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Improved Methods for Determining Compliance with Global Food Contact and Food Additive Requirements through Government Industry Collaboration

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Background: Determining a manufacturer's or processor's obligations with regard to requirements applicable to the safety of food additives and food contact materials in a global market is a complex task for a large company, but especially challenging for a small or medium-sized organization. It can be equally challenging for regulators to assist stakeholders in determining compliance. Such requirements may differ in procedure and substance between countries of use. In addition, these regulations are in flux, making it difficult to keep current. Regulatory compliance is a critical control point in safety of the food supply chain of a global marketplace.

Methods: FDA/OFAS and Decernis have established a collaborative agreement and developmental project to make available an international regulatory compliance reference system. Through this cooperation between government and industry, FDA has developed and shared databases of critical information regarding food safety and FDA requirements. Using its multi-lingual document and data management technologies, Decernis has integrated this information together with other national requirements into a consistent system for keeping up to date with global food safety requirements.

Results: FDA and Decernis have developed a collaborative system - called gComply -- that is today used by both government and industry. FDA Consumer Safety Officers can use the integrated system in answering questions more efficiently. Further, FDA links the system to its internal databases, allowing greater depth in review and analysis. Domestic manufacturers, importers, and non-U.S. companies access the Decernis system, obtaining better information for assuring compliance for the development and shipment of food products within and to the United States. The project makes available more comprehensive, current information to the regulated public in an accessible form, and provides a consistent approach to determining compliance on a global basis. It also aids FDA in having more comprehensive information.

Conclusions: The collaboration of the FDA/OFAS and Decernis has resulted in a reference system that can reduce the complexity and costs of compliance, and improve the effectiveness of decisions made in marketing foodstuffs in a global marketplace.

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