Office of Advocacy
www.sba.gov/advocacy

Advocacy: the voice of small business in government

Testimony of

Charles Maresca
Director of Interagency Affairs
Office of Advocacy
U.S. Small Business Administration

U.S. House of Representatives
Committee on Small Business and
Committee on Science, Space, and Technology

Date:	April 25, 2012
Time:	10:00 a.m.
Location:	Room 2318 Rayburn House Office Building Washington, D.C.
Topic:	How the Report on Carcinogens Uses Science to Meet its Statutory Obligations, and its Impact on Small Business Jobs

Created by Congress in 1976, the Office of Advocacy of the U.S. Small Business Administration (SBA) is an independent voice for small business within the federal government. The Chief Counsel for Advocacy, who is appointed by the President and confirmed by the U.S. Senate, directs the office. The Chief Counsel advances the views, concerns, and interests of small business before Congress, the White House, federal agencies, federal courts, and state policy makers. Issues are identified through economic research, policy analyses, and small business outreach. The Chief Counsel's efforts are supported by offices in Washington, D.C., and by Regional Advocates. For more information about the Office of Advocacy, visit ***http://www.sba.gov/advocacy****, or call (202) 205-6533*

409 3rd Street, SW · Washington, DC 20416 · 202/205-6533 ph · 202/205-6938 fax
www.sba.gov/advocacy

Chairman Graves, Chairman Hall, Ranking Member Velázquez, Ranking Member Johnson, Members of the Committees: good morning and thank you for the opportunity to appear before you today to discuss small-business concerns relating to the Department of Health and Human Service's Report on Carcinogens (RoC).

As Director of Interagency Affairs at the Office of Advocacy (Advocacy), I manage a team of attorneys who works with small businesses and federal government agencies during the rulemaking process to reduce regulatory burdens on small businesses. Advocacy is an independent office within the U.S. Small Business Administration (SBA) that speaks on behalf of the small-business community before federal agencies, Congress, and the White House. The views in my testimony do not necessarily reflect the views of the Administration or the SBA and this statement has not been circulated to the Office of Management and Budget for clearance.

After reaching out to small businesses, Chief Counsel for Advocacy Winslow Sargeant submitted a letter to the Department of Health and Human Services (HHS) on November 22, 2011, conveying small-business concerns with the Report on Carcinogens, Twelfth Edition (12^{th} RoC). These concerns are primarily twofold: that substances have been listed in the RoC based on inaccurate scientific information, and the peer review and public comment processes need improvement.

The Report on Carcinogens serves an important federal purpose. Small businesses and the public rely on the scientific integrity and rigorous process underlying the chemical risk characterizations the report contains. To this end, Advocacy continues to strongly support the President's call for sound science. The President's 2009 Memorandum on Scientific Integrity states "Science and the scientific process must inform and guide decisions of my Administration … The public must be able to trust the science and scientific processes informing public policy decisions." This memorandum was later followed by Executive Order 13563 which states that "Our regulatory system must protect public health, welfare, safety, and our environment, while promoting economic growth, innovation, competitiveness, and job creation."

Accurate and credible scientific assessments are vital for small businesses that provide products derived from chemicals in the marketplace. Listing a substance in the RoC has the potential to substantially curtail its use. This is also true when a substance is mislabeled as a carcinogen, or even as a potential carcinogen.

In this instance, small businesses may experience economic hardship. These include the following:

- Reduced demand for the product in American and international markets by businesses and consumers;
- an increase in the likelihood of additional regulations;
- an increase in the cost of insurance and worker's compensation premiums;
- increasing sourcing costs; and
- increased tort litigation.

Technical labels used in the RoC can be misinterpreted and lead to questions about the true nature of risks to health and safety. For example, although the RoC lists substances as "reasonably anticipated to be a human carcinogen" or "known to be a human carcinogen," the RoC includes the caveat that "listing of substances in the RoC only indicates a potential hazard and does not establish the exposure conditions that would pose cancer risks to individuals in their daily lives."[1] In other words, a listing in the RoC flags a potential hazard but does not mean that the substance presents a risk to human health. However, this distinction is not conveyed to or understood by consumers. Consumers and businesses are likely to be more aware of whether the substance is listed than the disclaimer.

As this caveat highlights, the RoC listings are based on a hazard assessment, which is an assessment of anything that can cause harm, and not a risk assessment, which can provide an estimate of the number of persons who may be harmed and the degree of that harm.

[1] National Toxicology Program, U.S. Department of Health and Human Services, Report on Carcinogens, Twelfth Edition (2011), p 3.

Many chemicals, such as styrene and formaldehyde, occur naturally in the environment in food, our bodies, and water, but in much smaller doses than would cause cancer. The RoC's use of the hazard assessment does not indicate the dose or conditions needed to cause cancer in humans.

Advocacy has met and spoken with small businesses who have experienced some of the impacts listed above. For example, some small businesses have already reported that the 12th RoC's listing of styrene as "reasonably anticipated to be a human carcinogen" has led to increases in insurance and worker's compensation costs.

Further, while the RoC is not itself a regulatory document and was not meant to form the basis of regulations, some entities use the RoC to inform their rulemaking. For example, the RoC has led to additional regulation in California, where under Proposition 65, the Safe Drinking Water and Toxic Enforcement Act, a listing in the RoC may trigger a listing in California.

