Issue 1, 2021 ASEAN

Select Solutions™ Magazine

Avery Dennison® application-specific portfolios

Featuring Complete Compliance: everything you need to know about label compliance

New and updated product information

AVERY DENNISON

About Avery Dennison

Avery Dennison (NYSE: AVY) is a global materials science company specializing in the design and manufacture of a wide variety of labeling and functional materials. The company's products, which are used in nearly every major industry, include pressure-sensitive materials for labels and graphic applications; tapes and other bonding solutions for industrial, medical, and retail applications; tags, labels and embellishments for apparel; and radio frequency identification (RFID) solutions serving retail apparel and other markets. Headquartered in Glendale, California, the company employs more than 30,000 employees in more than 50 countries. Reported sales in 2020 were $7.0 billion. Learn more at www.averydennison.com.

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Select Solutions™ Collection

Sometimes the most commonly available materials aren't right for an application. That's why we created the Select Solutions Collection. Here, you'll find label solutions for hundreds of kinds of specific applications, options for mixing and matching materials, and a technical team ready to create custom solutions when nothing else will do.

Product Portfolio

Labels for specific products. Labels that do specific jobs. Labels made of specific materials. Whatever your product, whatever your industry, whatever challenging substrate or environment your labels have to contend with, it's likely that our vast and varied Select Solutions Portfolio includes a solution that delivers —and if not, we can create a custom solution that does.

Mix & Match™

Our Mix & Match Portfolio lets you choose from a set range of unconventional label constructions created to address your unique application and performance needs. Select from a variety of unique facestocks, in combination with some of our best-performing adhesives and liners. Benefit from a customized label solution with low minimum order quantities, rapid pricing, and the quality, service, and expertise you expect from Avery Dennison.

Engineered Solutions

Our Engineered Solutions service helps you to develop custom-made labels that differentiate your business and grow your bottom line. If we don't already have a solution for your specific needs, we'd love to work with you to create one. Our Technical Excellence team includes some of the industry's most experienced professionals. They'll explain the latest market developments and trends in innovation, and then use that knowledge as the foundation for developing your unique solution.

Meet the Avery Dennison Technical Excellence Team

When even we don't have a label that fits the bill, our Technical Excellence team can develop custom labels designed specifically for your application.

Holmes Ong
Responsible for Specialty in the ASEAN region, Holmes has 10 years of experience in the digital printing industry. He works closely with sales, technical support, and R&D teams to develop the right products for the market and customer needs.

Neil McArthur
A chemist with more than 30 years of technical experience with Avery Dennison. Neil works closely with the R&D and product divisions, providing the total solution to customers technical/product queries.

Kanokwan Pankhet
As an Assistant Product Manager for Specialty, Kanokwan is responsible for new product development and closely involves in R&D projects. She also works with sales and marketing teams to provide the right product for the market and customers.

Silvia Tan
As a part of the product management team, Silvia is responsible for the Durables portfolios across ASEAN. She not only manages a wide range of products, but also develops the right solutions for different applications to ensure the overall industry needs are addressed.

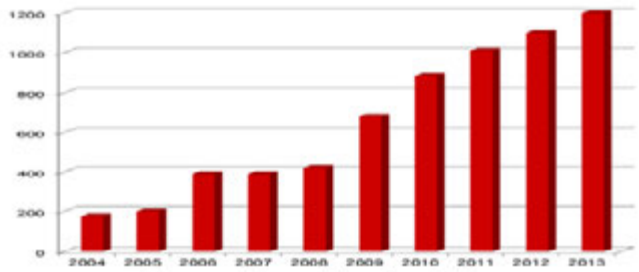
Complete Compliance

The easy way to meet regulatory demands

Rapidly increasing regulatory demands are making a big impact on label converters. It means that a new philosophy is needed – a way of reliably and simply meeting the growing pressures from legislation.

by Steven Marks, Director, Product Compliance

There has been a major, and sustained, growth in regulatory demands over the last few years. It has left label converters facing a bewildering array of rules affecting food, pharmaceuticals, home & personal care and even durables. We estimate that there were around 1,000 new product regulations in 2013 alone.



New product regulations since 2004

Consumers are also expecting to see more information on packaging credentials. The piecemeal approach to compliance that might have worked five years ago, or even more recently, is no longer sustainable. Label converters need a way to ensure compliance quickly, so that an application can be designed, agreed, created and delivered on a reasonable timescale and with minimal effort. They also need complete confidence that a decision on compliance was the correct one.

The challenge is a global one. For example, meeting EU regulations on REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) may be enough to ensure confidence in a solution for Europe, but converters can then face entirely new hurdles if asked by a brand owners to look at markets elsewhere.

There are also many other regulations to consider, even in Europe. Prominent examples include RoHS (Restriction of the Use of Certain Hazardous Substances governing certain chemicals in electronics; EU Packaging Directive; EU Food Safety Framework, EUTR (EU Timber Regulation) relating to legal timber sources; and European moves to eliminate conflict minerals sourced from central Africa and elsewhere.

Countries introducing new regulations in one recent quarter

The Complete Compliance philosophy

Compliance should be viewed as a driving force in product and application development, rather than something to be added at the end of the process in a pick-and-mix lottery. Improvements in both compliance and sustainability have always been important for Avery Dennison, and we have moved towards a new Complete Compliance model for all research and production.

Avery Dennison Materials Group Europe received more than 1,500 customer requests for compliance data and certifications in 2014. Our goal is to provide converters not only with products, but with expertise, training, market intelligence, service responsiveness, networking and resources. In short, the decision has been made that Avery Dennison needs to equip converters with everything needed to ensure compliance when using our products for any application – to take the problem away and bring it back solved.

Our dedicated Complete Compliance Centre is the first port of call for converters wanting advice and information, but the philosophy underpinning it extends much further: compliance is a strategic priority across the Avery Dennison organisation. Materials Group Europe has established a Product Compliance Marketing Strategy Council, whose mission is to assess all regulatory and marketing developments and drive action wherever it is needed in the organisation.

Segment requirements

Exactly how demanding regulations might be depends on the segment. For example, durables labelling does involve compliance activities. In this segment, Avery Dennison meets rules that include REACH, and in some cases RoHS and IMDS for automotive applications, as well as notifications to converters on Substances of Very High Concern (SVHC). However, it is in segments such as food where the complexities of ensuring compliance are greatest.

