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Aspects related to the sanitary control of stretch plastic films for domestic use

Aspectos relacionados ao controle sanitário de filmes plásticos esticáveis comercializados para uso doméstico

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Introduction: Flexible and stretchable plastic films are the most used in residences and commercial establishments. Plastic materials, when used in direct contact with food, under appropriate conditions of use, cannot transfer contaminating or toxic substances to food, in quantities that represent a risk to human health. **Objective:** Evaluate stretch films plastic for domestic use purchased in commercial establishments for domestic use, simulating contact with fatty foods and make an approach on aspects related to labelling, food safety, and environment. Method: The overall migration test was carried out by contacting plastic film with the fatty food simulant, 95% ethanol solution (v/v), for a period of 10 days at 40°C and for 24 hours at 20°C. The mean percentage values of mass loss of plastic films were determined after the migration test. Results: Stretch plastic films for domestic use in Brazil, analysed in contact with the fatty food simulant, showed overall migration values above the limit established in the legislation. Imported plastic films presented values of overall migration at adequate levels and were considered safe; only one film presented a value above the maximum tolerable limit in Mercosul. In PVC stretch films, the percentage results of mass loss were from 21.75 to 25.67 (%) and in LDPE plastic films, percentage results were less than 1.00 (%). Conclusions: Data obtained in this study show the need for continuous monitoring in the quality control of stretch films plastic when used in direct contact with fatty foods. Both information on the plasticizer used in the stretch plastic films on the commercial packaging label, and guidance actions on the use and application of stretch plastic films should be implemented and encouraged by agencies for sanitary and environmental control, and for consumer protection.

KEYWORDS: Plastic Films; Commercial Films of PVC; Stretch Plastic Films; Tests Migration and Food Safety

RESUMO

Introdução: Os filmes plásticos flexíveis e esticáveis são comercializados visando o uso doméstico em residências e estabelecimentos comerciais para embalar ou proteger diversos tipos de produtos alimentícios. Os materiais plásticos, quando utilizados em contato direto com alimentos, em condições de uso, não podem transferir substâncias contaminantes aos alimentos, em quantidades que representem risco à saúde humana. **Objetivo:** Avaliar os filmes plásticos esticáveis destinados ao uso doméstico, adquiridos em estabelecimentos comerciais, simulando contato com alimentos gordurosos e realizar uma abordagem referente aos aspectos relacionados aos dizeres de rotulagem, segurança alimentar e meio ambiente. **Método:** O ensaio de migração total foi realizado por meio do contato do filme plástico com o simulante de alimentos gordurosos, solução de etanol a 95% (v/v), por um período de 10 dias a 40°C e por 24 h a 20°C. Os valores médios percentuais de perda de massa dos filmes plásticos foram determinados após ensaio de migração. **Resultados:** Os filmes plásticos esticáveis comercializados no Brasil para uso doméstico, analisados em contato com o simulante de alimentos gordurosos, apresentaram valores de migração total superiores ao limite estabelecido na legislação. Os filmes de



origem estrangeira apresentaram valores de migração total em níveis adequados e considerados seguros, sendo que apenas uma marca estrangeira apresentou valores superiores ao limite estabelecido no Mercosul. Nos filmes esticáveis de PVC, os resultados percentuais de perda de massa foram de 21,75 a 25,67 (%) e nos filmes plásticos de PEBD, os resultados percentuais foram inferiores a 1,00 (%). **Conclusões:** Os dados obtidos neste estudo evidenciam a necessidade de um contínuo monitoramento no controle de qualidade dos filmes esticáveis comerciais quando utilizados em contato direto com alimentos gordurosos. Informações do aditivo plastificante incorporado ao filme plástico esticáveis deveriam ser implantadas e estimuladas, pelos órgãos de controle sanitário, meio ambiente e proteção do consumidor.

PALAVRAS-CHAVE: Filmes Plásticos; Filmes de PVC Comercial; Filmes Plásticos Esticáveis; Ensaios de Migração e Segurança Alimentar

INTRODUCTION

Stretch plastic films, made of polyvinyl chloride (PVC), are sold in small coils (rolls) for domestic use and larger coils for commercial establishments. In commerce, it is common to find these films being used to pack and protect foods such as: meat, fish, chicken, cheese, vegetables, grains, cereals, fruits, etc.

