to be changed. As it has also been suggested by Bix et al. (2009), instead of excluding individuals with evident physical or mental disabilities, the ideal would be that all subjects that could pass the screening test with the packagings that are not child proof (see topic 4.1) should be considered able to participate in the test. Thus, wheelchair users, for example, could participate in the test.

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