Small businesses seek to improve the scientific practices supporting the RoC listings. First, because it is a hazard-based listing, not a risk-based listing, the RoC has little value for estimating actual cancer risk to the general public even though the listings appear to indicate that there is a cancer risk. Second, the National Toxicology Program's (NTP) weight-of-evidence analysis does not appear to account for inconsistent or contradictory data.

Regarding the listing of styrene as "reasonably anticipated to be a human carcinogen" one recent European Union review of the styrene health effects database determined that styrene should not be classified or regulated as a carcinogen. [2] A second report in 2009 by a blue-ribbon panel of internationally recognized epidemiologists concluded that the "available epidemiologic evidence does not support a causal relationship between styrene

[2] European Chemicals Agency, *European Union Risk Assessment Report: Styrene* (2008), *available at* http://echa.europa.eu/doc/trd_substances/styrene/rar/trd_rar_uk_styrene.pdf.

exposure and any type of human cancer."[3]

Further, the University of Alabama's Dr. Elizabeth Delzell, a styrene researcher, argues that there "is not sufficient science to conclude that styrene causes lymphoma, leukemia or other cancers."[4] Also, the International Agency for Research on Cancer decided to list styrene as a "possible" and not a "probable" carcinogen in a 2002 review.[5]

The RoC's listing of formaldehyde as "known to be a human carcinogen" for leukemia contradicts the National Academy of Sciences' (NAS) recent independent review of the Draft Integrated Risk Information System's (IRIS) Review of Formaldehyde. NAS found that the Environmental Protection Agency's own IRIS scientific evaluation of formaldehyde did not support EPA's conclusion that formaldehyde caused blood cancers. It is not clear if any of these reports or studies were factored into the RoC listing determinations for styrene and formaldehyde.

NTP could strengthen its scientific data and increase credibility by adopting a more robust weight-of-evidence analysis to ensure that the full range of scientific studies are considered so that the RoC decisions are made with the most comprehensive and accurate scientific analysis. Such an analysis would be more transparent and would ensure greater scientific credibility.

Small businesses are also concerned with the 12th RoC's preparation process, particularly regarding peer review and public comment. The 12th RoC process did not provide sufficient opportunity for meaningful peer review. According to small businesses, there was inadequate dialogue between NTP and the peer reviewers, lack of peer reviewer

---

[3] Boffetta *et al*, Epidemiologic Studies of Styrene and Cancer: A Review of the Literature, 51 J *Occup Environ Med*. 1275, 1275-87 (2009).

[4] Letter from Elizabeth Delzell, researcher, University of Alabama, to Barbara Shane, executive secretary, Board of Scientific Counselors, National Toxicology Program (Feb. 5, 2009), *available at* http://www.box.net/shared/static/slm4m8tp7a.pdf.

[5] International Agency for Research on Cancer (IARC), World Health Organization (WHO), *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Some Traditional Herbal Medicines, Some Mycotoxins, Naphthalene and Styrene*, (2002), *available at* http://monographs.iarc.fr/ENG/Monographs/vol82/mono82-9.pdf.

access to public comments, inadequate time and resources to perform the review, and inadequate NTP response to peer review comments.

Although the 12th RoC preparation process included several opportunities for public comment, small businesses found that NTP disregarded or did not respond meaningfully to their comments. Because public comment is the primary method by which small businesses can contribute to the RoC's preparation process, it is important that such opportunities be meaningful and include timely response to public comment.

Small businesses are concerned with NTP's recent review of the 12th RoC preparation process for three reasons: the review process needs improvement; the review of the 12th RoC preparation process was a process-based review only and did not address any substantive scientific concerns; and the new preparation process for the upcoming 13th RoC should bolster opportunity for peer review or require NTP response to peer review and public comment.

Notably, the 12th RoC review process has resulted in two positive changes: One additional opportunity for public comment and two additional opportunities for interagency comment have been added.

Advocacy commends the improvements NTP has made. Advocacy looks forward to working with NTP to improve the review process. Specifically, the review process should address the substantive scientific concerns involving the weight-of-evidence analysis. The process should also increase the number of peer review opportunities and provide for meaningful dialogue and NTP response to peer review and public comments.

Considering continued scientific advances in both the understanding and control of potentially carcinogenic substances, it also is important for NTP to have a robust process for reviewing substances for delisting. Small businesses seek to improve the process by which chemicals are listed and delisted.

This need to improve the process is highlighted by the attempt to delist glass wool which was listed as "reasonably anticipated to be a human carcinogen" in the 7th RoC published in 1994. In 2004, after ten years of research, North American Insulation Manufacturers Association nominated glass wool for delisting. The matter was not concluded until the publication of the 12th RoC. However, instead of delisting the substance in the 12th RoC, NTP modified the definition of glass wool to exclude certain types of glass wool that are "not biopersistent" in the lung. In the 12th RoC, glass wool is still listed as "certain glass wool fibers (inhalable)." This process of "delisting" non-biopersistent glass wool fibers took over 20 years.

Small business relies on accurate, credible, and reliable science. NTP's review of the 12th RoC demonstrates that it is aware that there are concerns with the RoC. However, NTP needs to make further improvements in order to ease concerns. To the extent that NTP can improve the substantive underlying science, the preparation process, and the clarity of the listings of the RoC, there will be an important and measurable burden reduction on small businesses.

I would like to thank you once again for inviting me to speak to you today. I commend the Committees' interest in improving the RoC, as well as reducing uncertainty in the RoC listings and fostering their legitimacy.