PVC films require the incorporation of plasticizing and stabilizing additives to acquire good properties of flexibility and malleability¹. Additives are substances intentionally added to the material formulation to achieve a physical or chemical effect during the manufacture of the plastic, being present in the composition of the final material or object². Currently, more than 300 different types of plasticizers are known, of which between 50 and 100 are in commercial use, of which 95% are produced for final use in PVC. It is important to emphasize that plasticizers are not just additives, such as fillers or pigments, but are important compounds that determine the physical properties of polymeric products3³. In Brazil, PVC stretch plastic films with plasticizers incorporated into the polymeric matrix are the most used in homes and commercial establishments to protect different types of food products4⁴. The PVC stretch film is considered practical for storing food, as it adheres well to other surfaces and is highly permeable to gases, which makes it a great option for the packaging of products in natura.

The most common plasticizing additives added to PVC are di(2-ethylhexyl) phthalate (DEHP) and bis(2-ethylhexyl) adipate (DEHA), also known as doctyl phthalate (DOP) and dioc-tyl adipate (DOA), respectively⁵. Phthalates are widely used in the industry for the manufacture of PVC films⁶, as they are the plasticizers that offer the best cost/benefit ratio for the production of plastic films with satisfactory conservation properties and practicality⁴. In Brazil, plasticizers such as DEHA and DEHP are used in a large number of commercial PVC stretch films, and greater awareness about the use of these plasticizers is needed⁶.

As research advances, it reveals the potential human health risk and effects of acute and chronic exposure in different populations exposed to phthalates^{7,8,910,11,12,13,14,15} and adipates^{16,17,18}. One of the main sources of human exposure to plasticizers DEHP and DEHA has been reported through food intake^{5,8,19,20}. In the case of DEHA, this is due to the migration of the plasticizer added to the PVC film, in particular for fatty foods such as cheese and meat²⁰. Thus, we can assume that, in the future, the use of synthetic plasticizers in PVC plastic films for direct contact with food will be increasingly restricted⁸.

There are some studies about plasticizers produced of natural sources from the epoxidation of vegetable oils or unsaturated esters, which appear as possible alternatives to synthetic plasticizers^{5,21,22,23,24,25,26,27,28}. However, any alternative free of synthetic plasticizers must be carefully evaluated based on toxicological studies, monitoring of long-term health effects, and their oper-ational effectiveness⁸.

In some developed countries, it is common to find stretchable plastic films for domestic use made with low-density polyethylene (LDPE) in commercial establishments. These films also show good flexibility and malleability properties, without the need to incorporate large amounts of plasticizing additives, which considerably reduces the risks of food and environmental exposure when compared to PVC films.

Currently, in Brazil, stretchable plastic films of different brands are sold, with different plasticizing compounds and other substances in the composition, including substances with antimicrobial action. Plastic films, when in direct contact with food, under the foreseeable conditions of use, must not yield to them undesirable, toxic, or contaminating substances that pose a risk to human health²⁹. The regulation, sanitary control, and inspection of products and services that involve risk to human health are the responsibility of public institutions that promote the protection of the population's health through sanitary control of the production and sale of products and services subject to sanitary surveillance.

Sanitary control of these packages is carried out through analyzes that, from a public health point of view, aim to determine the compatibility of the package with the food to be packaged, under the usual conditions of use, preparation, and storage. The potential for interaction of the packaging material and the level of indirect contamination of the packaged food product must be inspected by the Health Surveillance.

In Brazil, the Brazilian National Health Surveillance Agency (Anvisa) of the Ministry of Health is the body responsible for the legislation that regulates these products. These laws are



harmonized in the Southern Common Market (Mercosur) and establish the general criteria for the analysis of plastic packaging intended for contact with food. The conformity of plastic material for contact with food depends on the approval of Resolution No. 51, of November 26, 2010, by Anvisa, which provides "on migration of plastic materials, packaging and equipment intended to come into contact with food", also published by the Common Market Council, as in Mercosur Resolution No. 32, of June 15, 2010, on migration of materials, plastic packaging, and equipment intended to come into contact with food^{30,31}.

Resolution of the Common Market Group (GMC) No. 20, of November 13, 2021, establishes the overall migration limit (OML) of 10.0 mg/dm², modifying GMC Resolution No. 56, of December 15, 1992, which presents the general provisions for plastic packaging and equipment in contact with food^{2,32,33}. In Brazil, Resolution No. 589, of December 20, 2021, by Anvisa, establishes the overall migration limit (OML) of 10.0 mg/dm².

The objective of this work was to carry out the sanitary control of stretch plastic films intended for domestic use, purchased in commercial establishments, of different brands, sold in the national market and in other countries, simulating contact with fatty foods. After performing the sanitary control tests, an approach was carried out regarding aspects related to labeling, food safety and the environment.

