PSTC®
PRESSURE SENSITIVE TAPE COUNCIL
A bond you can trust.

PRODUCT COMPLIANCE TRENDS AND UPDATE

Steven Marks
Director of Product Compliance
Avery Dennison
Mentor, OH

Steven Marks is Director of Product Compliance for the Avery Dennison Corporation, a diversified Fortune 500 manufacturer of labeling, packaging, and medical products with over 200 locations globally. In this role, he has global responsibility to ensure that the company's products meet regulatory requirements in all countries where its products are sold, are safe for use by customers, and meet environmental standards. He also led the development of the company's product sustainability program, including implementing life cycle assessments to ensure that the company's products are as sustainable as possible.

Previously, he was global environmental manager for General Electric Consumer and Industrial, the division of GE that manufactures home appliances, lighting products, and electrical distribution equipment. In this role, he ensured that the division's operations minimized environmental impacts and achieved associated regulatory requirements. He has a bachelor's degree in chemical engineering from the University of Dayton and a Masters of Science in Engineering Management from Rose Hulman Institute of Technology.

PRODUCT COMPLIANCE TRENDS AND UPDATE

Steven Marks
Director of Product Compliance
Avery Dennison

1.0 INTRODUCTION

This paper will provide an overview of current requirements and future trends in regulatory requirements and issues that impact tape products, with a global perspective on current issues in product safety, chemicals of concern to regulators or the marketplace, and environmental issues.

The paper is divided into two main sections:

- **Current regulatory requirements.** A brief description will be provided of a selection of key requirements of major regulatory programs that affect tapes globally, including REACH in the EU and other countries, RoHS, Toy Safety, and Food Contact. This is not intended to be an exhaustive discussion and only includes certain selected topics, but strives to provide the reader with an introduction to some of the most important regulatory issues that affect tape products.

  In some cases, such as food contact and toy safety, multiple countries or regions have regulatory programs covering the same general topic. In such cases, the topic is usually presented from the perspective of only one program, but the reader should be aware that other similar programs may exist in other countries.

- **Regulatory trends and how they may affect the industry**. The paper will examine the underlying trends that may lead to future regulations and well as changes that can be anticipated in current regulatory regimes. As environmental, health, and safety regulations on manufacturing operations have matured, regulation of the safety and chemical content of products, especially those used by consumers or incorporated into consumer products, is growing rapidly, a trend that is expected to continue for at least the next five years.

2.0 CURRENT REGULATORY REQUIREMENTS – NORTH AMERICA

2.1 U.S. Toxic Substance Control Act (TSCA)

TSCA is a broad legislation that covers many areas and requirements. The most basic requirement is that any chemical that is manufactured, imported, or used in the U.S. must be listed on the national TSCA chemical inventory, or qualify for an exemption. Canada has a similar requirement called the Dangerous Substance List (DSL) and a number of other countries around the world have similar programs. The TSCA inventory requirements are especially important for any company that manufactures chemicals (which may include compounded chemicals or mixing of adhesives) or imports chemicals from outside the U.S. It is important that these companies have strong programs to ensure that their

chemicals, or the component chemicals, are listed or qualify for an exemption. Many exemptions, like the exemption for polymers, have specific recordkeeping and reporting requirements. Importers must provide a certification at the U.S. Customs entry point that the chemicals that they are importing are compliant with all TSCA rules.

Some chemicals are subject to Significant New Use Rule (SNUR) requirements, which are very chemical dependent. Manufacturers, importers, or users of chemicals subject to SNURs must follow the requirements that are specified for the chemical in the regulations.

Lastly, a chemical that is not listed on the TSCA inventory must be added to the inventory before it can be introduced into commerce. This is done through a pre-manufacture notice process (PMN), which must be completed at least 90 days before the first import or sale of the new chemical.

More information on TSCA can be found on the U.S. EPA website at http://www2.epa.gov/laws-regulations/summary-toxic-substances-control-act

2.2 U.S. Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA) regulates many sectors in which tapes are used, including the food, pharmaceutical, health and beauty, and medical fields. The requirements are quite different for each type of product and even a high level overview of the requirements for each area would take many pages to discuss in even a cursory manner and are beyond the scope of this paper. Thus, a few highlights are discussed that are relevant to tape products, but the reader is encouraged to seek expert help if they will be selling into these markets.

