Table 1 Summary of stakeholder comments on Definition

Issue	Summary of views	NICNAS response
1.1 1-100nm range for nanoscale	Some submissions raised that there is "no toxicological basis" for a 100nm cut-off. Nanomaterials >100nm have in some instances been shown to have novel properties leading to toxicological concern, i.e. carbon nanotubes. Alternative ranges proposed were 0.3nm-300nm and 0nm-500nm. Another point of view on this issue was that the definition would be helpful as it would provide clarity but it should not be exclusive to <100nm. This viewpoint stipulated that any particles >100nm in size that display novel properties (not in the bulk form) should be classed as nanomaterials. Some submissions argued that size was less effective for the purpose of a definition than other nanomaterial characteristics and should not be included as this could create gaps if particles were considered to be just outside of the given range, while still possibly having novel properties, as manufacturing can not always be precise. The use of the word "typically" when referring to this size range in the definition was criticized for being unclear, or should be written "…typically, but not exclusively,…".	The proposed range of 1-100nm is consistent with the OECD, ISO and comparable national and international regulatory authorities. It is NICNAS's understanding that this size range is based in general on the potential for substances to display nano-specific characteristics. While larger ranges have been proposed by some stakeholders, these comments do not supply a clear basis for proposing either 300nm or 500nm for definitional purposes. The studies that have been cited to reference these arguments often refer to agglomerates or aggregates of nanomaterials that are made up of particles <100nm. These are captured because they are nano-structured. See issue 1.3, below for further consideration of agglomerates and aggregates.
	Support for the use of the 1-100nm range came from recognition that it is important to retain consistency with definitions nationally and internationally. At the moment the use of the 1-100nm is common to current working definitions from peak organizations such as the OECD and ISO. Comments emphasized that the term 'nanomaterials' encompasses a large variety of materials and an effective definition needs to distinguish substances such as particles and films/interfaces that are only nanoscale in one dimension.	NICNAS will actively monitor progress of national and international reviews and other scientific developments and re-assess the size specifications in our working definition as required as scientific knowledge progresses.
1.2 'Intentionally produced'	Several submissions asserted that "intentionally produced" was a critical element of the definition. This part of the definition excludes unintentional nanomaterials (made in processes such as welding) that would not be appropriate to regulate in this context. It was also stated that it is not necessary to account for small amounts of unintentionally produced nanomaterials that may have been present in products for many years that do not pose risk and are already taken into consideration in regulation of the bulk material. Also, the use of this term would adequately consider materials (such as latexes) that may undergo a transformation that makes the material become part of a larger particle, and are already risk managed. Some stakeholders argued that it is necessary to include unintentionally produced nanoparticles in the definition as these may pose safety concerns when created in processes such as grinding.	The concept of "intentionally produced/manufactured" or "engineered" is included in a range of national and international working definitions. The rationale for including such a descriptor is to avoid regulating unintentionally produced substances. A note will be added to the working definition as an explanation so it is clear that accidentally produced substances are not subject to regulation.