METHOD

Fifteen samples of commercial flexible PVC and LDPE films from different brands were analyzed in triplicate, eight brands manufactured by Brazilian companies and seven imported brands.

In the domestic market, all eight brands declared on the packaging label that they marketed stretch plastic films produced with PVC. In the international market, of the seven brands analyzed, two sold polyethylene films declared on the label of the commercial packaging, one brand sold PVC films declared on the label, and the other four brands did not disclose information on the labels related to the type of plastic material used. Of the seven brands, five mentioned on the label not having the substance bisphenol A in the formulation.

In this work, samples of national commercial film brands were identified by NS and samples of imported commercial film brands by IS.

Analytical methodologies for migration tests are described in the technical regulations and standards: EN 1186-1 (2002): Materials and articles in contact with foodstuffs. Plastics - Part 1: Guide to the selection of conditions and test methods for overall migration; EN 1186-14 (2002): Materials and articles in contact with foodstuffs. Plastics - Part 14: Test methods for substitute tests for overall migration from plastics intended to come into contact with fatty foodstuffs using test media iso-octane and 95 % ethanol, and EN 1186-12 (2002): Materials *and articles in contact with foodstuffs. Plastics - Part 12: Test methods for overall migration at low temperatures*^{34,35,36}.

For the overall migration test, three sections of the plastic film measuring 10 cm x 10 cm were cut with the aid of a mold, making a total area of 1 dm on each face. Each section of the plastic film was completely submerged in the fatty food simulant (95% (v/v) ethanol solution), in a 250 mL glass beaker, covered and conditioned in an oven at 40°C for 10 days, simulating a condition of contact between the plastic film and the fatty food at room temperature for a period longer than 24 h. To simulate the contact of the plastic film with the fatty food for a period between 4 and 24 h, at a temperature of 5°C to 20°C, the migration tests were carried out in a climate-controlled room at 20°C for 24 $h^{30,31,34}$.

At the end of the contact period, the films were removed from the 95% (v/v) ethanol solution and the extracts obtained were evaporated in porcelain capsules identified for each sample and after total evaporation of the extracts, the migration residue was quantified and expressed in milligrams (mg). The overall migration result was calculated in mass of migrated residue (mg)/packaging material area (dm²), by averaging the results of the three sections of the plastic film tested and cut from each roll of PVC and LDPE commercial flexible film^{34,35,36}. The overall migration test was conducted in triplicate, with three analytical blanks and two porcelain capsules as controls, one accompanying the entire overall migration test and the other weighing the migration residue. In calculating the overall migration value, an area of 1 dm² was considered, as a surface in contact with food, as defined in item 9.2 of standard EN 1186-1 (2002)³⁴.

Due to the fact that the plastic films were acquired directly from retail, it was not possible to carry out the evaluation of the formulation of the PVC and LDPE films, against the positive lists published in the resolutions pertinent to the subject, also impairing the identification of substances that have restrictions such as limits of composition and specific migration.

The quantification limit (QL) of the method was calculated based on the standard deviation of the blank sample, with six independent replicates using the experimental conditions of the method. The overall migration results between different films from different brands were submitted to analysis of variance (ANOVA), at the 5% probability level.

The commercial packages that contain the stretch plastic films were visually analyzed, observing illustrative images, information, and words described on the packaging label.

RESULTS AND DISCUSSION

Evaluation of PVC stretch plastic films - national

To study the migration potential of chemical substances added to commercial PVC films, the eight samples were analyzed in contact with a fatty food simulant (95% (v/v) ethanol solution), under test conditions at a temperature of 20° C for 24 h, simulating contact conditions for a maximum of one day, and 40° C for 10 days, simulating contact conditions for more than one day, of the plastic film with the food product.



The results obtained showed that the samples of stretch films, in contact with the fatty food simulant, presented different migration values. The results of the overall migration of the films in contact with the simulant ethanol at 95% (v/v), conditioned at a temperature of 40°C for 10 days, showed mean values of the order of 18.2 to 33.9 mg/dm² and, when stored at a temperature of 20°C for 24 h, showed mean values of around 17.1 to 29.7 mg/dm².