In all cases, the legal responsibility lies with the final manufacturer of the product that is introduced into the regulated market (for example, a bag of chips or a prescription drug in a pill bottle). However, these manufacturers often rely on certifications or compliance statements from their component suppliers to prove compliance. This can be in the form of a Drug Master File (DMF), where the supplier files a detailed profile of the product with the FDA, which the customer can then reference in their application for a premarket clearance. The FDA does not share any information with the customer, but uses the DMF to evaluate the application for approval. The customer can also ask for compliance statements from the suppliers. In some cases, the manufacturer will request a full disclosure of the chemical formulation of the supplier’s components so that they can conduct their own evaluation.

For food and health and beauty products, preapproval by the FDA is usually not required. The manufacturer self certifies based on its own assessment of the regulations and the suitability for safe use. This assessment can be based on

testing, chemical disclosures, or supplier statements or a mix of the above. In all cases, the manufacturer must be able to show that the product is safe and suitable for use in contact with food (direct contact) or food packaging (indirect food contact).

For pharmaceutical and medical products, pre-approval by the FDA is usually required. In this case, the manufacturer submits an application for a premarket clearance. The customer will need either detailed information on every supplied component from their suppliers or the ability to reference a DMF for each supplied component.

The requirements vary significantly depending on the material, intended end use, environmental conditions (e.g., temperature), and even the manufacturing process. Manufacturers and suppliers must review and understand the relevant regulations and the detailed requirements, which are quite prescriptive in many cases. Of special interest to tape manufacturers is 21 CFR 175.105, which provides compliance requirements for the use of adhesives in many food contact applications.

Canada has a similar program, but the specific details are different. Expert help is encouraged in navigating the requirements in either the U.S. or Canada. More information can be found on the FDA website (http://www.fda.gov/) or the Health Canada website (http://www.hc-sc.gc.ca/index-eng.php).

2.3 U.S. State Requirements

Many U.S. states have imposed individual requirements on products, especially on the chemicals in products. Over half of the 50 U.S. states have some type of product restriction on chemical content or reporting requirement.

Perhaps the most well known state requirement is California Proposition 65, which requires that a warning label be placed on any product that contains any of hundreds of potentially carcinogenic or other hazardous chemicals listed by the state of California. This affects even tape manufacturers that are located in other states, because their customers often ask if the tapes contain any Proposition 65 chemicals since the final product may be sold in California.

California has also recently passed the so called California Green Chemistry program, which requires manufacturers of certain consumer products that contain one of the listed chemicals of concern to conduct and submit an alternatives analysis for substitute chemicals. The program allows the state to restrict or ban the listed chemicals in certain products if it determines that the alternatives analysis does not justify continued use of the chemical. The program is not yet fully functional, but the first regulated products are expected to be listed in 2014 and the program to grow to include more products and chemicals over the next several years.

The state of Washington's Children's Safe Products Act requires manufacturers of products that are intended for sale to children to report to the state if any chemicals listed on the state's Chemicals of High Concern for Children (CHCC) list are present in the product. It also restricts the amount of lead, cadmium, and phalates in children's products. Several other states have similar restrictions or reporting requirements, but the specific details vary.

Lastly, 17 states have specific requirements that limit certain chemicals in packaging, especially cadmium. This is especially relevant for tape manufacturers, where tape is often used on or a component of packaging. While not exactly the same, the requirements for packaging are very similar in these states.

The patchwork of state regulation makes compliance very challenging for tape manufacturers and others that sell in the United States. There is some discussion in Congress about preempting some of these requirements to establish more uniform standards, but the outlook is uncertain since some of the states are resistant to changing their programs. It is quite important that manufacturers develop systems to track these requirements and incorporate them into product designs.

3.0 CURRENT REGULATORY REQUIREMENTS – EUROPE

3.1 Registration, Evaluation, and Authorization of Chemicals (REACH)

REACH is a far reaching regulation that affects almost every chemical used in the European Union (EU) and most products. The main requirements (not necessarily the only requirements) that affect tape manufacturers are registration, authorization, and downstream user communication requirements.

