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Environmental Health & Safety

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<u>Life Technologies' statement to be delivered at the California</u> <u>Environmental Policy Council (CEPC) public hearing on 10/27/10</u>

I'm Janet Martinez, Senior Regulatory Analyst and a toxicologist with Life Technologies; a company which employs over 3000 Californians at its global headquarters in Carlsbad and sites in Foster City, Pleasanton, and Benicia, CA.

Life Technologies is a global biotechnology tools company dedicated to improving the human condition. Our systems, consumables and services enable researchers to accelerate scientific exploration, driving to discoveries and developments that make life even better. Life Technologies' customers do their work across the biological spectrum, working to advance personalized medicine, regenerative science, molecular diagnostics, agricultural and environmental research, and 21st century forensics. We employ approximately 9,000 people world-wide, have a presence in 160 countries, and possess a rapidly growing intellectual property estate of approximately 3,900 patents and exclusive licenses. Our products are used in nearly every major academic and commercial research laboratory in the world.

Life Technologies is employing green chemistry practices with numerous projects in the pipeline. We invite you to visit our website at www.lifetech.com/responsibility to learn about some of our successes in applying green chemistry principles.

Life Technologies appreciates the participatory nature of the proceedings leading up to the Green Chemistry Proposed Regulation for Safer Consumer



Products Alternatives under consideration today. However, we share many of the concerns voiced throughout these proceedings regarding the overly broad scope of the regulations, the breadth of which will unavoidably result in a significant adverse impact on public health through the delay or disruption of critical scientific research into treatments/cures for multiple, serious disease states. As all present well know, the actual discoveries themselves – drugs and devices developed with our research tools - have been exempted from these proceedings.

The stated intent of the regulation in section 69301.1(d) is the prioritization of products and chemicals posing the greatest public health and environmental threats, which are most prevalent in commerce, and have the greatest exposure potential. In light of that three-part standard – (i) "greatest public health and environmental threat," (ii) "most prevalent in commerce," and (iii) "greatest potential exposure," biotechnology products would be a near-zero priority for regulation. A more thoughtful framing of a manageable scope of defined "consumer products" is worthwhile to avoid negative economic and public health consequences.

For example, the draft regulation encompasses biotechnology research and development tools and chemicals used to develop many of the therapeutics and devices which themselves are specifically exempted by the legislation. Here are just a few examples of our products beneficial to public health falling under the regulations' broad definition of consumer products:

• Kits to detect H1N1 virus, food pathogens, and water contamination



- Forensics and human identification tools and kits used for solving crimes and combating human trafficking
- Tools used to research underlying mechanisms of disease, including genetic diseases
- Products used to identify candidate sources of biomass and products for conversion of biomass to biofuel.

The negative financial impact of these regulations is difficult to estimate but is likely to be substantial. If reformulation was required for kits used by government, academic, and biopharma entities conducting regulated testing and research, there would be a financial cascade effect. In all likelihood, if a Life Technologies product did become subject to an alternatives assessment, the intuitive conclusion would be that benefits of the product outweigh the risks. Life Technologies products are used in extremely low quantities with low potential for exposure, and by a relatively small subpopulation (mainly technically trained scientists involved in research and using Prudent Laboratory Practices). The likelihood for exposure to sensitive subpopulations is even lower. Meanwhile, the lengthy alternatives assessment process would divert resources away from developing other beneficial products.

On the basis of all these factors as well as concerns raised by the Green Chemistry Alliance, we unfortunately cannot support promulgation of the regulations as written. Thank you for your consideration.