Analyzing Figure 1, it is observed that the eight samples of commercial PVC stretch films, from different brands sold in the city of São Paulo, analyzed in contact with the simulant of fatty foods, presented mean overall migration values higher than the maximum tolerable limit established in the legislation of 10 mg/dm² ³³. Considering the reduction factor of the fatty food simulant, conventionally used to consider the greater extractive capacity of the 95% ethanol simulant (v/v), in relation to the extractive capacity of the food in question. The overall migration values may present results above and below the established limit, depending on the type of food that will be packaged in direct contact with the plastic film^{30,31}.

In this study, it was observed that contact for a period of 24 h between the plastic film and the fatty food simulant (95% ethanol) at a temperature of 20° C was sufficient for the migration of additives added to the PVC plastic film to occur.

Analyzing the migration potential between groups of films with migration values greater than the maximum tolerable limit in Mercosur legislation of 10.0 mg/dm² ³³, it was observed that there was a significant difference ($p \le 0.05$) in the overall migration values between the different brands of films due to the time and temperature of contact with the fatty food simulant (95% ethanol solution).

The migration process in stretch plastic films depends on the properties of the polymer, the nature, mass, amount of plasticizer, the production process, the homogeneity of the compound, and the contact area³⁷. The temperature, contact time, and the nature of the simulant are parameters that also influence the migration process³⁸.

Evaluation of stretch plastic films - Imported (foreign origin)

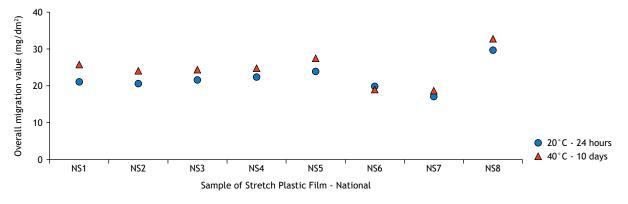
The potential for migration of chemical substances added to imported stretch films was studied by analyzing the seven samples in contact with a fatty food simulant (95% (v/v) ethanol solution), under test conditions at a temperature of 20°C for 24 h, simulating contact conditions of less than one day, and 40°C for 10 days, simulating contact conditions of more than one day, between the plastic film and the food product.

Analyzing Figure 2, it is observed that, of the seven samples of commercial stretchable films, from different foreign brands and acquired in different countries, when analyzed in contact with the simulant of fatty foods, conditioned at a temperature of 20° C for 24 h and at a temperature of 40° C for 10 days, only one film sample (IS1) showed average values of overall migration of the order of 21.1 mg/dm² for contact at 40° C for 10 days and 19.7 mg/dm² for contact 20° C for 24 h. The other six samples showed values lower than the quantification limit (QL) of the method of 2.0 mg/dm².

In general, low values of overall migration were observed in foreign films sold for residential use, demonstrating a low potential for migration of substances added to these films when in contact with the fatty food simulant. The IS1 film sample is described on the label as being produced in PVC resin, with epoxidized aliphatic polybasic acid ester plasticizers and vegetable oil stabilizer. In this study, the IS1 sample showed migration values above the maximum tolerable limit of 10.0 mg/dm^{2} ³³, following the same behavior as the national samples made of PVC.

The overall migration results of the imported film samples were not submitted to analysis of variance (ANOVA), at the 5% probability level, as the migration results of six different brands of plastic films showed results lower than the quantification limit of the method ($QL = 2.0 \text{ mg/dm}^2$), as shown in Figure 2.

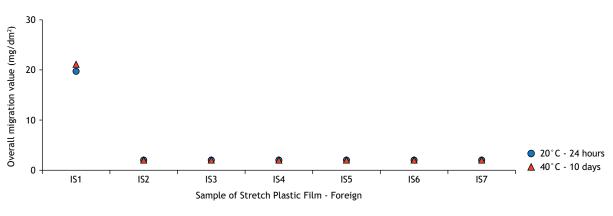
A greater susceptibility to the migration of substances incorporated into stretch plastic films produced and sold in Brazil was observed, when compared to the migration results of stretch plastic films produced and sold in foreign countries. The



Source: Elaborated by the authors, 2022.

Figure 1. Results of overall migration in samples of PVC stretch films sold in the city of São Paulo, in contact with the 95% ethanol simulant (v/v)





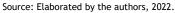


Figure 2. Results of overall migration in samples of PVC stretch films sold in different countries for domestic use, in contact with the 95% ethanol simulant (v/v)

occurrence of migration of substances incorporated into the plastic material can impair the quality of food products, which can directly interfere with the sensory characteristics, the shelf life of the product and contribute to toxicological symptoms after ingestion, as well as causing harmful effects in the medium or long term³⁹.

