MINIMIZING DIETARY DIOXIN EXPOSURE THROUGH PATHWAY IDENTIFICATION AND REDUCTION

Richard A. Canady¹ and David J. Zorn²

1 Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, USA 20857 2 Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD, USA 20740

In 2001, the Joint FAO/WHO Expert Committee on Food Additives and Contaminants provided an assessment of dioxins in the food supply and concluded, as have others, that the dose of dioxins received by a large percentage of the world's population from the current food supply exceeds screening level hazard assessment values¹. This agreement by experts in an international forum left little doubt among regulators that the traditional approach to managing contaminant risks suggests that we must reduce dioxin exposures via food. However, substantial obstacles stand in the way of achieving those reductions. In fact, these obstacles are so substantial that they have the ironic effect of reflecting back on the process that we use to make risk management decisions and make us ask whether there are significant public health costs of regulating dioxins. There is the potential for such costs, and this situation has probably affected how governments have approached risk management of dioxins so far. While we cannot adequately address public health costs in this forum, examining the approach USFDA has taken so far and a rough outline of some obstacles and options is useful toward a discussion of efficient risk management for dioxins.

Several years ago the USFDA began a dual strategy of increased sampling and working with other US government agencies to leverage the information gained into the discovery of pathways by which dioxins enter the food supply. USFDA adopted this strategy due to the lack of information regarding the causes of variation in dioxin concentration, the costs of analyzing for dioxin in the context of resource limitations, and recognition of the need to reduce dioxin exposure where feasible. USFDA's strategy is to try to use lot-to-lot variation in dioxin levels in food and feed as an indication of variation in sources of dioxins, and focused investigations of higher sources to point the way to potentially avoidable sources.

USFDA's approach is similar in concept to the approach of the European Commission in the sense that the focus is on simple variation in dioxin levels with the overall goal of identifying and stopping avoidable sources^{2,3,4}. The EC stated, in their development of 3 tiers of guidance levels, that the levels themselves were part of a coordinated approach to remove dioxins, and that the levels were intended at least in part to stimulate the discovery of sources.

"The action levels are designed to trigger a proactive approach from competent authorities and operators to identify sources and pathways of contamination and to take measures to eliminate them."²

One difference between the US and EU approaches (beyond the promulgation of levels) is how resources are leveraged for the discovery of sources. In the EC approach, resource burden for discovery of sources can be expected to be borne more heavily by the food industry in order to

avoid their food being identified as contaminated (i.e., exceeding either the maximum or action limits). In the USFDA approach the discovery of sources is primarily the responsibility of the government in that "point in time" peaks across individual lots of food are not targeted. Instead, foods with higher levels point government investigations toward dioxin sources (or enrichment) in the animal feed production process. Those sources and practices that result in higher levels of dioxin become the target of further action.

The contrast in leveraging points to the underlying issues of resource limitation, public health and welfare costs of inefficient resource allocation (largely lost opportunity costs), and ultimately who bears the cost (in money or appropriate health equivalents) of reducing the risk posed by contamination. If managing the risk of dioxin consumption were free, we would not be here. The problem is to select an efficient option for managing the risk of dioxin in food. The choice of an efficient risk management strategy depends on both the costs and the benefits of strategy options. One strategy may focus on reducing high levels of contamination in a narrow set of products, while another strategy may cover a much larger set of products but which have a significantly lower average level of contamination. Without an investigation of both the amount of risk reduced by each option and the costs of achieving that reduction in risk, it is impossible to say which risk management option is most efficient or which is the best at achieving society's broadest goals. There are numerous dioxin reduction options available.

One option is to require that all foods where animal fat is an ingredient bear a statement that the product may contain dioxin. This would inform consumers and allow each individual to make their own risk management decision. An obvious problem with this approach is that consumers would not have information on the level of contamination in any particular package or even any class of products. More importantly, since all products with animal fat would have to bear the label, no manufacturer would have any incentive to take steps to control dioxin contamination in their products. The incentives under this system do not lead to improvements over time.

Another option is to set a maximum allowable level of dioxin in food. It is important to realize that in order to substantially affect the average body burden of dioxin within a short period, a very restrictive level probably needs to be chosen given that dioxin's half-life in the body is seven years (therefore average intake tends to be more important than peak) and that the distribution of dioxin in food is right-skewed. Establishing a level also requires that an analytical method be specified by which compliance would be determined. The level established would have an effect on what analytical methods are sufficient for the task. Lower levels require more expensive methods.

Apart from the difficulties of determining levels for various foods and analytical methods, many other issues have to be addressed. Decisions must be made about the burden of testing. Will food processors be required to test for dioxin or will all compliance testing be the responsibility of regulators? Regardless of the answer, a sampling plan must be developed. Requiring sampling by processors will achieve broader coverage throughout the food supply than will regulatory sampling, given the very limited regulatory resources available and the many competing risks associated with food.

If processors are required to sample, then the sampling regime must be suited to today's production technologies. Many foods are processed in a continuous flow from raw materials to

packaging and shipping. Sampling regimes are much more complex in the absence of identifiable batches. Requiring the artificial creation of batches is quite disruptive to the production process and costly to the economy.

If government regulators alone have responsibility for sampling, then the limited resources available for enforcement purposes will force the targeting of sampling to food products most likely to be violative. This means that violations in unexpected products are not likely to be detected. However, regulators often have an advantage in the interpretation of sampling results that individual firms do not have. By sampling products across firms with different practices or inputs, regulators can sometimes discern patterns of contamination levels that an individual processor could not see. Such patterns can suggest problems with certain inputs or practices that may be much more generalizable than for just the products sampled.

Another option is to set a maximum allowable level in animal feed in order to reduce the levels that may reach human food, but not set levels for human food. The major advantage that this option has over setting a level for human food is that the problem is being addressed closer to the source of contamination, making investigation and corrective action easier. Additionally, action can be taken at a stage of production before more value has been added to the products.

The approach of focusing on simple food and feed dioxin variation has led to reductions in the amount of dioxin entering the food supply and provided insight into how to better apply resources toward further reductions. An important public health issue to consider is whether the approach taken by USFDA is more efficient than the one taken by EC in utilization of resources toward the reduction of dioxin exposure.

References

- 1. WHO 2002. Safety Evaluation of Certain Food Additives and Contaminants, WHO Food Additive Series No. 48, WHO, Geneva, 2002.pp 451-675.
- EC 2001a. Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee. Community Strategy for Dioxins, Furans and Polychlorinated Biphenyls. EC COM (2001) 593
- Council Directive 2001/102/EC. Council Directive 2001/102/EC of 27 November 2001 amending Council Directive 1999/29/EC on undesirable substances and products in animal nutrition. Official Journal of the European Communities. 10.1.2002. L 6/45-49.
- Commission Regulation 2001/466/EC. Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs. Official Journal of the European Communities 16.3.2001. L 77/1-13.