

Appendix C: Response to Comments from 60-Day Federal Register Notice

We responded with individual letters to the individuals/institutions offering comments as a result of the Federal Register 60-day announcement of our intent to conduct this research.

Dennis Paustenbach of ChemRisk, LLC provided many reasons why the proposed research was not necessary. An important argument was that his company was not able to replicate some findings of NIOSH analyses of company-supplied spirometry and job title/work area data using different modeling techniques. However, ChemRisk's criticism of NIOSH statistical techniques were incorrect in that we did not use methods that would be influenced by correlated data from serial pulmonary functions. ChemRisk confirmed that an excess of restrictive spirometric abnormalities existed in the production workforce under spirometry surveillance. However, ChemRisk argued that the subgroup with lower potential for flavoring exposure among the production workforce was a control group with no exposure in their models, whereas substantial evidence existed that nearly all had flavoring exposures. ChemRisk's assumption of no exposure for the subgroup with lower potential for flavoring exposure resulted in showing that no exposure-response existed. Their models did not address the exposure-related excessive decline in lung function during employment that we had demonstrated with SPIROLA, a NIOSH free software product. We outlined these issues for ChemRisk and justified our continuing with the proposed research by our disagreement with their mis-characterization of our methods as flawed.

Mr. Paustenbach also had many comments regarding limitations of our draft questionnaires, which we have modified in partial response. He also made many comments previously submitted in response to the 2011 draft NIOSH criteria document for recommended standards for diacetyl and 2,3-pentanedione, criticizing the conclusions from the published epidemiology, animal toxicology, and risk assessment that form the basis of the proposed recommended standards. These comments are not directly pertinent to the proposed study and will be responded to in the public record when the criteria document is revised and released in late 2013. We indicated this in our letter response.

John Hallagan of the Flavor and Extract Manufacturers Association expressed concern that the early draft document that he had requested from CDC was too incomplete to provide adequate review. We provided him information about the two health hazard evaluation reports for the two workforces subject to further study and where to find them. Mr. Hallagan pointed out that our earlier publications did not explore the occurrence of restrictive spirometric abnormalities in flavoring-exposed populations, and we indicated how subsequent publications motivated us to readdress our historical omission of looking at a broader spectrum of possible lung disease in this current research proposal. Mr. Hallagan argued that we should not be conducting further research until the draft Criteria Document was finalized, and we pointed out that this research will not delay the efforts on the Criteria Document since the co-investigators conducting the research are not working on the Criteria Document.

Both individuals/institutions provided helpful queries and comments in our preparation of the final OMB package to clarify our objectives, methods, and questionnaire instruments in the proposed research.