REACH requires that any chemical that is manufactured or imported into the EU at a level of over 1 ton per year to be registered with the European Chemical Agency (ECHA). Registration must be performed by every importer or manufacturer, but is in coordination with registrations submitted by other affected companies. It requires extensive toxicological and environmental data and can be quite expensive. The requirement to register was phased in over 10 years, with all chemicals over the 1 ton per year threshold to be registered by 2018.

Certain chemicals are designated as Substances of Very High Concern (SVHC). These chemicals are listed on the Candidate List of chemicals for authorization. Once listed, the presence of any SVHC in any product at a level over 0.1 percent by weight must be communicated to a company's customers (downstream users) and reported to the ECHA.

Some SVHCs are designated as Authorization Chemicals. Once listed on the authorization list, the chemical is banned from being used in the EU unless authorization is received from the ECHA for the use. This involves submission of an application by the manufacturer or others and is expected to be very time consuming and expensive, with no guarantee of a favorable outcome.
Lastly, ECHA does have the ability under REACH to restrict the uses of some chemicals in some products. There are a number of such restrictions, with the most noticeable for tapes being a restriction of 0.1% of less of toluene in adhesives intended for consumer use.

More information on REACH can be found on ECHA's website:
http://echa.europa.eu/web/guest/regulations/reach

3.2 Restriction of Hazardous Chemicals (RoHS)

RoHS restricts certain heavy metals and brominated flame retardants in electronic products. The restricted chemicals are:

1.Lead (Pb)
2.Mercury (Hg)
3.Cadmium (Cd)
4.Hexavalent chromium (Cr6+)
5.Polybrominated biphenyls (PBB)
6.Polybrominated diphenyl ether (PBDE)

The chemicals can be present in electronic products at a level of no more than 0.1 percent by weight, except for cadmium, which is restricted to a level of 0.01 percent by weight.

There are many exemptions to these restrictions, which depend on the specific end use. More information on RoHS and these exemptions can be found on the European Commission website: http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/restriction-of-hazardous-substances/index_en.htm

3.3 Heavy Metals, Phtalates, and Flame Retardants

In addition to RoHS, several other EU programs restrict the amount of heavy metals, phalates, or flame retardants in certain products.

Particularly noteworthy for tapes is the EU Packaging Directive, which restricts the amount of heavy metals in packaging, primarily to protect the environment at end of life disposal. Cadmium is a particular focus, since it can be found in some films as a pigment and is considered to be particularly risky, but attention should be paid to any heavy metal.

The EU Toy Directive also imposes restrictions on heavy metals, phalates, or flame retardants in products that are intended for children. In similar fashion, the U.S. CPSIA restricts lead and phthalates in children's products. The directive requires the application of the CE mark to any toy product as the manufacturer's certification that the product complies with all EU toy safety standards, including the chemical restrictions. The programs also cover many other aspects of toy safety which are generally not relevant to tapes.

4.0 CURRENT REGULATORY REQUIREMENTS – ASIA

4.1 Registration, Evaluation, and Authorization of Chemicals (REACH)

For some time, Japan has implemented a Chemical Substance Control Act (CSCL) program which is often called "Japan REACH". The CSCL requires reporting of certain listed hazardous substances and associated restrictions. These requirements generally apply to the manufacture and import of chemicals into Japan and do not generally impact products. Thus, tape manufacturing sites in Japan will need to pay close attention to these requirements, especially for adhesives and other chemicals such as topcoats or release liners. Certain chemicals undergo a detailed assessment by the government which can result in restrictions. Unlike many other countries, there is no standard national inventory list and determining if a chemical is approved for manufacture or input can be quite challenging.

China also has a program that requires the notification of new chemical substances that is often called "China REACH". Any chemical that is manufactured, imported, or used in China must either be on the inventory of existing substance (IECSC) or a notification must be submitted to the government. There are several tiers of notification depending on several factors and the cost and complexity, including data requirements, can vary significantly. Unlike EU REACH, polymers are not exempt and must also be notified. It is also important to note that, in many cases, China will only accept data that derives from Chinese approved testing facilities, usually based in China. Thus, the ability to utilize data from EU REACH registration or other sources may be limited.

Korea also passed a REACH law in 2013 that is largely patterned after the EU REACH program and will supersede the existing Toxic Chemicals Control Act. Although the law becomes effective on January 1, 2015, the implementing regulations are currently in development. A major difference from the EU REACH, which applies to all chemicals, is that Korea will periodically issue a list of priority chemicals that will require registration. Thus, developments will need to be closely monitored to determine if registration is required for any particular chemical. The regulations should be issued later in 2104.