Food labelling involves two broad categories: direct food contact and indirect food contact (where the label is placed on top of another material). A common misconception is that direct contact approved labels are 'safer'. This is not the case if applications are properly designed, and an indirect contact material choice can sometimes give the best cost and performance without compromising safety in any way. The all-important issue in food packaging is migration of chemicals into package contents. Foods that are high in fat, acid or moisture present more of a labelling challenge than dry foods, and so there are six categories of food used when assessing food safety and compliance:

- Dry foods (e.g., cereal)
- Moist or aqueous foods (e.g., cake or soft drinks)
- Acidic foods (e.g., pasta sauces)
- Fatty foods, non-dairy (e.g., meats)
- Fatty foods, dairy (e.g., butter or milk)

EU food compliance is regulated under the Food Safety Framework, EU 1934/2004 and related Directives, but there are also separate regulatory regimes in the US, EU and China dealing with food contact.

All of this is designed to address more than merely theoretical risks. Notable food packaging related safety scares include uncured UV inks on baby milk boxes (in Italy) and Methyl Benzophenone passing through cardboard and plastic packaging into cereal (in Belgium). However, it's important that label converters and brand owners should still be able to use a range of different labelling technologies, to allow differentiation on the shelf. The Avery Dennison food-approved portfolio is extensive, and gives converters both the freedom they need when designing applications and the confidence they need when responding to brand owners and regulators.

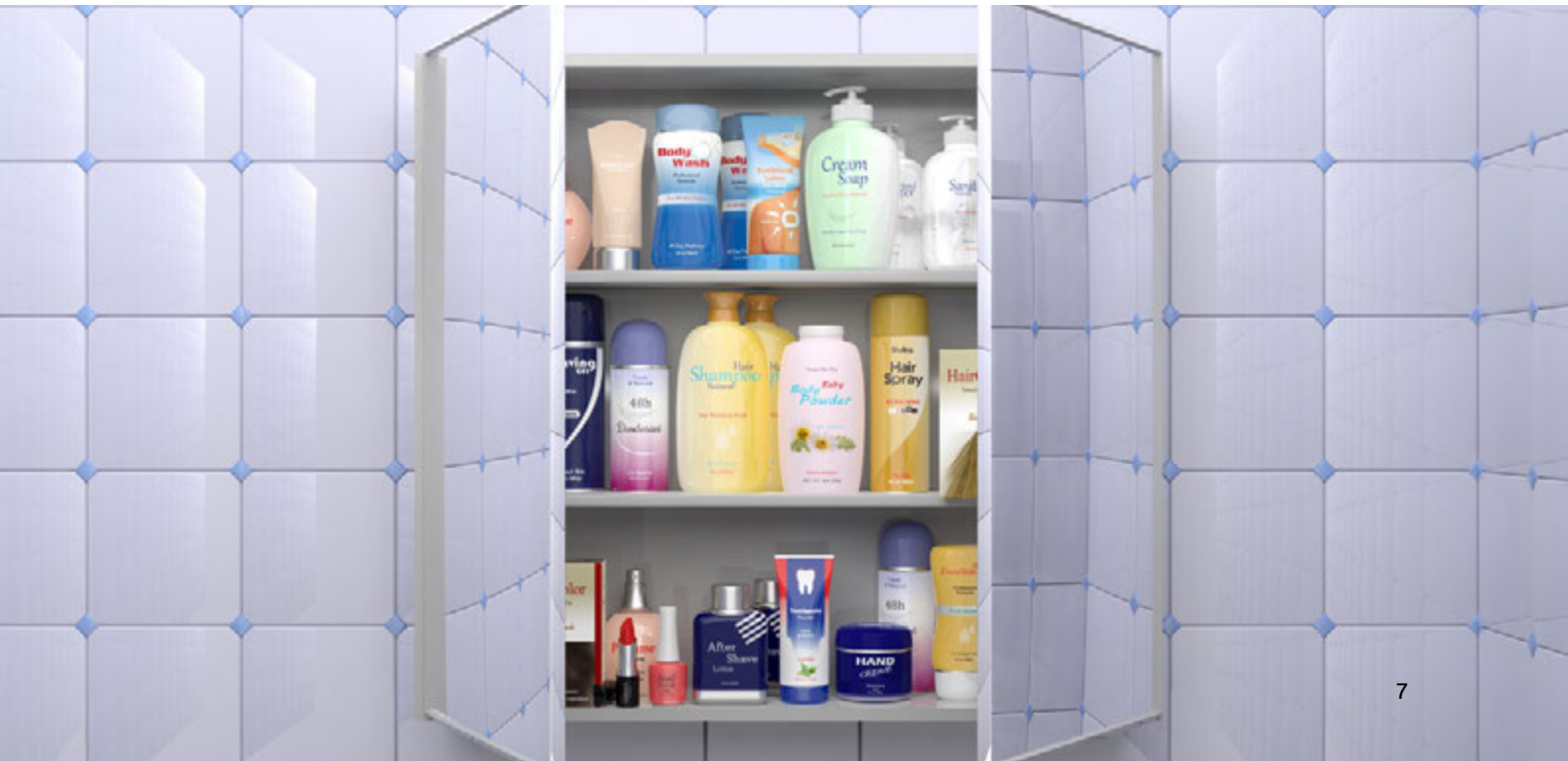
The pharmaceuticals segment is another area in which regulation is intense. In this case, as in food, there are difficult technical challenges to address. For example, an adhesive may need to give strong adhesions to a plastic container with a very small radius, while simultaneously avoiding any adhesive migration.

Making it happen

Choosing Avery Dennison materials is one way to be sure that all applicable registration obligations have been met by a product, wherever on the globe that you want to sell it, and you will also receive extended compliance information and updates wherever you happen to be in the supply chain.

More importantly, compliance is an integral part of the in-depth application support provided by Avery Dennison's technical teams. We can help you with anything from advice on one particular application through to training on registration management and communications downstream.

A range of new tools is also on the way that will help all customers to track and manage their compliance needs, including major improvements to compliance information directly from the Avery Dennison web site. ■



Compliance Made Easier

We explain how the Avery Dennison Complete Compliance program can take away your compliance worries and help you win business.

Increasing regulations intended to protect the environment and human health—and the variation among such laws from country to country—can create considerable complication and uncertainty, never mind the amount of time and expertise it takes to track and comply with them. In a recent interview with **Vinayak Shete**, Compliance Manager at Label and Graphic Materials, he described how our Complete Compliance service —and our time-saving Compliance Portal—is helping converters breathe easier while giving converters an edge.

Let's begin with an understanding of compliance. Why is it a challenge for converters?

The regulations governing the labelling industry around the world are extensive, and they have been increasing steadily for more than a decade. They are also, globally speaking, decentralized and hard to track. Regulations are enforced by many different national and transnational bodies. Different rules apply to every segment, with sensitive segments such as food and pharma facing the strictest requirements. And complying with these regulations once they are in force is mandatory. If you're out of compliance, you can be prohibited from selling products in a certain segment. Your products can be recalled. You can be fined and have your packaging lines shut down. There can be contractual liability. So compliance is utterly essential —not just for converters, but for brand owners, and for companies like Avery Dennison that make and market label materials.

