To Whom It May Concern:

The Global Industry Council for FluoroTechnology (FluoroCouncil) appreciates the opportunity to submit comments on the review of the National Industrial Chemicals Notification and Assessment Scheme (“NICNAS”) that is being conducted as a Better Regulation Ministerial Partnership between the Minister for Finance and Deregulation and the Minister for Health and Ageing. We welcome this review at the Ministerial level and offer the comments below for consideration.

The FluoroCouncil is a global membership organization representing the world’s leading manufacturers of fluoropolymers, fluorotelomers, and other fluorinated surfactants and surface property modification agents. The FluoroCouncil has a fundamental commitment to product stewardship and, as part of its mission, addresses science and public policy issues related to fluoro-technology. In addition, there are FluoroCouncil members that actively participate on the NICNAS Technical Working Group on Perfluorinated Chemicals.

The solicitation for comment on the NICNAS Review specifically asks commenters to identify potential case studies that could be used to “illustrate/clarify key issues” regarding current NICNAS policy and procedure. In response, FluoroCouncil recommends that the NICNAS Review examine how new products that would substitute for long-chain perfluorinated chemicals (“LCPFCs”) have been, and are being, assessed and regulated by the Australian government. The substitutes for LCPFCs offer a particularly valuable topic for case-study analysis because there is a history of NICNAS regulation of these substances that extends back to 2005, including policy issues about these materials that are currently before the agency. Many of these issues are related to the topics raised by the NICNAS Review, as well as the recommendations of the Productivity Commission Research Report: Chemicals and Plastics Regulation, July 2008 (“Productivity Commission Report”).

2 A definition of long-chain perfluorinated chemicals can be found at the OECD Web Portal on Perfluorinated Chemicals: www.oecd.org/ehs/pfc.
The shift that is occurring from LCPFCs to alternative materials, primarily short-chain substances and other fluorochemicals, is an example of industrial innovation, carried out in collaboration with government, in the face of uncertainty about risks to public health and the environment. Concerns about certain LCPFCs, most notably perfluorooctane sulfonate (“PFOS”) and perfluorooctanoic acid (“PFOA”), arose over ten years ago. These substances have now been the subject of substantial research, multiple data collection efforts, several governmental risk assessments and risk management actions by regulatory agencies in several countries. Nonetheless, there still is not a global consensus among governments about the significance of the risks presented by LCPFCs.

The leading manufacturers of these substances, however, did not wait for such a global consensus on risk to develop before responding to public and customer uncertainties about the scientific and regulatory status of LCPFCs. Both as a matter of product stewardship and one of reducing uncertainties for customers, these companies invested substantial resources in the development of technologically effective alternatives to the LCPFCs that also offered health and environmental benefits in the form of improved hazard and exposure profiles.

Government voluntary programs have encouraged these efforts, and there have been frequent consultations between manufacturers and government agencies on the health and environmental profiles of the emerging alternatives to the LCPFCs. Specifically, these alternatives have been reviewed under new chemical review programs comparable to the NICNAS program and permitted into commerce for a wide range of uses, subject to additional information collection obligations. The LCPFC alternatives that have successfully passed through these regulatory reviews are now moving into global commerce. NICNAS has reviewed some of these alternatives and will be reviewing several more over the next several years. Thus, it is timely for the Australian government to examine, at a strategic level, how it will respond to this important technological transition.

The NICNAS approach to assessing alternatives to LCPFCs has raised policy and scientific concerns in four primary areas:

A. Risk Assessment

NICNAS has clearly articulated that its policy is to evaluate new chemical substances based on the well-established principles of risk assessment that include evaluation of hazard and exposure information to determine the risks of those chemical substances. (See the “Our Approach to Risk Assessment” section of the NICNAS Website.) This approach, however, was not used in 2005 as the basis for the NICNAS determination that the LCPFC alternative perfluorobutane sulfonate (“PFBS”) should be banned from dispersive uses. In that case, the NICNAS assessment determined that PFBS was “not bioaccumulative or toxic to aquatic organisms, however it is persistent, and levels may build up and be distributed widely in the environment over time.” Based on this conclusion, NICNAS placed an annotation on the Australian Inventory of Chemical Substances (“AICS”) limiting all “dispersive” uses of the substance.

This NICNAS decision to impose broad risk management measures on PFBS was not based on important information related to the hazards of the substance, its behavior in the human body or the potential for exposure to the substance in specific applications. Based on draft documents that have recently been shared by NICNAS, it appears that a similar approach will be pursued for other LCPFC alternatives, including alternatives that may degrade to form short-chain perfluorocarboxylic acids (PFCAs) with 6 carbons or less. This is particularly problematic because there is a growing body of toxicity data on short-chain perfluorocarboxylates, such as perfluorohexanoic acid (PFHxA) and perfluorobutanoic acid (PFBA), and this scientific information certainly warrants consideration before risk management measures are imposed.
The policy implications of the NICNAS approach to these LCPFC alternatives is potentially profound. Besides constraining Australian access to the strategic value of the LCPFC alternatives, a regulatory strategy that bans dispersive uses of chemicals based solely on their environmental persistence would have profound impact and would ignore critical scientific information. The physical world is necessarily made up of elements (e.g., metals) and compounds (e.g., glass, concrete) that are by definition “persistent”. In addition, critical technology often demands the use of materials that are resistant to harsh conditions (e.g., heat, light, chemical insult), meaning that such materials must be very stable and so maintain some level of environmental “persistence”. A ban on all environmentally persistent chemicals from dispersive uses would yield profound economic and social changes in Australia and would be fundamentally inconsistent with globally recognized principles of scientific risk assessment.