In stretch films made with PVC, a plastic material widely used in national brands, it is necessary to add plasticizing compounds in order to increase internal mobility and make the plastic more flexible and easier to process¹. Despite the high flexibility and versatility of PVC films, low molecular weight additives have a high mobility and can migrate from the plastic material³⁷. The use of flexible PVC plastic films in direct contact with fatty foods can contribute to the migration of plasticizers with known toxicological potential, which may cause harmful effects to human health in the long term. Despite the importance of seeking new technologies to obtain or improve some specific properties of the plastic resins used in the production of packaging and films, the permanent addition of substances with potential risk to human health has also been noticed. Synthetic plasticizers such as DEHA and DEHP continue to be used in a large number of flexible PVC films⁵.

The results obtained in this study demonstrate that, through the overall migration test, it was possible to verify the transfer potential of substances or additives incorporated in the plastic material to the fatty food simulant during the period of interaction between the packaging material and the food.

Calculation of the percentage of mass loss of stretch plastic films after overall migration test

The flexible and stretchable plastic films of national and imported origin were weighed before and after the overall migration test, aiming to quantify the mass of substances incorporated into the plastic film that could be transferred to the fatty food simulant (95% ethanol solution (v/v)), and evaluate the migration potential of the plastic film, after the overall migration test. The mass loss results of the national NS and

imported IS plastic films, after the overall migration test, are shown in the Table. In this overall migration test, the plastic films were conditioned at a temperature of 40° C for 10 days in contact with the fatty food simulant.

The percentage results of mass loss after the migration test were around 21.75 to 25.67 (%), in the national flexible films made of PVC, identified by NS1-NS8. In foreign plastic films, from different brands, the percentage results of mass loss ranged from 0.17 to 22.29 (%) for films identified by IS1 to IS7. In the foreign plastic films identified on the commercial package label as being LDPE, the mass loss after the overall migration test was less than 1% for each sample.

Analyzing Figure 3, the loss of mass and the potential for migration of substances or additives incorporated into the plastic films when in contact with the fatty food simulant is demonstrated. It is observed, in samples of national NS films made of PVC, that the addition of approximately 20-25% by mass of additive compounds is necessary. The presence of the low molecular weight plasticizer reduces the interactions between the PVC polymeric chains, increasing the free spaces and mobility of the additives and, subsequently, promoting their diffusion³⁹. In samples of imported IS films, it was observed that less than 1% by mass of the additive compounds had mobility in the polymeric matrix to migrate from the packaging system to the fatty food simulant.

The results obtained in this study demonstrate that, by calculating the mass loss of the stretch plastic films after the overall migration test, it was possible to verify the transfer potential of substances or additives incorporated into the plastic material to the fatty food simulant, during the period of interaction between the packaging material and the food.

Aspects related to information and words on commercial packaging labels, food safety, and the environment

The reading, observation, and interpretation of the information and the words described on the packaging labels allow



the consumer to know which the elements that make up each product. Visually analyzing the labels on the commercial packages of national stretch plastic films, marketed for domestic use, illustrations with images of food on some commercial

Table. Average values of the mass (g) after weighing the stretch plastic
films, of national origin NS and imported origin IS, before and after the
overall migration test.

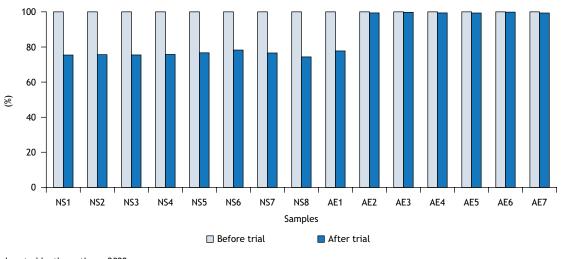
Plastic Film Sample	Mass Loss Calculation (g)			
	M1	M2	(M1-M2)	(%)
NS1	0.1125	0.0849	0.0276	24.57
NS2	0.1020	0.0771	0.0249	24.39
NS3	0.1052	0.0795	0.0258	24.54
NS4	0.1037	0.0785	0.0252	24.27
NS5	0.1259	0.0966	0.0293	23.30
NS6	0.0943	0.0738	0.0205	21.75
NS7	0.0850	0.0651	0.0199	23.45
NS8	0.1326	0.0985	0.0340	25.67
IS1	0.1027	0.0798	0.0229	22.29
IS2	0.1084	0.1077	0.0007	0.61
IS3	0.1016	0.1010	0.0006	0.29
IS4	0.1425	0.1415	0.0010	0.57
IS5	0.1156	0.1148	0.0008	0.62
IS6	0.1010	0.1005	0.0005	0.17
IS7	0.0949	0.0943	0.0006	0.63

Source: Elaborated by the authors, 2022.