What this means on a practical level is that staying informed about current and emerging regulations, and knowing how they differ from country to country, is an enormous—and enormously important– job. And then you have to be able to confirm that the materials you're converting will meet

the regulatory requirements anywhere the product you're helping to package will be sold. There can be testing involved. All of it adds up to a Herculean task for converters who want to pursue business in heavily regulated segments.

How do regulations in Asia differ from those elsewhere?

While there are common regulations followed by all regions, food and durables are especially important in Asia. And regulation is expanding in Asian countries much faster than in the rest of the world. That means there's a lot more for converters to keep up with. Regulators in the region also sometimes use regulatory approaches that are different from those of their peers in other regions and the details can be different, which adds to the complexity.

Tell us about Avery Dennison's Complete Compliance program. Why is it an advantage for converters?

Simply put, it takes the worry and chore of compliance off of converters' plates and gives them quick access to comprehensive compliance information that their prospective customers often require. Through Complete Compliance, we collect timely and accurate compliance information on everything from the raw materials we get from our suppliers to testing of the label constructions we make to product formulations and more. We have all of the most up-to-date information on hand, so that we can make it available immediately for converters when they need it. Converters, in turn, can, with a few clicks, immediately provide prospective customers with documentation showing that their materials are compliant, and thereby win more business.

So Complete Compliance is an online solution?

In large part, yes. We've structured it so converters can get most information on-demand, as they need it. We provide access to a special website—our Compliance Portal. There, they can instantly download whatever information their customers require. There are large food corporations, for example, that require converters to complete a 60-page document describing the converter's ability to comply with regulations. With our Compliance Portal, converters can provide that information quickly and accurately, giving them a significant edge over the competition. They can also provide far more documentation that the simple data sheets that other label makers provide to their customers. Complete Compliance does more than save time and labor for converters. It's a competitive advantage.

Can you share a recent example of how the program has helped a converter?

There are many examples in any given week. But here's one: recently, the marketing team for a brand of bananas chose an adhesive for their labels that wasn't suitable. Since it was a food application, regulations were more stringent, but our compliance team was able to quickly suggest a better alternative. Neither the brand nor the converters had to invest in testing or validation of the adhesive to make sure it was compliant, because our team had already done that work. The solution, and the accompanying documentation, were ready to go.

How does Avery Dennison keep up with all these expanding regulations around the world?

We partner with several global institutions, trade organizations, and consultants to monitor regulations around the world. We call this our Early Warning System. We share learnings from the Early Warning System with various stakeholders, including our R&D team, customers, and suppliers. We also incorporate it into our strategic planning and product development. The idea is that we stay on top of these issues so our customers don't have to.

What are some of the key things label converters should watch out for when it comes to compliance?

The major challenge is the rapidly changing regulatory environment, which means that there are constantly new challenges to solve. Making the situation even more complex is that more countries are adopting unique requirements, so that a global company must track many different jurisdictions. Lastly, knowledge of a wide range of countries and industries is required, which means that the number of professionals in the world who have the expertise and experience to properly assess and stay up to speed with this ecosystem is quite limited. Most converters and end-users simply don't have this kind of expertise in-house.

What do you expect the compliance landscape in Asia to look like over the next three to five years?

We expect many more compliance requirements related to product safety and environmental issues, especially in the area of chemical management and food contact requirements. India's REACH law, similar to the EU REACH regulation, is going to be launched next year, and similar new or expanded requirements are expected in China, Malaysia, Thailand, Indonesia, and Australia. At the same time, a substantially stricter and more detailed regulatory program for materials that come in contact with food is being developed in China and Japan. A number of other countries are also developing food contact programs, including Thailand, Malaysia, and Australia. We expect to see other new regulatory programs, affecting electronics, automotive, and pharmaceutical, in this same timeframe.

Any last words?

We're really proud of Complete Compliance. There's nothing else like it. For us, it's not just a program, it's a whole, comprehensive approach to compliance that drives not only our service to converters, but how we think about and design our own products. It's proactive and forward-thinking. And best of all, it can save our converting customers a lot of time, headaches, and money, while helping them increase business opportunities and sales. It's a perfect example of the caliber of service we strive to provide.

To learn more about the Avery Dennison Complete Compliance program, simply reach out to your local Avery Dennison sales representative for assistance. ■

Complete compliance helps manufacturers navigate the maze of government regulations

Avery Dennison service is simple and reliable

There's no doubt the world is constantly changing, and the same holds true for government regulations impacting the label and packaging materials industry. During the 1980s and '90s, most government regulations focused on safety and environmental issues.

A decade ago, between 200 and 300 new regulations affected the label and packaging materials industry and its customers annually. In recent years, the addition of more government regulatory bodies and areas of regulation has resulted in 1,000 to 1,500 new regulations each year.

The challenge to keep abreast with new regulations is complicated by the many industries involved – from food and pharmaceutical to automotive, chemicals and electronics – and various regulations in different countries. China's restriction of the use of certain hazardous substances (RoHS) for electronic communication products is, for example, very different and more extensive in certain areas than the European Union RoHS.

Many new regulations relate to recycling, with a number of states and local jurisdictions introducing regulatory programs to reduce the use and disposal of certain packaging materials. Companies seeking to package products in new containers, for example, are encouraged to use recycled materials and must explain why they cannot use widely recycled packaging materials such as rigid single-use food containers or PET, the type of plastic used by most soda bottlers.

In addition, consumers demand more information on packaging to assist them with in-store purchases. They want to know the product price and price comparisons along with reviews/ratings, special offers, ingredients, health claims and recycling details.

Responsibility for compliance varies

Large corporations typically employ specialists who keep abreast of new government regulations and provide the company with regulatory updates to ensure company labels and packaging are compliant. Small to medium size companies and local entrepreneurs, however, are not as fortunate and must rely on industry resources.

A food manufacturer, for example, may want to include product price and other details on a newly designed packaging system for a food product. Since the product will be sold in the U.S., both the label and the packaging must comply with FDA regulations.

The food manufacturer often has no one on staff that is sufficiently knowledgeable about packaging regulations, and so it contacts the converter for help. The converter, in turn, often relies on the label and packaging materials manufacturer to provide compliance data.

Some label and packaging materials manufacturers offer data sheets and other regulatory information online. Reviewing the information and determining what regulations are applicable, however, takes time – sometimes several days.

Considering regulatory requirements early in the product development cycle rather than as an add-on at the end of the process can help save time and money. But to accomplish this objective, companies must be able to access regulatory information and purchase fully compliant labels and packaging materials in a timely manner.

