



National Industrial Chemicals Notification and Assessment Scheme Proposal for Regulatory Reform of Industrial Nanomaterials

Public Discussion Paper – October 2009

Have Your Say Questionnaire

All submissions will be placed on the NICNAS's website. For submissions made by individuals, all personal details other than your name will be removed from your submission before it is published on the NICNAS website. Confidential material contained within submissions should be clearly marked. Reasons for a claim to confidentiality must be included in the submission coversheet. Where possible confidential material will be redacted from information published on the NICNAS website.

1. What is the significance and/or consequence of this working definition for 'industrial nanomaterials'?

The definition encompasses not only man made materials but also the naturally formed material particles which may not have been processed to date as nano materials. This has the potential to significantly broaden the number of nano materials covered and capture a large volume of naturally occurring chemical and biochemical materials which would not be regarded as nano materials.

2. How do you think the proposal to limit access to exemptions for nano-forms of new chemicals will contribute to protecting health and the environment?

The limitation to exemptions will provide restriction in general exposure of the public to nano materials however the limitations to R&D need to be supported by guidance and recommendations as to good laboratory practice. Nano particles are distinct from normal materials in surface area and quantum effects. In order to study the impact of materials as additives in coatings and composites it will be necessary to utilise more than 100g/yr without offering material for trial. In order not to inhibit innovation larger volumes should be considered but with clear guidance on use and exposure

3. Describe any ways in which you think self-assessment by an independent third party could be used to effectively achieve the same results?

A 3rd party offering certification of a research laboratory could be an effective way to manage industrial testing and give confidence to workers and public. It would need to be supported by a re-certification process on a rolling time period. A key issue will be the cost involved and the establishment of such a competent authority.

4. If in R&D, what, if any, practical issues arise from the proposed administrative amendment for annual reporting of R&D exemptions? Would it require a significant

increase in reporting? If so – how much?

The limit of 100g/yr is such that potentially it would increase the amount of record keeping/reporting and so inhibit the extended evaluation in R&D of nano materials. and so impact on competition nationally and internationally

5. What are your views on the impact of the proposal to regulate nano-forms of new chemicals with the above changes to the permit and certificate categories? Can you identify additional advantages or disadvantages?

The use of a permit system prior to introduction of materials for specific purposes would not be an issue for substances to which the public might be exposed. Use of a nanomaterial in a closed system however ie a catalyst used for production of a substance would warrant a certification procedure. It would be useful to consider a differentiation on use as to whether permit or certification would be better.

6. What are your views on a system that is sufficiently flexible to amend permit conditions where new data indicates a new risk profile?
No objection
7. What are your views on the impact of the proposal for mandatory once-off, use specific reporting for nano-forms of 'existing chemicals'? Can you identify additional advantages or disadvantages?

The success or failure of a mandatory once off assesment will be dependent on awareness and the definition of nanomaterials. It is possible that there will be significant confusion unless the definition used is clarified to exclude naturally occurring materials. Inclusion of natural materials will increase the burden on reporting and reduce the likelihood success. The financial burden should also be taken into account, a detailed report on the nanomaterials in the market will require significant effort to collect data. A two tier program should be considered with initial simple reporting of basic chemical data, particle size etc w and followed by a more detailed registration over a period of time in the manner of REACH. This would help industry spread cost and provide time for data collection.

8. Explain how you think the potential burden of once-off, use specific reporting could or could not balance community expectations in relation to health and environmental standards?

.A once off reporting would only give benefits to community expectations if accompanied by public reporting indicating the nature of containment, exposure and risk. Such documentation while valuable to the public will also demand significant understanding to evaluate risk.

9. What are your views on making the information gathered through streams 1A and 1B publicly available?

Subject to protection of proprietary processes and intellectual property this would be acceptable

10. What are the advantages and disadvantages of the introduction of a system that required a mandatory notification and assessment program for all nano-forms of existing chemicals? What are the reasons for this answer?

This will present a level playing field for nano materials, in order to be effective a clear unambiguous definition is required and a campaign to raise awareness.

11. What are current issues that affect the feasibility of such a program?

Knowledge of nano materials, whether man made or natural and the boundaries of the definition together with the effort required to collect and verify the data required.

12. What are your views on making the information gathered from assessments of nano-forms of existing chemicals publicly available?

A register of the types and uses could be made available. Specific declarations by company and process or material would impact on intellectual property but a simple register of materials and generic end uses could be considered

13. How might an integrated approach provide for more effective regulation of industrial nanomaterials compared to the package of options proposed in sections 3a and 3b?

The existing proposal forms a firm foundation for future regulation, an integrated package in line with other chemical regulation and taking account directly of use and process will provide a sound basis for long term development in the use of nano materials.