4.2 China Restriction of Hazardous Substances (China RoHS)

China has a RoHS program that regulates the same products and substances as the equivalent EU program. However, China's program is structured quite differently. The first phase of China RoHS required a label that indicated the Environmentally Friendly Use Period (EFUP), which is an estimate of how long it will take before any of the regulated substances begins to leak out of the product. The second phase, which is still be implemented, involves the issuance of a catalogue of regulated products, which outlines the specific requirement for each product category. Once a product is listed in the catalogue, then any such product sold in China must meet the requirements listed in the catalogue. By contrast, the EU program applies to all products and imposes standard restrictions, with many exemptions that depend on the product type and usage. It is expected to take some years before China's catalogue is fully developed. Most other countries have adopted the EU program almost verbatim (or have no program), so the Chinese program is unique.

4.3 China Food Contact

Most countries will accept a product for use in food contact if it shown to be compliant with either the U.S. or EU food safety requirements. Until recently, this was also true in China, which issued its own food safety program a few years ago. Unlike its U.S. and EU counterparts, which depend mostly on showing that migration of any chemicals into food is at a safe level, the Chinese programs takes a strictly "positive list" approach. Any chemical component that may contact or be incorporated into food must be on China's approved list of food contact chemicals. This requirement also applies to reactants and polymers. There are no exemptions, so if the chemical is not listed, it may not be used until it is approved by the government.

This approach is similar to the recent EU Plastics Implementing Measure, which also uses a positive list approach. However, the EU program does have some exceptions and provides for additional flexibility. China's program is not fully implemented at this time as the government has reviewed the positive list to ensure that it is sufficiently comprehensive, but is expected to be fully enforceable sometime in 2014.

5.0 REGULATORY TRENDS

5.1 Global and Growing

The regulation of product safety and especially chemicals in products is a growing phenomenon. Within a three month period in 2013, over 30 countries released a new requirement of some kind on product safety or chemicals, supply chain management, or end of life disposal. The activity in this period was in all regions of the world except Africa. Globally, over 1,000 new product regulations were issued in 2013 somewhere in the world, compared to an activity level that was less than half of that level prior to 2005, and the trend continues to accelerate. This accelerating pace of product regulation is expected to continue for at least 3 to 5 years and perhaps longer.

The activity has been taken place in the U.S. and EU for a number of years. More recently, the amount of activity has been accelerating most quickly in Asia, especially in Japan, China, and Korea. Individual U.S. states have also been issuing new regulations at a feverish pace. These two areas should be watched especially closely. There is much legislative discussion occurring in South America, particularly around producer responsibility and RoHS requirements. The discussion has so far produced relatively little in the way of actual requirements, but is expected to start turning into legislation more frequently within the next few years.

5.2 Product Regulation Trends

Although the details can vary quite widely, there are distinct trends in the types of regulations being issued or contemplated. Some of these trends that are most relevant to tapes include:

- **Chemical Registration and Disclosure**, which includes programs like the EU REACH program. These programs change the paradigm of product safety responsibility. Manufacturers or importers of chemicals are increasingly responsible for understanding, managing, and communicating the hazards of the chemicals that they provide. Chemical manufacturers are now being asked to provide more information to the government or public about their chemicals, including chemical identity and it is becoming more and more difficult to protect proprietary information. The requirements on what and how to provide information on the hazards of chemical products is becoming more complex and prescriptive as the Globally Harmonized Standard (GHS) is being implemented globally.

- **Nanotechnology**. There is significant government concern about the potential health hazards of nano materials, which exhibit difference properties than their macroscale counterparts and are also easily absorbed into the body because of their small size. The U.S., EU, and others have dedicated staff working on researching the health issues with nanotechnology and considering policy options. To date, the actual regulatory restrictions have been restrained, but future regulation may be quite significant if health effects are found to be a major concern.