Complete Compliance

Avery Dennison introduced Complete Compliance to provide converters with regulatory expertise, training, market intelligence and resources to help ensure compliance. The company typically receives more than 10,000 regulatory

requests from converters and end users every year and can usually respond with regulatory information in one day.

Complete Compliance is a service designed to protect converters' business against regulatory risks while allowing converters to offer end-users the right materials for specific applications. Avery Dennison tracks regulations in the U.S. and around the world and employs technical and compliance specialists who review applicable regulations and check that products are still compliant before releasing it to the Avery Dennison sales team and customers.

Requests for support regarding regulatory requirements come from various industries and different countries. A manufacturing company planning to distribute a new product internationally may meet European Union regulations on REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals), but may need help with REACH regulations in other parts of the world since REACH requirements are different and enforced on a country-by-country basis.

Regulations for various market segments

Depending on the product and targeted geographic market and product segment, manufacturers must consider a wide variety of regulations and requirements (besides the FDA, RoHS and REACH requirements mentioned above), such as the following:

- UL (Underwriters Laboratories), an American worldwide safety consulting and certification company. Products that bear the UL mark must be tested and certified to comply with the applicable UL Standard(s);
- The Lacey Act, a U.S. federal law designed to prevent trafficking in certain wildlife, fish and plants;
- The U.S. Consumer Protection Safety Improvement Act (CPSIA) of 2008, which created a variety of labeling, testing, and certification requirements, and is one of several U.S. statutes that deals with product safety;
- International Material Data System (IMDS), the automobile industry's global standard used by nearly all OEMs;
- Food Safety Framework, EU 1934/2004;
- EU Packaging Directive;
- EU Food Safety Framework;
- EU Timber Regulation (EUTR) relating to legal timber sources.

The extent of the applicable regulations varies among industries. For example, Avery Dennison registers all of the raw materials used to make its products, as applicable, under EU and other country REACH regulations and the products comply with RoHS as well as IMDS requirements for automotive applications. The company also provides notifications to converters on Substances of Very High Concern (SVHC).

Avery Dennison's Customer-Ready Durables Portfolio includes many UL 969-listed products as well as an extensive line of ribbons and press inks that converters can

easily adopt into their own UL files. This capability greatly reduces the time and expense that would be required for converters to obtain UL listing on their own.

Regulations are especially complex within the food industry, where the migration of food packaging chemicals into package contents continues to create concerns. Foods high in fat, acid or moisture present more of a labeling challenge than do dry foods.

As mentioned earlier, the FDA regulates food products in the U.S. while EU food compliance is regulated under the Food Safety Framework, EU 1934/2004, EU 10/2011 and related directives. In Asia, China has its own regimes dealing with food contact. Avery Dennison's regulatory knowledge and extensive food-approved portfolio provide converters and brand owners the freedom they need to design labels that differentiate their products on the shelf while meeting regulations in whatever country where they want to sell.

Regulations are intense in other segments, such as pharmaceutical, which presents specific technical challenges. An adhesive, for instance, must be strong enough to securely adhere to a plastic container with a very small radius while simultaneously preventing any adhesive migration.

Converters who help industrial drum manufacturers adhere to Globally Harmonized System (GHS) standards can sidestep costly and time-consuming BS 5609 testing. The Avery Dennison UL-certified laboratory can quickly certify for BS 5609 Section 2 and 3 at no cost to the converter customer. Avery Dennison's certification library includes a wide variety of certified materials, printers, ribbons and ink combinations.

All Avery Dennison materials meet applicable registration obligations in all countries in which it manufactures its products. The company also provides back up documentation confirming that labels and packaging materials are safe for their expected use. If a food product, for example, undergoes an FDA inspection, Avery Dennison, as a third party, will provide backup information to assist the end user with documenting compliance.

Avery Dennison also provides companies with extended compliance information updates when needed.

Compliance as an opportunity

Noncompliance with government regulations is never an option. Companies that do not meet applicable regulatory requirements cannot sell their product and may lose sales and market share. The government can also levy fines and penalties if non-compliant products are sold, depending upon the product and country.

On the other hand, when customers can have full confidence that products and packaging meet compliance regulations, the company's brand image is protected and can be reinforced. Manufacturers in every industry sell their reputations when they sell their products.

Awareness of government regulations and the ability to provide compliant labels and packaging materials can help converters grow their business. Large food corporations, for example, may issue a 50- to 60-page document requesting an explanation of a converter's ability to comply with government regulations. Companies that respond must be able to provide the information requested in a timely basis to qualify for the business … those that do so quickly and accurately can have a significant edge.

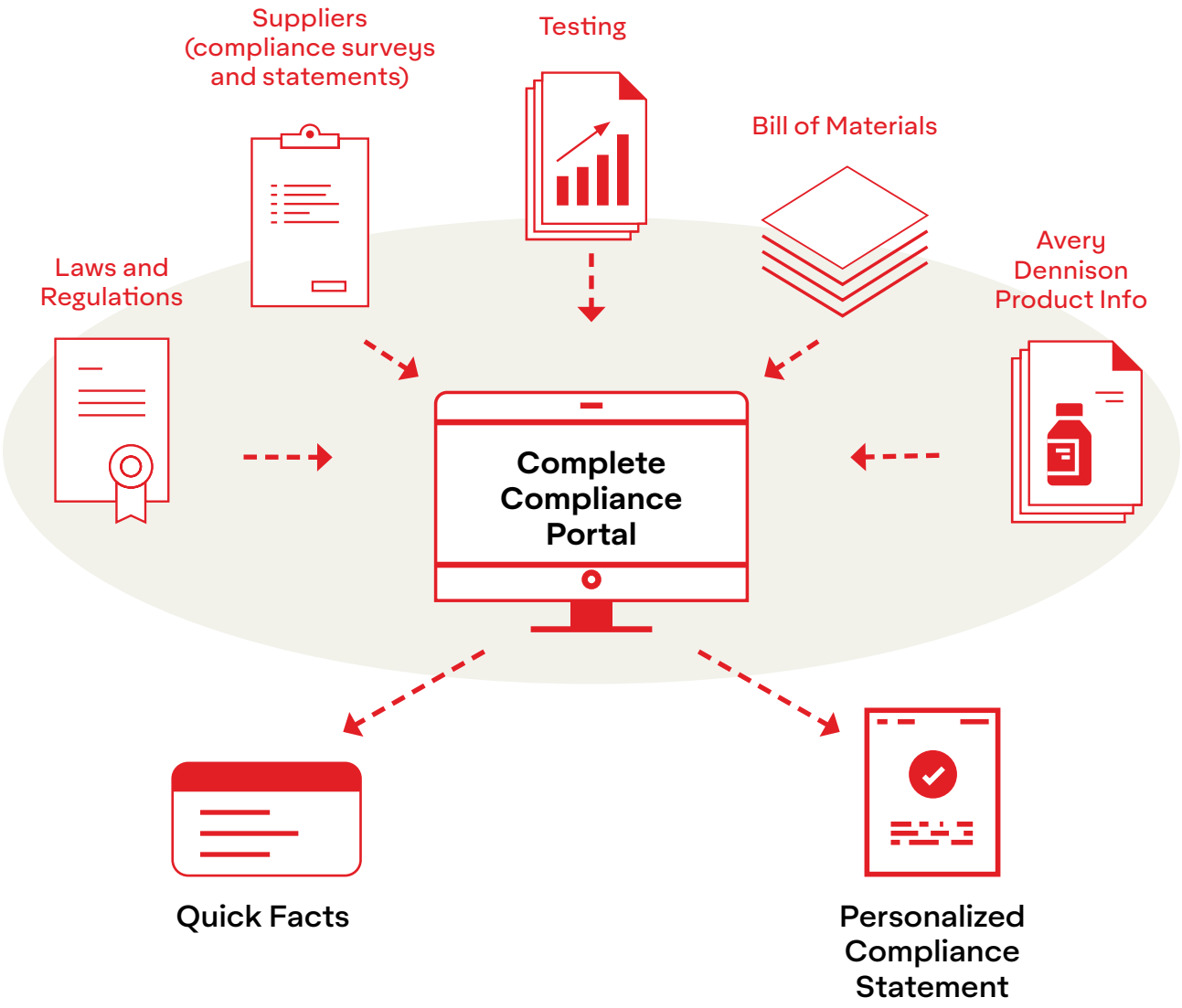
Unfortunately, no Compliance 101 course or documentation exists to educate and update manufacturers about government regulations and requirements for compliance. Manufacturers, however, have a compliance partner with Avery Dennison's Complete Compliance and its wide range of compliant labels and packaging materials solutions.