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1.3 Agglomeration and aggregation	Some submissions argued that aggregates and agglomerates of nanoscale particles must be considered in a definition and particles in these forms may be at the nanoscale and the stability of these forms may be uncertain. Surface and internal nanoscale structures in particles larger than 100nm can contribute to novel properties. It was recommended that NICNAS adopt the ISO TC229 working definition in this regard that states that a nanomaterial is "a material with any external dimension in the nanoscale or having internal or surface structure in the nanoscale." This will include materials with nanoscale precipitates and materials with nanoscale textures on the surface, thus the definition will apply to a material containing agglomerates or aggregates made of nanoparticles that are greater than 100nm in diameter.	The broad working definition originally proposed by NICNAS was intended to capture agglomerates and aggregates. However noting the feedback received during the public consultation NICNAS proposes to clarify this intent within the definition, by revising the working definition to include "nanostructured substances" (i.e. having an internal or surface structure at the nanoscale). Aggregates and agglomerates are nanostructured substances, and NICNAS will provide further clarification through use of notes to the definition. It is noted that the OECD and ISO both include nanostructured materials within their respective working definitions.
1.4 Mixtures (intentional or as 'contamination') containing a % of nm.	It was emphasized that nanomaterials that are a part of a mixture should be captured in this definition. A threshold for nano content or contamination was proposed by some submissions, with the example that a mixture that comprised of >5% primary particles or agglomerates below 100nm in size and/or a mixture that contains >50% primary particles or agglomerates below 200nm in size should be considered in nanomaterial regulation. Another view was that nanomaterials in mixtures/products present different risks to the raw material in the occupational environment. If introduced in a product, it should be characterized as it appears in the final product.	Stakeholders have suggested that NICNAS should include nanomaterials in mixtures within the working definition. While we are not aware of any other national or international definition that includes a threshold concentration of nanoscaled substances for the purpose of regulation, we are aware that several overseas regulatory authorities are considering appropriate thresholds. NICNAS is not proposing to include a threshold within its working definition, rather it will be included in notes to the definition, guidance material and NICNAS risk assessment protocols and practices. In NICNAS's revised working definition, this note states that substances whose particle size distribution indicates that 10% of the number of primary particles fall below 100 nm, NICNAS proposes to consider this substance to be a nanomaterial unless scientific information is provided to demonstrate that the substance does not display nano-specific characteristics. This approach and threshold will be reviewed and revised as the science advances.
1.5 Insolubility and biopersistance	The view that insolubility should not be used to define a nanomaterial was based on an argument that solubility is poorly understood and there is evidence that partially and even completely water soluble nanomaterials may be toxic. The view that biopersistance should not be used to define a nanomaterial was based on an argument that biopersistance has not been fully researched and is not yet properly understood and nanomaterials that are not biopersistant may still be toxic. Another view submitted claimed that insolubility and biopersistance should be included in the definition, as used by EC Cosmetics regulations. This is seen to be beneficial as it assists in narrowing scope, to concentrate on those materials of greatest risk.	Insolubility and biopersistance are not included in the proposed working definition. NICNAS is not proposing to use these concepts as inclusion/exclusion criteria within the working definition as this approach can potentially limit regulating nanomaterials that pose health and/or environmental concern. We note however that the EU Cosmetics Directive has included these properties in its definition of nanomaterials. To our knowledge the European Commission is yet to respond to this recommendation. These characteristics will be used as triggers for determining circumstances where additional information on particle size distribution, surface properties, surface area and other nano-specific information may be required for risk assessment of nanomaterials. This does not exclude nanomaterials that are not classed as biopersistant or insoluble from assessment.

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1.6 Functionality, surface area	Stakeholder views on nano-specific characteristics such as functionality and surface area were mixed. While some respondents were of the view that these novel properties may be independent of size and therefore should be included in the definition, others recognised that based on the current state of the science it may be preferable to retain a broad definition to avoid ambiguity at this stage. Many submissions emphasized that nanomaterials should be defined by the novel properties/performance that is dependant on characteristics other than size. These included such things as functionality, and surface area inducing quantum affects or other properties not seen at the bulk scale. Some respondents were of the opinion that these features are too ambiguous and may create loopholes, and until testing of functional properties is established, it may be better to have a broader definition.	The revised NICNAS working definition includes "produced, manufactured or engineered to have unique properties or specific composition". Therefore the concept of nano-specific characteristics in encompassed in the definition. Some international definitions include these phenomena within the working definition and others do not. NICNAS does not propose to specify nano-specific characteristics within the definition, rather to request this information during the risk assessment process as required on a case by case basis. Further elaboration may also be given in guidance information.
1.7 The impact of low volumes/concentrations	Some noted that the proposed working definition would not take into account the difference in risk when nanomaterials are included in small amounts in a product (e.g. cosmetics).	The impact of low concentrations is dealt with in the NICNAS risk assessment rather than the definition.
1.8 Consistency with other regulatory agencies and international governments and organizations.	It was generally recognised that consistency is necessary to ensure an efficient national regulatory approach and to have consistence with international definitions for maximum effectiveness. Many stakeholders expressed that the government should be clear that health and environmental issues raised by this technology should be treated with a precautionary approach.	NICNAS has developed a revised definition that is generally consistent with comparable national and international regulatory authorities.
1.9 Flexibility of regulation	It was generally recognised that flexibility is necessary to ensure national and international consistency and accommodate developments in the future that reflect an increase in understanding of nanomaterial properties.	Retaining a working definition rather than a legislative definition will give NICNAS the ability to amend it quickly and relatively easily if required.