- **Restricted Chemicals in Consumer Goods**. The primary, and sometimes only, focus of government regulators is on products intended for the general public, particularly products intended for children or pregnant women. Thus, certain chemicals such as bisphenol A, phthalates, brominated flame retardants, and carcinogenic, mutagenic, or reproductive toxin materials have received a great deal of focus. Recently, nonyl phenol ethoxylates have received focus for mostly environmental reasons, because of their alleged impact on the reproductive cycles of fish. Another important trend is that the

chemicals in packaging is receiving more scrutiny, as evidenced by the EU packaging and cadmium directive and similar laws in individual U.S. states.

- **Restricted Chemicals in Food**. Food safety has received more attention recently from government regulators, especially food packaging or other materials that will come in contact with food. The EU recently issued a new set of regulations targeted toward plastic materials in contact with food and is developing new updates for other materials such as adhesives and paper. China launched a new food safety program a few years back and more attention is being given to food safety enforcement in South America. This trend is expected to continue to accelerate, especially as the EU programs unfold and other countries follow suit.

5.3 Producer Responsibility

Governments and the public have increasingly adopted a philosophy that manufacturers are responsible for their products all the way from product to final end of life disposal. This has led to regulation of various aspects of the product life cycle. One of the first examples was the EU Waste Electrical and Electronic Equipment (WEEE) Directive, which requires that manufacturers develop or participate in schemes to collect and recycle a certain percentages of the products that they manufacture at the end of the product's life.

Similarly, various countries have passed laws or regulations that specify or encourage an Eco design of products (e.g., Energy Star); require labeling of product content, environmental impact, energy use, or other sustainability information; specify requirements for the packaging of products; or provide product fact sheets with health or environmental information. These types of requirements do not usually directly impact tapes. However, these criteria will sometimes drive customers' design and product component decisions. Frequently, customers will also need certain information about supplied components such as tapes in order to comply with these requirements.

5.4 Supply Chain Management

Governments and the public have increasingly adopted a philosophy that manufacturers are responsible for social issues that are associated with their products or their suppliers. From a regulatory standpoint, the U.S. conflict minerals regulation requires that public companies identify if any of four conflict minerals originate from conflict regions in Africa, where the proceeds from mining of these minerals are used to fund armed conflict groups. The EU Timber Regulation requires manufacturers to confirm that the pulp used to make paper in products originate from legal forest operations. Many companies are also insisting that the paper in the products that they purchase come from sustainable forests. These regulatory and market driven requirements mean that customers must have or obtain a level of visibility into their

supply chain that has not been present historically. Obtaining this type of information is often very difficult, complex, and expensive.

Some governments and, more often, companies and advocacy groups are pushing companies to use their purchasing leverage to ensure that their operations, and the operations of their suppliers, are meeting social responsibility standards for humane and proper treatment of employees and others. For example, companies are asked to ensure that their suppliers do not use child or prison labor, pay the proper wages including overtime, and provide safe and environmentally protective operating conditions. This trend is leading many companies to make significant investments in auditing, surveying, or otherwise understanding and verifying that their suppliers operate in a socially responsible manner.

6.0 CONCLUSION

Product regulation is the new frontier of health, safety, and environmental regulation. As programs have matured that limit the discharges and impacts of manufacturing operations, government regulators and advocacy groups have turned more of their attention to the rest of the product life cycle. Much of the recent focus has been on the use phase of the life cycle and how the chemicals in products impact the health and safety of the consumer, and sometimes the environment. Manufacturers are being asked to manage more of the life cycle of their products, from the mining of the raw materials to the disposal at the end of life.

Just as important, many customers, especially those with high public visibility, are insisting that their suppliers manage the issues of chemicals in their products and other life cycle impacts as well as ensuring that their whole supply chain acts in a socially responsible manner.

These trends mean that tape manufacturers must have strong compliance programs that not only focus on government requirements but also market and public expectations. To compete effectively in the future, tape manufacturers need to ensure that they have the following elements in place:

- Dedicated, trained, and skill compliance staff with strong leadership
- A full understanding of the components and risks associated with their products
- Strong compliance documentation and data management systems
- High expectations of their suppliers and a robust audit or verification process
- Robust systems for tracking regulatory and non regulatory developments as they occur
- Full integration of the compliance program into the core of the business, especially R&D, product development, marketing, and procurement
- An active and adaptable strategy to incorporate these issues into the business strategies

These trends do present risks to tape manufacturers, but also opportunity. Those companies that invest in a strong and effective program have a competitive edge both as a differentiator in selling products and in more effective product development and marketing programs.