Whether manufacturers work in food, pharmaceuticals, home and personal care, durables or any other segment, Avery Dennison provides access to the expertise, market intelligence, networking and resources to solve compliance issues in the U.S. and around the globe.

Avery Dennison will continue to expand services available through Complete Compliance in an effort to help manufacturers and converters reliably and simply meet the growing demands represented by expanding legislation as a way to grow their business. ■

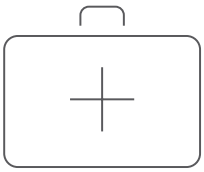
Avery Dennison **AD***vantage*

Complete Compliance

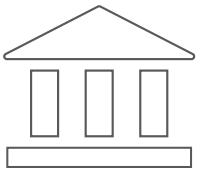


Why is compliance important?

Inability to sell a product in a segment or end use application



Contractual and legal liability



Government fines, penalties and even production line/facility shutdowns

Product recalls or withdrawals

The importance of regulatory compliance in food packaging

By John van Bruchem, Product Regulatory Compliance Engineer & Jenny Wassenaar, Compliance & Sustainability Director, Avery Dennison

Making sure a product is compliant with regulation – and that it stays compliant – is one of the top three concerns for business owners. Continued regulatory compliance gives businesses confidence that they are complying with all applicable laws, regulations and directives whether local or international. Maintaining a strict overview of constantly evolving regulation is crucial. Only reliable regulatory compliance can avoid severe legal repercussions, including fines or even withdrawal of the product from the marketplace. Compliance is also the foundation that gives customers confidence that they are purchasing safe materials for their intended application.

The global regulatory environment is diverse, making it difficult to keep track of all compliance responsibilities. Food packaging is a perfect example, with regulatory variations that affect material use, regional implementation and issues within large supply chains. Any packaging material must comply with all regulations in every country or region where it might end up. For example, food contact regulations differ in their migration limits and barrier assumptions.

Understanding the business landscape is essential in order to connect different elements within the regulations. In the supply chain for food packaging, end users have to be sure that materials sold to consumers follow local regional regulations. This means that end users will contact their suppliers for information on product safety and regulatory compliance. A vast network of suppliers and pre-suppliers is involved, so this exercise is time consuming and complex – especially if it is not clear how to find the right data. Compliance depends on sharing facts throughout the entire supply chain. When seeking answers to questions about product regulation, what matters most, therefore, is knowing where to get them.

It is essential to establish what is meant by 'compliance' in the context of a particular application. This depends on pinpointing who should take responsibility for determining compliance. Such clarity is, in fact, the goal that many small-to-medium enterprises (SMEs) struggle with – it is a non-trivial task for them to understand their own position and responsibilities. Collectively, SMEs represent around 99% of businesses in all countries, so they are a very significant element in the supply chain.

The unfortunate outcome can be a large amount of unnecessary work, undertaken because a business does not understand that compliance responsibilities actually sit elsewhere in the supply chain. By contrast, an effective strategy for SMEs centres on asking what would be the quickest and most effective solution. Each member in the supply chain should make sure that they know their position and responsibilities, but most importantly they should also act collaboratively and communicate on the issue.

This article highlights an example of how companies can support each other in sharing the right information in the supply chain – how they can remove ambiguity around data interpretation by creating real transparency.

Regulatory compliance: strategy and team

Building a strong regulatory compliance team, with an effective strategy, is required in order to establish the right

conformity data. The risk of non-compliance is twofold from a business point of view. First, there can be legal repercussions, and second, customers can start choosing other more trustworthy alternatives.

Regulatory compliance strategies generally include the following:

- A clear vision of the supply chains involved in your business
- An understanding of your counterparts in the supply chain: their position, size and regulatory knowledge/need for information
- A clear communication strategy
- A plan for staying up to date on the latest regulations and directives (for example by making use of advisory groups and consultants)
- A plan to connect your regulatory compliance team with other stakeholders in the organization. For example, research and development teams who are at the forefront of new product developments need to ensure that new products comply with current and future legislation; and purchasing needs to have a link to correct regulatory information from suppliers.
- Testing protocols for analysis of materials in order to validate the compliance status of products for the intended application.

Focusing on a clear communication strategy can be split into two parts. First, the regulatory compliance team plays an important role in warning, advising and educating the internal and external organization on, for example, chemical, food and regional legislation developments.

Secondly, it is important to answer customer questions diligently, with a quick turnaround in order to prevent a possible halt to product sales or a recall. Generally this revolves around creating data that supports compliance claims, achieved either by (analytical) testing or by inquiring within a network of specialists. Data has to be brought

together from different sources and can have several levels of complexity. For example, a general food contact statement can be generated by a review of the migration and levels of each of the components in the packaging. However, in order to create a full food contact statement, further information is required such as migration limits and test methods used.

