The importance of regulatory compliance in food packaging

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Making sure a product is compliant with regulation - and that it stays compliant - is one of the top three concerns for business owners[1,2]. 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.

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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 (large retail companies) 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[3]. 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.
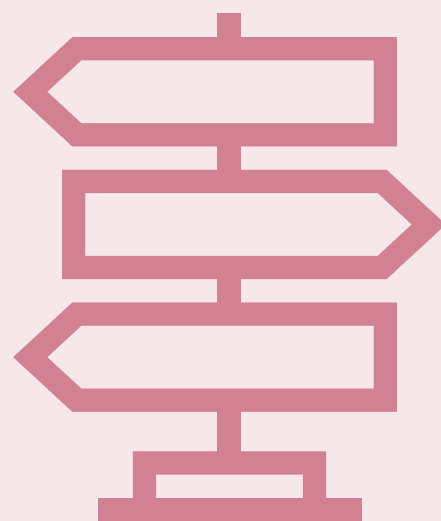
Regulatory compliance: strategy and team

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).
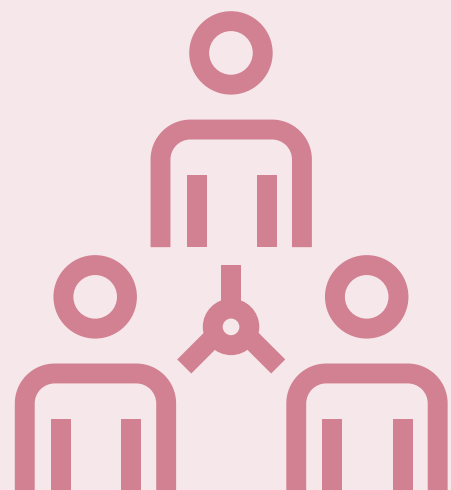
The food contact information maze - a labelling example

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?"

List of articles consulted:

1 www.adp.com/~/media/White%20Papers/TSR-TopConcernsBusiness_MKT264.ashx

2 www.leanmethods.com/resources/articles/top-ten-problems-faced-business/

3 legisway.wolterskluwer.de/en/why-small-to-medium-enterprises-find-regulatory-compliance-so-difficult

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