M1: Average values of the mass in grams of the stretch plastic films before the full migration test; M2: Average mass values in grams of stretch plastic films after full migration test; (M1-M2): Calculation of mass loss in grams of plastic film after migration test; (%): Percentage of plastic film mass loss after migration test. packages of national films and information on some labels describing the film as being safe, protective, practical, and non-toxic were observed. One brand mentions the use of a vegetable plasticizer in the composition and another brand mentions the use of a vegetable antimicrobial. However, according to data obtained in this study, PVC stretch plastic films sold in Brazil, when in contact with fatty foods, have a high potential for migration of substances incorporated into the polymeric matrix. At this point, it is important to comment that the Brazilian consumer is purchasing a product and is not getting information about the plasticizer used in the film formulation, which may be a synthetic plasticizer or one of natural origin. The consumer also does not have information about other added substances, including substances with antimicrobial action.

Information on the label of the commercial packaging, informing which plasticizer additive is being used in the formulation of the stretch plastic film, would contribute to a safer eating practice by the population and would avoid or minimize the risk of exposure to synthetic plasticizers, in particular for the elderly, people with comorbidities, pregnant women, babies, and children. In this specific case in relation to the use of DEHP, attention must be directed to the risks of children's exposure to phthalic compounds that have restrictions on their use established by law, when used in concentrations greater than 0.1% by mass of the plasticized material². Resolution (RDC) No. 326, of December 3, 2019, by Anvisa, establishes the specific migration limit (SML) of 1.5 mg/kg for DEHP and restricts its use as a plasticizer in plastic material that will come into direct contact with fatty foods and sets the specific migration limit (SML) of 18 mg/kg for DEHA².

Based on the results of this study, it was observed that the labels of stretch film packages, marketed for domestic use in Brazil, do not contain guidance information to avoid direct



Source: Elaborated by the authors, 2022. NS: national plastic films; IS: imported plastic films.

Figure 3. Percent mass distribution (%), before and after overall migration test in samples of flexible plastic films commercialized in Brazil and in other countries.



contact with fatty foods. There is also no information or illustrations guiding consumers and commercial establishments that during the application of PVC film as a protective film in packaging systems, direct contact with fatty foods should be avoided. In commercial establishments, mainly, it is possible to avoid the direct contact of the PVC stretch film with the fatty food, making use of thicker plastic trays, in which the food would be packed without being in direct contact with the stretch plastic film.

Also considering the disposal of stretch plastic films in the environment, it is important to mention that synthetic plasticizers such as phthalates are already considered a widespread environmental contaminant, being present in water, air, and soil¹⁴. Therefore, plasticizer information on the commercial packaging label would contribute to the correct disposal of this type of packaging. They would also help companies that produce stretch plastic films in the implementation of reverse logistics policies, assuming the return of their discarded products, treating, reusing, or giving the correct destination, always with the collaboration of consumers, retail, and government, as defined in the National Solid Waste Policy⁴⁰. However, with the increasing requirements of environmental protection and health safety, limiting the application range of phthalates will be a trend in the future²⁸.

CONCLUSIONS

The data obtained in this work demonstrated the viability of sanitary control using the overall migration test in the evaluation of the quality of stretch plastic films destined to come into direct contact with food. They also highlighted the need for continuous monitoring and inspection in controlling the formulation of PVC stretch films sold to consumers and used commercially, with a view to eliminating or minimizing the health risk involved in the application and use of these films with plasticizing additives incorporated into the polymeric matrix.

The commercial PVC films analyzed in this study, when in contact with the fatty food simulant, showed overall migration values higher than the limit established by law. However, depending on the type of food that will come into contact with the plastic film, the migration value may decrease according to the reduction factor that will be applied.

Nevertheless, in order to promote the consumption of safer foods by the population, information on the product packaging label, mainly in relation to the plasticizer used in the stretchable plastic film, guidelines for use in direct contact with fatty foods, and application and disposal of these films in homes and commercial establishments could be discussed and implemented by sanitary control, environment, and consumer protection bodies.

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Author's Contributions

Bernardo PE - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. Murata LTF - Conception, planning (study design), data interpretation, and writing of the work. All authors approved the final version of the work.

Conflict of Interests

The authors inform that there is no potential conflict of interest with peers and institutions, politicians, or financial in this study.



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