Understanding customers' needs is therefore key - a general statement might be sufficient in certain circumstances, while in others there will be a need for more in-depth analysis. To support all of this, several systems need to accommodate information gathering, storage and sharing. The ideal tool does all of this; in the case of Avery Dennison, that tool is the Product Integrity Management System (PIMS).

The food contact information maze - a labelling example

European food contact regulations relating to the packaging industry are useful to consider as an example, although it should be noted that there are many other aspects to legislation, such as Registration, Evaluation, Authorisation and Restriction of Chemical Substances (REACH) for chemicals.

Contact with food is a topic that arises frequently in packaging applications, and requests for information increasingly require more technical data to answer in full. As a global materials science and manufacturing company, Avery Dennison designs and manufactures a wide variety of specialised labelling materials and functional materials. Labels are generally placed on the container holding the food product (or any other product), but in some cases they will be placed directly onto the food itself.

Where the label is placed on packaging, what the container is made from will be important. This will determine the extent to which a barrier is formed between the foodstuff and the chemicals in the label (the chemicals contained in the adhesive, facestock and inks). For direct food contact there will be no such barrier, and so we have to ensure that the chemistry used to produce the label is safe to use for its intended purpose. Even the smallest traces of certain chemicals have to be considered in migration models, so working together with all suppliers and suppliers-of-suppliers is critical in order to find the correct information, and to be able to guarantee the safety of the materials.

Generally a label consists of three layers: a front material (facestock), an adhesive and a release liner. The liner is not applied to the food product itself, and so the focus of food contact regulatory compliance is on the facestocks and adhesives used.

When producing an adhesive, Avery Dennison is bound to requirements laid out in the 1935/2004 Framework Regulation, because there is no specific regulation for this type of material. There are also several guidelines and recommendations available from different industry groups and governments (Feica, FINAT, BfR, etc.) which can be used in order to establish compliance with food contact.

The challenge for a label material or adhesive manufacturer is that the end-use purpose and location is not always known specifically. This means that a material has to receive a general qualification level that fits all purposes and markets. We approximate the most stringent application requirements for our materials by testing according to migration principles from the 10/2011 regulation. Generally, adapted testing is performed to simulate application of an adhesive to a foodstuff directly, which is considered the worst case. These results are then analysed and communicated where needed.

For the facestock, a request is made to the manufacturer for their Compliance Statement. Because of an increasing global supply chain, overcoming the regulatory maze requires the right communication to work towards valid measurements and product information.

Creating a helicopter view of the maze

Part of a regulatory compliance team's role is to take the complex information collected from different sources - suppliers, tests at internal and external laboratories, and the latest regulations - and translate this into understandable and complete documentation for customers. This allows product selection decisions based on information that relates to the intended purpose.

Maintaining good interaction with suppliers and laboratories is crucial, in order to receive their latest updates and to create an effective network of understanding across regulatory compliance topics. However, even with the best interaction, the process for obtaining relevant data for all products and product variations is time consuming and challenging. Data has to be translated in the right language, and cut and pasted together from different sources, making the final result look like individual case files for each food contact compliance request.

Support from suppliers is critical because the quality of data outputs is only as good as the quality of the inputs. The role of the compliance team at Avery Dennison has therefore changed. Rather than simply following up with suppliers to provide data, the team fosters healthy discussions with suppliers around the quality of the data and documentation, in order to support the important statements made.

Product Integrity Management System (PIMS)

Avery Dennison has implemented a tool called the Product Integrity Management System (PIMS). It shows the way through the maze of information, and avoids running round in circles or meeting dead-ends. The objective of the overview is to create transparency for regulatory compliance information and 24/7 access to that information for customers.

Customers need information quickly, and the 'helicopter' view provided by PIMS is designed to be navigable easily by any user. On the input side of the tool, all input information from suppliers and external labs is combined into one document, with the same look and feel for all products sold. Customers can then extract what they need quickly, without interference, in the format of a formal Compliance Statement.

The Compliance Statements are available in multiple languages, and customers can personalize the statements with their own name and address. Users can download multiple documents at once, allowing them to look for a list of regulatory information over multiple products. They can also select which statements they would like to receive, based on different regulations. The PIMS tool can be accessed online 24/7.

Transparency and clarity are essential for all parties in the supply chain, as a route to faster and more productive applications and as a way to avoid breaches in regulations. The principle embraced by Avery Dennison is that regulatory questions should be taken as a starting point for a wider discussion of important issues.

With reliable and easily accessible information, customers can move beyond a simple "how do I get to my data?", and answer a far more critical question for any business: "what can we do together to build the most trustworthy and safe materials for our customers?" ■

Food labels - Removing the guesswork from compliance

When it comes to selecting labels and packaging for food products, the primary concern is always safety. It's important to understand Food and Drug Administration (FDA) regulations regarding food labeling and packaging and why labels and adhesives are compliant with those regulations.

Food additives and food contact substances

The FDA is the agency within the U.S. Department of Health and Human Services that administers the Federal Food, Drug, and Cosmetics Act (FFDCA). The statute provides the FDA the authority to ensure food is safe by regulating the food additives that are directly or indirectly added to food.

Direct food additives such as flavorings, preservatives and anti- caking agents become food ingredients — and they are consumed. Indirect additives, such as printing inks and food packaging coatings, are used during processing, packaging, storage and transportation and have no impact on the food's function. Their contact with the food, however, is still regulated by the FDA.

The FDA recognizes three types of food contact substances (FCS): direct, indirect and incidental contact:

- Direct contact substances touch the food product, such as the adhesive on an apple label.
- Indirect contact substances have a functional barrier placed between the substance and the food but have the potential to come into contact with the food. For example, an indirect food contact approved adhesive could be used in a package of baked goods that utilizes a peel and reseal label to close the container provided that there is a functional barrier between the adhesive and the food.
- Incidental contact substances may have unintentional contact with food, such as a food product that accidentally touches a part on a processing machine.

The use of adhesives

Title 21 Code of Federal Regulations (C.F.R) Section 175.105 allows adhesives to be used in food-contact applications if a functional barrier is present that prevents substances from migrating to the food. A functional barrier is a layer or multi-layers within food contact materials that prevent a substance behind the barrier from migrating into the food.

A glass jar of jam with a label, for example, uses the glass as a functional barrier between the label adhesive and the jam inside the jar. As another example, when an adhesive is used with a film, a layer must be added between the adhesive and the food. A heat seal liner such as a 1.2 mil PET would serve as a functional barrier.

Labels that already include a direct food contact adhesive do not require a functional barrier. These types of labels are often applied to foods such as watermelons or eggplant. A reclosure solution using a direct food contact approved adhesive does not require a functional barrier, allowing for the use of thinner packaging films.

