Editorial

Introduction to a Special Issue of the Journal of Regulatory Science on Regulatory Applications of Portable Tools and Methods to Monitor Toxic Substances in Consumer Products

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The mission of the U.S. Food and Drug Administration (FDA) is "protecting consumers and enhancing public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products" [1]. The globalization of trade, potential presence of toxic substances (i.e., elements, metals, and/or organic compounds), the increasing problem of counterfeit products, and the huge numbers of products entering U.S. commerce pose a challenge. While it is neither feasible nor possible to test all domestic and imported products, the use of new and emerging tools to perform simple, rapid, and relatively inexpensive tests represent a new paradigm that can provide significantly improved monitoring and oversight of consumer products.

Recent decades have seen major progress in the development and application of handheld and field portable tools for rapid chemical analysis. These tools include near IR/Visible/UV, FTIR, and Raman spectrometry systems, X-Ray Fluorescence (XRF) analyzers, Laser-Induced Breakdown Spectrometers (LIBS), and Ion Mobility Spectrometers (IMS). Many of these tools have already been adopted for use by regulatory and law enforcement agencies for field screening type applications. While Mass Spectrometry (MS) instruments have had limited use in

field work due to the challenges posed by reducing their weight, size, and power requirements, techniques such as Direct Analysis in Real Time and Desorption Electrospray MS (DART-MS and DESI-MS) show great promise for rapid and reliable identification of toxic substances in complex matrices.

The scope of these field portable tools is typically multi-fold. They are most frequently used for screening or detection, which involves determining the presence of a toxic substance above an implied if not stated detection limit. They ideally are capable of performing qualitative analysis and some form of physical and/or spectral separation to provide reliable identification of the target substance(s) in complex sample matrices. In some cases, they are used for quantitative or semi-quantitative analysis to determine the analyte concentration, which can often be difficult given matrix effects and the limitations posed by a field screening environment. Providing these capabilities along with high sensitivity and selectivity, low false positive and negative rates, minimal or simplified sample preparation procedures, rapid analysis, small size, portability, and low cost poses significant challenges, especially in regards to analyzing a wide variety of "real world" samples.

This special issue describes the work of several researchers who have taken on these challenges and used these portable tools for a number of different regulatory applications. Casillas et al. describe a method based on the use of a portable XRF to quantify iron in vitamins and supplements, thus demonstrating that such portable tools can provide accurate quantitative results. Patrick Grey describes a low-cost sample preparation procedure coupled to a colorimetric method to speciate and quantify low part-per-billion levels of arsenic in rice and cereal products in the field. Mark Witkowski and coauthors describe recent advances in the use of a Counterfeit Detection device (CDx) utilizing near IR, visible, and UV spectrophotometry to identify

counterfeit drugs. Joshua Moskowitz and coauthors report on the use of portable Raman and near IR analyzers to identify adulterated food products. Sara Kern et al. describe an approach based on the use of a Direct Analysis in Real Time MS (DART-MS) system for rapid detection of opioids and drugs. Randy Self discusses a new MS-based method to monitor decomposition in seafood.

These papers represent success stories in the use of portable tools to protect the public from unsafe products and in bring the tool to the samples (instead of the more common mode of operation in which samples are brought back to a lab for analysis). The authors are to be commended for making efforts to shift the paradigm of how regulatory science is done from often *ipso facto* lab-based analysis of the chemical composition of consumer products to a more proactive model in which these products can be tested at import centers, mail facilities, and manufacturing facilities. Such work typically requires compromises to make the methods more suitable for field use, generation of validation data to assess reliability and analytical figures of merit, hands-on training to facilitate the use of these tools by non-experts in a field setting, and an overarching focus on efficiency, simplicity, and low cost. There is much to be learned from this work about developing new methods, using teams that represent both field investigators and subject domain experts, validating the methods to document their capabilities and limitations, and in recommending best practices for more efficient use of these portable tools in field settings.

Tomas Hirschfeld, a talented and prescient analytical chemist who played a highly influential role in the development of modern instrumental analysis, once wrote that "*provided there are enough samples… it become(s) possible, and indeed beneficial, to take advantage of such highly sophisticated instrumentation*" [2]. This most certainly applies to screening and

regulatory-type analyses of toxic substances in consumer products. It is hoped that the future will see increased adoption of these methods by international, federal, state, and local regulatory agencies, manufacturers and non-profit organizations to improve oversight of domestic and imported consumer products (at), reduce costs through the use of portable tools versus lab-based instruments, and provide for "sample triage" by rapidly screening large numbers of samples for toxic substances.

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