Submission to NICNAS Consultation Paper 2

6th April 2016

Introduction

It is immediately clear from the consultation paper that the driver of these reforms is industry. For example, NICNAS states that "some stakeholders suggested that the reforms would not result in an improvement on the status quo and sought further information about how the reforms would reduce regulation and streamline existing processes, enabling faster access to market for new safer chemicals." (p. 13)

The vast majority of proposed changes to current regulations represent a reduction in regulation and benefit industry – not society more broadly. These changes are not supported by evidence that they are needed or that they will improve public health and environmental outcomes.

The notion that an already weak system of regulation and assessment can possibly be improved through these measures is clearly false.

There is little analysis or evidence of the problems that justify these deregulatory measures - except that industry complains about regulatory burden. There is no analysis as to whether a regulatory burden exists. There is no analysis of current levels of exposure to industrial chemicals and the environmental and health impacts associated with such exposure to a wide variety of chemicals. There is no analysis of the degree of uncertainty regarding impacts because of the approximately 30,000 untested chemicals currently permitted on the market. This information is critical as reform must occur in the context of present realities, including levels of exposure, levels of risk, levels of uncertainty and the scale and types of impacts that are or may be occurring.

This proposal contains a significant element of voluntary or self-regulation. There is substantial evidence that in the vast majority of self-regulatory approaches fail to meet promised outcomes or legitimate public expectations. If self-regulation is to be used, it should be mandatory, enforceable and enforced and subject to regular audits and review. The proposed levels of audit and review are not sufficient to ensure an efficient self-regulatory system.

NICNAS's admission (p. 26) that these deregulatory moves do not conform to best practice internationally is critical. While other countries move towards more sophisticated metrics for assessing the impacts of chemicals in different circumstances, this proposal is moving in the opposite direction.

These proposed changes reflect a pro-industry bias that is deeply concerning. While lip service is paid to environmental protection and human health, there is no analysis of how these measures will improve current environmental or public health outcomes. Instead, this proposal appears to further entrench a destructive and dangerous system of permitting chemicals with little assessment and little oversight.

This is a deeply disappointing document.

Specific comments

Part C—Key changes since Consultation Paper 1

Friends of the Earth (FoE) oppose the proposed change in the definition of direct release to the environment (p. 11, Attachment A). NICNAS proposes to "to ensure that only chemicals with releases to the environment of a significant nature are captured in the definition." Attachment A makes it clear that 'significant' is purely a volume based definition. Ecologically, this is a deeply crude approach to environmental protection.

FoE support the 100% presumed direct environmental release for cosmetics and domestic products (p. 11).

FoE oppose the "greater acceptance of data from similar chemicals (analogues)" (p. 11). This is similar to the discredited notion of substantial equivalence and does not form a basis for ensuring chemicals are safe for human health or the environment.

Part D—Impact of the reforms and changes in terminology

FoE oppose the dramatic reduction in the number of chemicals subject to assessment. In order to even begin to justify such a position, a thorough inventory of chemical presence and analysis of the environmental and human health impacts would be required. This has never been done. In fact, in light of the number of unassessed chemicals in the environment and to which humans are exposed it is doubtful it could ever be done.

The reduction in reporting requirements is also problematic. There is already too little information regarding the quantities of chemical used, where the use occurs, exposure pathways and how this data informs risk assessments. A compliance statement is simply useless from any regulatory or environmental or health perspective. FoE recommends an increase in the data that must be reported, more effective use of that data by NICNAS and other regulators, as well as open access to that data.

FoE oppose reductions in toxicological or other testing and opposes the so-called flexible approach to data requirements. This appears to be little more than a euphemism for reduced data requirements.

FoE oppose the increase in thresholds for pre-market assessment. One of the ways in which chemicals are being made 'safer' is greater toxicity and lower doses – meaning less of a chemical is being used but not necessarily reducing the hazards associated with that chemical. The lowering of the threshold – as with the volume based hazard matrix – is simply not justified from a scientific or ecological perspective.

FoE oppose the ≤1 per cent concentration standard for the same reasons. The assumption that 1 per cent represents a safe threshold for environmental and human health exposure is both arbitrary and unsupported in the discussion paper.

Part E— Categorisation of new chemicals and the risk matrices

The use of a risk matrix may oversimplify the nature of risks that should be considered. For example, there are a variety of risks associated with exposure of a variety of organisms and systems to industrial chemicals, including mortality, morbidity, cumulative, interactive and long term impacts to be considered as well as uncertainty.[i]

FoE agree with NICNAS's statement that "a data gap does not confirm the existence of a specific hazard, but does not allow an assumption that there is no hazard" (p. 19). While FoE support the position that "it is the introducer's responsibility to either source or generate the information if it is a requirement for the exposure band into which the chemical falls," the nature of this obligation is not clear. It appears that an absence of data will result in the chemical undergoing assessment by NICNAS but not necessarily in the data gap being filled. Nor is it clear what criteria is to be applied to data gaps and the extent of the obligation to fill them. For example, if there are no long-term feeding studies for carcinogenicity, toxicity, genotoxicity etc. associated with a new chemical, will manufacturers be required to produce that data? Too often chemicals have been introduced with an assertion of safety by both manufacturers and regulators, which has turned out to be false. Once on the market, these products are much more difficult to recall, even when the evidence indicates that approval should never have been granted.

It is deeply concerning that NICNAS does not require a precautionary approach to uncertainty and data gaps but 'may' use it (p. 20). This should be mandatory and the manner in which precaution is applied should be clearly articulated.