The FDA publishes lists of permitted food contact substances in the Code of Federal Regulations (CFR) Section 21, Parts 170-199. These lists include some Generally Recognized as Safe (GRAS) materials and substances that have already been reviewed as part of the food additive request process.

Food packaging designers ultimately bear responsibility for determining the functional barrier that is required for a specific food package. The functional barrier needed will depend on the substances on each side of the barrier, such as the adhesive and the type of food.

Use of adhesives and pressure-sensitive adhesives

The Title 21 Code of Federal Regulations Section 175.105 allows the use of adhesives in the following circumstances:

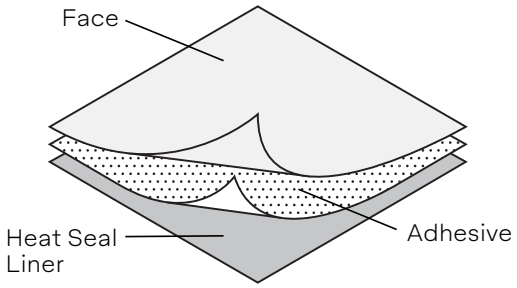
1) The adhesive is used with dry food and the quantity of the adhesive that contacts the packaged food does not exceed the limits of good manufacturing practice (GMP);

2) The adhesive is used with fatty and aqueous foods and the quantity of the adhesive that contacts the packaged food does not exceed the trace amount at seams and edges of packaging laminates within the limits of GMP. A die cut line is an example of a seam and edge.

Title 21 Code of Federal Regulations Section 175.125 addresses the use of pressure-sensitive adhesives:

a) Pressure-sensitive adhesives prepared from one or a mixture of two or more of the substances listed in this paragraph may be used as the food-contact surface of labels and/or tapes applied to poultry, dry food and processed, frozen, dried or partially dehydrated fruits or vegetables.

b) Pressure-sensitive adhesives prepared from one or a mixture of two or more of the substances listed in this paragraph may be used as the food-contact surface of labels and/or tapes applied to raw fruit and raw vegetables.



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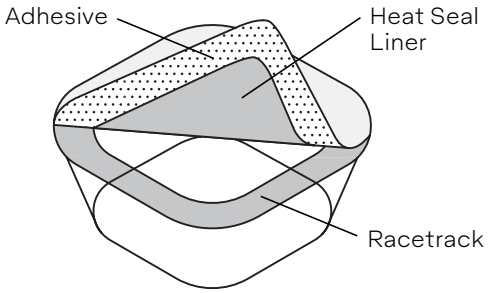

OPEN FOOD CONTAINER

Food contact notifications

Some food contact substances (FCS) may not have prior FDA approval and may require the manufacturer or supplier to submit a food contact notification (FCN) to the FDA before the substance can be manufactured or used. The FCN must include a description of the substance and its use along with information supporting the claim of safety.

The regulations in the sidebar provide guidelines for self determinations; submitting an FCN offers more opportunities to obtain a food contact clearance. All FCN's are proprietary and apply only to the submitter and its customers.

The Avery Dennison heat sealable reclosure system

Avery Dennison's R1490 adhesive has an FCN and it is one of only a few FDA-compliant direct food contact pressure-sensitive adhesives in the industry. The adhesive can be used directly on food, offering the opportunity for lower cost/less material usage when specifying a packaging system. If a layer is needed between the adhesive and a surface as part of a structure, that layer does not need to serve as a functional barrier and can, therefore, have minimal thickness.

This system has a heat sealable liner for direct adhesion of the entire construction to a rigid PET container, with the liner located between the adhesive and the food. Using the heat sealable reclosure system with R1490 eliminates the need for the liner to serve as a functional barrier, thereby reducing plastic packaging and landfill waste as both the liner waste and clamshell lids are eliminated. The system offers a sustainable solution for packaging baked goods and any food marketed in rigid plastic containers, such as tomatoes, berries and lettuce.

Avery Dennison compliance assistance

Developing inks, coatings and adhesives safe for food contact applications can be challenging and confusing. Avery Dennison maintains a compliance team with professionals who are experts on the requirements that apply to the products we sell for food packaging and labeling. These product compliance specialists are also involved in product development to confirm the materials we use in food contact products comply with FDA requirements.

Avery Dennison also offers a product compliance program to conduct the necessary analysis of our food contact products and obtain clearances as needed. Our product compliance team is available to support converters and brand owners with food product compliance data, including migration test results and other details relative to the suitability of specific products for use with food. We provide food grade declaration and other certifications as necessary and applicable. ■

Planning ahead for compliant labelling

From bisphenol A to mineral oils

Constantly changing legislation presents an ongoing challenge to both brand owners and label converters. Regulations arise frequently, such as the REACH deadlines for 2018. There are also consumer-driven campaigns to consider – often involving as-yet unregulated components. This article considers two examples of components relevant to label safety, bisphenol A and mineral oils, one of which is regulated and the other unregulated as yet.

Regulations governing the labelling industry are extensive, and enforced by many different national and transnational bodies. Rules apply to every segment, with sensitive segments such as food and pharma facing the strictest requirements.

Complying with regulations once they are in force is mandatory. Therefore it is important to act in good time and secure a dependable source of qualified materials.

To act or not to act?

Before compliance becomes mandatory the decision to respond to emerging information on possible regulation changes, or to related consumer-drive social media campaigns, can be a challenge. Even if information and claims are incomplete, or even wildly inaccurate in some cases, brand owners must still sometimes offer an appropriate response in good time, before reputation or sales are impacted.

Above all, staying informed and ahead of the game is essential. By preparing in advance, any required transition to new materials can be straightforward. There can also be some potential competitive gains from adopting early, if a product can be promoted as 'Chem-free'.

The bisphenol challenge

An instructive example is bisphenol A (BPA), a raw material used since the middle of last century. The chemical has one of the highest production volumes across the world, and most consumers will come into contact with its products one way or another on a daily basis. It is used in the manufacture of some plastics and epoxy resins, including coatings on the inside of food and beverage containers. Most uncoated direct thermal papers contain BPA. Such papers are widely

used in the retail segment in applications such as thermal paper receipts and weight scale labels. Note that apart from some uncoated and semi-topcoated direct thermal labels, all other types of pressure sensitive labels in the Avery Dennison portfolio are typically produced without the use of BPA.

The safety of BPA has been studied most notably from the late 1990s onwards, with researchers focusing in part on its weak mimicry of the human hormone estrogen. Public concern grew over time, with a particular emphasis on plastic bottles made for feeding babies, and the potential effects on infants of ingesting BPA.

As late as 2010, a World Health Organisation (WHO) expert panel considering BPA concluded that "initiation of public health measures would be premature." Prior to this date, however, brand owners were already hearing and responding to public concerns. Manufacturers of baby products, in particular, were reassuring parents that their plastics were BPA-free.