B. Alignment with Global Policies

We are not aware of any other government in the world that has, or is contemplating, a broad ban on the use of the LCPFC alternatives in all dispersive uses. So, it appears that the Australian government is pursuing a unique position. Ironically, it is a position that will tend to perpetuate the use of LCPFCs, such as PFOA, which are not facing a ban in Australia.

Our experience indicates that other leading governments are taking a different approach. The members of FluoroCouncil have worked extensively with the U.S. government in its review of LCPFC alternatives under the Toxic Substances Control Act (“TSCA”). As reported by the U.S. Environmental Protection Agency (“EPA”), over 150 alternatives to the LCPFCs have now been reviewed by EPA and cleared for commercial use; many of these short-chain alternatives contain four or six carbon perfluoroalkyl moieties. As an example, EPA’s review of the available hazard and exposure information on short-chain chemistry that may degrade to form perfluorohexanoic acid or shorter chain PFCAs led them to conclude several years ago that these alternatives offer “a different and less toxic profile” than PFOA. Based on this conclusion, EPA has required manufacturers to generate additional toxicity, fate and transport, and exposure information about these alternative short-chain substances, but has not restricted uses of the substances. In short, the prevailing approach among other governments is to allow LCPFC alternatives into commerce while obligating manufacturers to conduct further testing, triggered by production volumes, to inform further refinement of the health and environmental profiles of these substances over time.

Given the interest of the NICNAS Review in assessing how current policies compare to “international best practice,” the situation with the LCPFC alternatives becomes a particularly useful case study.

C. Consideration of Technological and Economic Benefits

Fluorochemicals are high-value materials because they offer performance characteristics such as chemical and thermal stability, high dielectric coefficient and oleophobicity that cannot easily be replaced.

These substances have provided substantial benefits in an array of existing applications from high technology industries (e.g., aerospace, semiconductors) to consumer product industries (e.g., textiles, paper). New applications are also being developed for industries that are part of a sustainable future, including areas like solar energy, fuel cells, next-generation automobiles and low-water-consumption industries.
It is important that these potential benefits be weighed before the Australian government reaches a risk management decision to bar these substances from entry into the economy for dispersive uses. NICNAS does not evaluate the potential technological and economic benefits of a new substance as part of its review. This limitation of the NICNAS process was a subject of concern in the Productivity Commission Report (at p. 63). Specifically, the Commission noted that the imposition of use restrictions by NICNAS through annotations on the AICS prevents the kind of regulatory impact assessment that the Australian government generally conducts before taking a risk management action that might have important societal consequences.

D. Regulatory Strategy and Tools

The NICNAS approach to LCPFC alternatives also raises several examples of specific regulatory issues that warrant attention. As noted previously in this letter, the 2005 decision to restrict the uses of PFBS was implemented through an annotation on the AICS. Recommendation 4.3 of the Productivity Commission Report recommends that the annotation authority “to ban or phase out chemicals” should be removed from NICNAS. Since an action by NICNAS to ban broad categories of use for a particular chemical is a variation on such a ban authority, the experience with the LCPFC alternatives is directly relevant to that recommendation.

There also are substantial questions about how NICNAS would define “dispersive” (banned) and “non-dispersive” (permitted) uses. For example, it is not clear what stages of a chemical’s life cycle (manufacture, processing, use, or disposal) are relevant when considering whether a particular application falls into the “dispersive” category. There are questions about whether a material incorporated into permanent structures (e.g., paints, electrical cables) represent “dispersive” uses. If the distinction between dispersive and non-dispersive uses is to become a centerpiece of the Australian regulatory strategy for LCPFC alternatives and other chemicals, the specifics of these definitions, and their potential impact, should be rigorously analyzed and discussed.

It is also important for Australian regulatory authorities to consider the business challenges facing companies when they consider adopting new technologies and materials. It is rare that there are “drop-in” substitutes for critical materials in industrial production. Transition to new materials often requires significant performance testing, new equipment and adjustments in plant practices, including those affecting worker safety. Before making such investments, companies need to have clear signals from government agencies that a new material is acceptable for its intended use. Policies suggesting that a material may be allowed only on a tentative or interim basis usually stifle adoption of that material for commercial use, which in this case makes it difficult to replace chemicals of greater concern.

We again wish to thank the ministries involved in the NICNAS review for this opportunity to comment. For the reasons described above, FluoroCouncil believes that the Australian government’s approach to the LCPFC alternative products would offer an excellent case study for examining how NICNAS policy and procedure responds to important new technology. FluoroCouncil and its members would be happy to work with NICNAS, and any other relevant parties, to help develop the information and analysis that would make such an effort productive.

Please contact me at jessica_steinhilber@fluorocouncil.com or +1-202-249-6737 with any questions to further discuss these comments. Thank you for your attention to this matter.

Sincerely,

Jessica S. Steinhilber
Executive Director