PLANNING TO EXPAND YOUR OVERSEAS MARKETS TO THE EUROPEAN UNION?
READ THIS FIRST!

The European Union (EU) enacted new cosmetic legislation which became effective July 11, 2013. All products marketed in the EU must be registered in compliance with the new law. There are a number of differences between the new legislation, also known as the Recast, and the previous regulation. The chief advantage is that only one Poison Control Notification on the EU Electronic Portal is required and will be directly available to all Poison Control Centers.

Under the new legislation the Responsible Person (RP) has greater responsibilities for the products it represents, including providing a legal address, holding Product Information Files and Cosmetic Product Safety Reports, issuing filings for product and poison control notifications, reporting product failures to the Competent Authority and overseeing their inspections, knowing distribution locations and assisting with public inquiries on products.

Before deciding whether to begin the process of compiling safety information and determining who should act as your Responsible Person, consider the following questions:

1. What products will be marketed in the EU? Where and to whom will they be sold?
2. Is the revenue from the sale of these products in the EU sufficient to justify the cost of preparing the product safety information and notification?
3. Is there someone who can manage this process within the company, or is a consultant needed to acquire the information for the Product Information File and Cosmetic Product Safty Report?
4. Do you have all of the information required to complete the new safety section of the PIF? (There is a checklist of page 45 of the *ICMAD Guide to European Cosmetic Regulations, 3rd Edition.)*
5. If working with a filler/manufacturer, is product safety information easily obtained from them?
6. Are the products currently compliant with the requirements of the EU Recast? If not, or if it is unknown, is there a process in place to make that determination?

If you know the answers to all of these questions and have determined that your company is ready to enter the EU market, ICMAD has a program in place to assist in the complex task of preparing the required documentation for marketing in any of the 28 countries comprising the EU. By partnering with Biorius, located in Belgium, ICMAD members can receive assistance with both legal representation and regulatory compliance.

ICMAD's EU Program Process consists of the following steps:

1. Join ICMAD.
2. Review and sign the ICMAD EU Program Participation Agreement and the Biorius Legal Representation Agreement.
3. Obtain a Certificate of Insurance, naming Biorius as the additional insured. The certificate must indicate the presence of international or foreign liability insurance coverage.
4. Payment of the fees based on volume and services being requested.
5. Gather the data and documentation required by Biorius to prepare the PIF, including label copy. If using an outside filler, request their assistance with this process. Delays in obtaining this information can increase the time until the registration can be completed.

Both ICMAD and Biorius have staff who can answer additional questions and ICMAD has member consultants who can assist in gathering data and/or providing additonal information. Contact 800-334-2623 with any questions about the process .