Avery Dennison responded to the gathering concerns around BPA by offering BPA-free labelling products. The importance of not only responding to but predicting trends is illustrated by the fact that Avery Dennison quickly went on to offer additional products that contained no bisphenols of any kind (BP-free) and also entirely phenol-free products.

All of this demonstrates the power of the market, which can anticipate regulatory changes. It was only in 2015 that France finally led the way by banning BPA for direct food contact. Events moved rapidly after that: France went on to propose BPA as a (REACH Regulation) candidate substance of very high concern (SVHC). The regulation that followed sets a specific limit for BPA content in thermal papers of up to 0.02% bisphenol A (by weight) from January 2020. This limit will lead to BPA being phased out as a component added during manufacture of direct thermal papers and labels. Note that trace amounts of BPA in any type of direct

thermal paper are unavoidable, due to post- production contamination from various sources.

In Annex XVII to Regulation (EC) No 1907/2006, the following entry is added:	
'66. Bisphenol A CAS No 80-05-7 EC No 201-245-8	Shall not be placed on the market in thermal paper in a concentration equal to or greater than 0,02% by weight after 2 January 2020.

Avery Dennison offers a full range of label solutions that are made without using BPA. Additionally, the Avery Dennison labelling portfolio goes beyond regulation requirements, including direct thermal labels top-coated and uncoated materials produced without the use of bisphenol, and even solutions produced without use of phenol. These direct thermal papers are available in combination with the highest performance and most widely used adhesives for direct thermal applications (including both permanent and removable adhesives in combination with BPA-free thermal paper).

Avery Dennison is already well placed to help manufacturers find the best alternative solutions, and to be ready for the 2020 deadline.

Looking ahead – mineral oils

With the BPA story in mind, it's useful to look at the early concerns that are now starting to be expressed about the potential risks from mineral oil contamination in food packaging. The topic may be gathering pace in the same way as BPA. A 2009 recommendation by the German Institute for Risk Assessment (BfR), is also on record as saying that minimizing mineral oil exposure due to migration from food packaging was urgently needed.

Dealing with the question of mineral oils is more complicated than bisphenol A; BPA is an additive, so BPA-free products can be made by changing the formula during manufacture. Mineral oils, by contrast, are not only used as additives but are also present as a contaminant in recycled materials. They are contained in the printing inks on recycled paper, and so there is a complicated puzzle to solve. On one hand, using recycled materials is desirable for sustainability. On the other hand, we need to find a way to safely use those materials with food packaging (assuming that a risk is confirmed, and this is not yet the case for the low levels of mineral oil present in recycled packaging).

Many mineral oils pose no real threat to human health, and are in fact approved for food contact. The oils being looked at closely for possible health effects are low molecular weight mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH, including polycyclic aromatic hydrocarbons or PAH).

We are at a relatively early stage with mineral oil strategies, although the EU is now monitoring MOH in food, and in materials and articles intended to come into contact with food. As with BPA, there is a need to plan ahead. Avery Dennison is actively assessing the scale of the issue, working to understand and disseminate new information to converters and end users. We are also monitoring alternative sources of supply – for example, the US is beginning to see some de-inking taking place during the recycling process. Crucially, it is the role of a labelling material manufacturer to predict and anticipate 'what next', so that converters and brand owners are presented with answers rather than questions. ■

Small diameter labelling

Pharmaceutical containers, bottles, test tubes and syringes, are small - with typical volumes of 1-100 ml and diameters of 7-50 mm. Demand for these containers is growing rapidly, thanks to patient benefits that include dosage accuracy and sterile conditions.

Only the most advanced adhesive technology can cope with such small container diameters, and with low-energy surfaces such as polyethylene and polypropylene. Avery Dennison's small-diameter pharmaceutical portfolio offers the excellent mandrel performance that is essential for successful conversion and high speed dispensing.

Options include S692NP adhesive with exceptionally low-migration (important as plastic use grows), and S717P which minimises edge lift on low surface-energy substrates down to 10 mm in diameter.

Luminescent topcoats for syringes and vials are now available to give label converters far better flexibility in adhesive selection. Pharmaceutical manufacturers benefit from faster qualification times, since the luminescent topcoats can be combined with previously qualified adhesives.

Application areas

- Prescription medicines or drugs
- Over-the-counter (OTC) products
- Auto-injector pens for diabetics, autoimmune deficiencies and more
- Pre-filled syringes and vials
- Small diameter containers: 7-50 mm diameter
- Glass, PE and PP substrates (including treated, slip-coated or varnished)
- Low migration labels for thin-walled LDPE containers
- Any application requiring excellent mandrel performance

Key features

- Outstanding mandrel performance on small diameter containers
- Availability and change notification 12 months in advance
- Compliance with FDA and European food regulations

Meeting the pharmaceutical compliance challenge

All manufacturers of pharmaceutical packaging have to meet the challenges posed by new regulations and stronger packaging guidelines. There is growing pressure to understand rules in detail, and to make absolutely sure every package is compliant.

That means rising demand from pharmaceutical companies for customised tests and individual packaging material certification.

The Avery Dennison Pharma and Compliance Team is always on hand to give converters and pharmaceutical companies detailed information, and technical support. These are useful resources when navigating the complexities of pharmaceutical applications and making sure the end result is both successful and compliant.

Label and plastic packaging solutions should comply with the following:

- European food regulation 1935/2004/EC, including 10/2011/EU guidance on plastic materials and articles intended to come into contact with food – ISO 3826 - a norm that explains how to test plastics collapsible containers for human blood and blood components FDA 175.105 Food and Drug Administration (FDA) concerning indirect food additives, adhesives and components of coatings
- ISO 10993-5 dedicated test for vitro cytotoxicity
- ISO 10993-10 test for irritation and skin sensitization


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for soft contact lenses.
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that temporarily reduces
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200 TABLETS
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INGREDIENTS
ALLERGENS AND WARNINGS

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With our Select Solutions collection of application specific portfolios, finding the right solution is easy - just select it or create it.

Avery Dennison Select Solutions is a collection of proven application-specific portfolios designed to meet precise labeling needs. The collection offers a fast and simple route for converters looking for unique labeling solutions. All products in the collection feature low MOQs, fast shipping and are backed by our Engineered Solutions service. If we don't have a solution that works, our technical team can access readily available components to create a custom solution that does.

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Lubricant Oil

In-Line Labelling

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Pharmaceutical

Low Migration

Small Diameter

Low Temperature

Specialty

Chemical Drum

Durables

Tyre

NextGen

Industrial

Overlaminates

Tamper-evident

Polyimide

Air Egress

Cable

Automotive

Heavy Industrial

Customer Ready Durables Portfolio (UL/cUL/CSA Compliance)

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