It is even more concerning that even if the precautionary principle is applied, prohibition is implicitly ruled out in the statement that precaution may see an imposition of mitigation measures. (p. 20)

FoE strongly oppose the position that because of the variety of waivers and exclusions they will be decided upon on a case by case basis (p. 21). This is a recipe for arbitrary, ad hoc, and unaccountable decision making. Any proposed waivers should be publicly released for comment. Additionally, criteria for waivers must be developed and subject to public consultation.

FoE oppose the total deregulation of polymers that are deemed low risk. The literature points to a lack of understanding of degradation of polymers in the environment not their assured safety[ii] (p. 21)

Part F—Use of international information and assessments

We strongly disagree with the NICNAS view of bans from overseas (p. 24). It is true that Australia does not have a history of precautionary 'bans', however the literature suggests that this is a serious failing of Australian regulators. Nor does the evidence support the claim that these bans may have been 'unwarranted'. The opposite has been the norm. Australia has failed to adequately test and failed to adequately respond when the presumption of safety is demolished by peer reviewed literature. A report by the European Environment Agency has shown that global regulators have rarely prohibited a product unnecessarily and have frequently ignored the early signs that should have resulted in early action.[iii] The reluctance to prohibit, which is common amongst regulatory agencies in Australia, is not justified by the evidence.

Please note that FoE do not advocate automatic acceptance of overseas data or decisions, but we are not aware of any jurisdiction that lightly takes the step of prohibiting a product. Bans – far more than approvals – warrant immediate and public analysis, discussion and decisions.

The NICNAS view that it will however, rely on 'trusted' overseas regulators to eliminate regulation of chemicals (p. 26) suggests a completely unjustifiable double standard –one where elimination of regulation is likely to occur and prohibition of products is not – i.e. the demands of industry will be supported above the public right to safety.

Part H—Assessed chemicals (previously Class 3)

In the consultation paper it is proposed "that NICNAS could only determine the scope of assessment for NICNAS initiated assessments and not in circumstances where there is an applicant who is seeking an assessment certificate (and responsible for the costs of the assessment)". (p. 33) FoE oppose this proposal. NICNAS should be required to define the data that is necessary for an informed decision. If this means changing the scope of an assessment, regardless of who is paying for it, this should occur. It is also reasonable that this be considered a decision for purposes of the AD(JR) Act.

Part I—NICNAS initiated assessments

The criteria for mandatory calls for information (p. 35) are supported, but public rights should also be applied. In cases where a mandatory call for information is not made, the public should be entitled to seek and receive reasons for the decision and the decision should be subject to judicial review.

Part J—The Australian Inventory of Chemical Substances (AICS)

In the consultation document NICNAS states "will unassessed chemicals on the AICS require categorisation via the matrix prior to introduction? No. Chemicals that are on the AICS and that have not been assessed by NICNAS will not require categorisation." (p. 37)

FoE find this both reckless and incomprehensible. All chemicals in use in Australia that have not been assessed should be assessed. NICNAS cannot make a coherent assessment of the safety of new chemicals without knowing the impacts associated with existing chemicals.

Part K—Treatment of confidential commercial information

The law in relation to commercial documents and disclosure favours disclosure. It is not a matter of balancing two equal imperatives. (p. 40). The first step in dealing with claimed confidentiality is to recognise that the public interest in transparency is preferred to non-disclosure.

FoE recommend a more nuanced and public interest approach to what is commercial in confidence. Information, disclosure of which may have a commercial impact, does NOT in itself satisfy a confidentiality requirement. It must be remembered that this is an issue relating to public and environmental health. It is also government policy as reflected in the Freedom of Information Act that disclosure is a public good. Information that is protected from use by intellectual property rights or grants of exclusivity should be disclosed. Information relating to quantities of a chemical used, data on the formulations using that chemicals, and products in which it is or might be used should all

be disclosed. It should be mandatory for manufacturers to produce all test results, including negative and adverse results. It should be mandatory that in order to be valid, tests must be conducted in countries where all the data produced can be accessed. This information should be public. This will ensure that the public has sufficient information to allow independent analysis of the chemical, its mode of action and likely impacts.

Part L—Audit and monitoring

FoE strongly oppose the position that no notification of exempted chemicals is required. (p. 42). The precautionary principle and the obvious benefits of tracking what chemicals are in the environment strongly suggest that notification should be a minimum standard for all chemicals.

FoE urge NICNAS to support transparency in compliance processes, including publication of all breaches, any voluntary agreements entered into, audit and review materials and any penalties imposed.

Attachment A—Revised risk matrices

It is important that exposure levels and pathways be determined for all products that contain the relevant chemical, not simply those forms of the chemical over which NICNAS has jurisdiction. Additionally, exposure to chemicals of similar action must also be considered.

FoE support the inclusion of nanomaterials in hazard band E (environment) and band D (human health). However, it appears that low volume exposure rules also apply to nanomaterials. This is of serious concern as volume based exposure thresholds are not appropriate for nanomaterials. (p. 56)

As nanomaterials are now used and sold in a wide variety of consumer products, NICNAS should explicitly note that nanochemicals within the jurisdiction of NICNAS will be subject to assessment requirements even if the chemical is already on the market.

Attachment B—Proposed information (data) requirements for risk matrices

It is now well established that industry produced data is not as reliable as peer reviewed data and that exclusive reliance on industry data is not best practice. FoE urges NICNAS to implement specific precautionary measures in relation to industry data; specifically, that no chemical can be exempted from assessment based solely on industry data.

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[i] Stirling, A. and Gee, D. (2002). Science, Precaution and Practice. *Public Health Reports*. **117**:521-533

[ii] Lambert, S. (2013). *Environmental Risk of Polymers and their Degradation Products*. PhD Thesis, University of York.

[iii] Hansen, SF. *et al*. (2013). *Late lessons from early warnings*. European Environment Agency.