Final Draft

Food Industry Dioxin Working Group Comments on the Environmental Protection Agency's Draft Dioxin Risk Assessment

These comments are submitted on behalf the Food Industry Dioxin Working Group (DWG) [1], a coalition of food and agricultural trade associations, which represent a broad spectrum of on-farm agricultural production and food processing in the United States. The DWG appreciates the opportunity to provide comments to the Environmental Protection Agency's (EPA) Dioxin Reassessment as a part of the agency's peer review process.

Although there have been isolated industrial accidents in which foods have been contaminated with dioxin, dioxin is not inherently a part of any food, is not added to food nor is it created during food processing. To the extent dioxin becomes a constituent of food, it is the result of environmental contamination from sources outside the control of the food industry. The environmental sources of contamination should be the focus of EPA's study – not individual foods. But given the Agency's clear intent to proceed, the DWG offers the following comments for consideration.

Today's consumers are very interested in health considerations when making dietary choices. Communicating to consumers about theoretical risks must be done with the greatest of caution, because health risks – even when in the discussion stage – can rapidly be perceived as warnings and recommendations. Therefore EPA should exercise as much thought and care as possible about the reassessment's possible impact on consumer attitudes, purchasing decisions and consumption patterns.

Problems in Methodology

In general, there are serious problems with the statistical approaches used in the reassessment – problems so serious that they render the reassessment's conclusions invalid.

The U.S. is a nation of varied landscape and climate. Major analyses of the food supply require approaches that consider seasonal, climactic and landscape variation. A comprehensive study now underway by one of our coalition's members about the source of nitrate and nitrite in the food supply involves the purchase of a wide variety of foods in supermarkets across the nation during each of the four seasons.

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[1] Trade Association List: American Feed Industry Association, American Meat Institute, American Soybean Association, Corn Refiners Association, Institute of Shortening and Edible Oils, International Dairy Foods Association, National Cattlemen's Beef Association, National Cotton Council of America, National Cottonseed Products Association, National Fisheries Institute, National Oilseed Processors Association, National Pork Producers Council, National Renders Association.

While these comprehensive approaches are commonly used by food researchers, EPA's dioxin reassessment used grossly inadequate numbers of samples. For example, only eight composite samples were collected for milk and three for eggs. EPA also failed to discuss how the average dioxin level in these samples was computed or whether the value was adjusted for regional production.

For commodities, such as beef and poultry, EPA has used a larger sample size, but these samples are not normally distributed. Instead, they are skewed, with a few large observations significantly affecting the estimate of the mean. Statistical evaluation of the data is required to determine whether estimates can be appropriately derived from the data and used in any subsequent analyses. For example, it may mean that it would be more appropriate to use medians rather than means. Or it may be that no meaningful analysis can be reliably made. These standard statistical procedures have apparently not been conducted and the DWG urges EPA officials to reconsider their methodology before reaching any conclusions.

The data on residues in fish are extremely outdated and are derived from fish that are not representative of the seafood that Americans eat today. To make matters worse, while the Agency notes that residues of dioxin are declining in the environment generally, they assume no decline in fish. Such a notion is completely flawed and these data should be disregarded.

Further, measuring the presence of a component of food in the picogram/kg level (ppq) is heroic, but impractical and misleading. At these levels, the DWG expects very large analytical variation so that it would be difficult to determine whether an apparent reading represented a residue or system "noise." No evaluation to describe the analytical variation is presented. Certainly the variation, if expressed as the standard deviation, would be larger than the range of values reported. The DWG would further expect that the compounds would be bound in such a way as to be biologically unavailable in most foodstuffs.

Beyond the general statistical weaknesses inherent in the report, the Agency is deviating from its own standard practice, which requires adequate data collection before regulatory conclusions are made. EPA routinely rejects petitions for regulatory decision-making when there are insufficient numbers of samples to ensure that the data are representative. For example, the Office of Pesticide Programs requires many more samples than are used in the Dioxin Reassessment to evaluate the presence of pesticides in foods. Likewise the Office of Water bases its regulations on reliable estimates derived from large sample sizes. Why should the dioxin reassessment be any different?

Finally, it is apparent that the EPA's estimates -- even assuming 100% biological availability and no analytical variation -- are more a function of the values one selects for those congeners without detectable residues than where one sees detectable residues. For example, estimated exposure varies from 2 to 4-fold, depending on how samples without detectable residues are handled in the assessment. In using this flawed approach, EPA is not just chasing ghosts, it is creating ghosts to chase.

Consumer Practices

Consumer consumption practices are also not adequately characterized by EPA. The values that were used in the estimations of consumer intake made a series of assumptions:

- Residues that were present in the raw samples were still in the food as consumed even though the foods were cooked. The report does not adequately discuss the impact that cooking would have on exposures to dioxin.

- The report states that residues in fish filets are expected to be lower than those detected in whole fish, yet the assessment uses whole fish residues. Americans consume a much greater quantity of fish filets. So why the reliance of whole fish residue data?

- The impact of processing was reported but then ignored in the intake estimation. Why?

- Although there is some discussion of the value to use when no residues were detected, the actual intake estimates used only the higher concentration estimates. Again, why?

It is the view of the DWG that the overall estimates of dioxin intake via foods would decline significantly if the assessment were conducted to realistically simulate consumer practices in food preparation.

Furthermore, in estimating exposures the assessment has relied on default consumption estimates and default estimates of body weights. The source of the default values is not apparent. Regardless, neither of these assumptions is appropriate – or necessary. The U.S. Department of Agriculture collects detailed food consumption data that include body weights and allow for refined estimation of the consumption patterns of U.S. consumers. These are the proper data to be used and the DWG urges the Agency to recalculate based on these more accurate numbers.

The DWG reviewed the available documents regarding levels in food in some detail. The mechanics of calculating exposure to residues of dioxin are over-simplified and out-dated. Better techniques are currently available and are widely used by other programs within EPA. The DWG strongly encourages the EPA to use data regarding the impact of processing and cooking on dioxin levels in the actual risk assessment.

Finally, EPA is forecasting risks over a life span of 70 years. Therefore, it is appropriate to include the anticipated decline in residues of dioxins as a result of controls that have been implemented. This is particularly important since animals raised for human consumption have a definite and relatively short life span. This will significantly decrease the estimates of "lifetime" risks to consumers.

The DWG notes EPA has no regulatory jurisdiction over human food or animal feed products. The dioxin reassessment's focus on food therefore seems inappropriate and beyond the scope of EPA's charge. If any reassessment is required, it should be the primary responsibility of the Food & Drug Administration and/or the U.S. Department of Agriculture, entities with statutory responsibility.

Conclusion

In conclusion, the DWG believes that grossly inadequate exposure and consumption data, coupled with badly flawed statistical approaches, render the Dioxin Reassessment in its current form irrelevant to human health. Yet that is just how it will be perceived by the consuming public and the media if it is released in its current form. It is EPA's responsibility to revise this report in consultation with statisticians with expertise in food analyses who can help the Agency draw meaningful conclusions. To do otherwise will mislead the public and potentially create a health scare that doesn't exist.