



Australian  
Competition &  
Consumer  
Commission

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3 February 2014

Ms Louise Sales  
Friends of the Earth  
PO Box 1073  
HOBART TAS 7001

*Via email to: [louise.sales@foe.org.au](mailto:louise.sales@foe.org.au)*

Dear Ms Sales

**Request for access under the *Freedom of Information Act 1982***

I refer to your email of 19 November 2013 in which you sought access under the *Freedom of Information Act 1982* to documents relating to:

*'On July 24th 2012 Friends of the Earth Australia (FoEA) submitted complaints to the ACCC regarding alleged misleading contact by Antaria and Ross Cosmetics.*

*Pursuant to the Freedom of Information Act FoEA seeks the following:*

*1. The presentation given to the ACCC's Enforcement Committee on 4 April 2013, minutes from the meeting and the Committee's resolution.*

*2. All correspondence between the ACCC and the TGA, NICNAS and The Cancer Council relating to:*

- The definition of nanomaterial and its relevance to the complaint*
- The relevance of the safety of nanomaterials to the complaint*

*Documents should be between 24th July 2012 and August 29th 2013. Publicly available documents are not required.*

Thank you for your payment of 31 January 2014 for \$56.17, being the balance of the assessed charges; the ACCC's tax invoice receipt will be forwarded to you separately.

Enclosed are copies of the 2 documents which were "Granted" and 1 document "Part granted", as per the Schedule.

D14/11469

Yours sincerely

A handwritten signature in black ink, appearing to read "Sonya Petreski". The signature is fluid and cursive, with the first name "Sonya" written in a larger, more prominent script than the last name "Petreski".

Sonya Petreski  
FOI Administration Assistant  
ACCC Legal Group

## Telephone Interview

Dr Matthew Gredley  
Head  
Reform Program – NICNAS

ACCC: Peter Cromwell and Murray Beigel

Date: 23 January 2013 – 12.10pm

Dr Gredley confirmed the following:

- NICNAS talked to FoE about nanoparticles in sunscreens in about November 2012. The issue of legal concerns surrounding nano free claims were discussed and FoE were advised of the lack of a legal definition in Australia. Specific traders were not discussed.
- NICNAS' working definition of nanomaterial is not mandated by law.
- NICNAS looks at industrial chemicals and performance standards for cosmetics.
- There are 2 types of sunscreens. The TGA regulates therapeutic sunscreens (it has its own advertising and compliance responsibilities). NICNAS is responsible for cosmetic sunscreens.
- The TGA made a ruling last year that a company could not label sunscreen designated as "nano-free" as "safe" because it improperly implied that nano sunscreens were unsafe.
- Science about the safety of nano sunscreens is evolving. Current thinking is that nano particles may penetrate the very thin skin (such as for babies) and compromised skin (eg where the skin has burns or wounds).
- The reporting process to NICNAS by traders is currently under reform. The reason for this reform is NICNAS' position that the effect chemicals have on the environment is the same as they do on humans.
- NICNAS also wants changes to reporting requirements that will require companies to provide relevant data. This will allow NICNAS to assess chemicals in order to be able to make appropriate recommendations as to how those chemicals may affect the health of persons using that particular chemical.
- Traditionally, science viewed chemical properties as the same regardless of particle size. Gradually, companies have been enriching chemical powders by nano particles. Concerns have been raised by scientists and government that nano sized particles may have changed properties that could present health or environmental hazards (eg could increase toxicology). Concerns have also been raised that assessment of nano chemicals based on conventional science may not work.

- Currently, reporting is only compulsory for new chemicals. Therefore, as most sunscreens contain chemicals currently on the NICNAS existing chemicals list, sunscreens do not need to be reported even if the chemical in the sunscreen is being altered.
- As well as assessing new chemicals, the NICNAS system assesses safety of chemicals that are already listed on the chemical inventory (currently about 40,000 chemicals listed). NICNAS regulation of chemicals includes developing recommendations about risks associated with chemicals and recommendations for downstream regulators.
- Concerns have been raised that assessment of nano particles by conventional scientific methods may not work. The law does not currently allow the regulator to focus on chemicals in a nano form.
- A consultation process between NICNAS, relevant government departments and other interested stakeholders and industry of its processes in the nano area commenced in 2009.
- In 2012, a review of NICNAS' processes has commenced with a view to reform of its legislation. This has caused the process of reform in the nano area to stall because of the organisation review by the department responsible for NICNAS (Department of Ageing). It is unknown when the review process will be completed, however, while initially planned to be completed in 2013, it is more likely to be completed in 2014.
- NICNAS does not have power under law to scrutinise/regulate existing chemicals (of which most chemicals in Australia are). As it stands, nothing needs to be done with respect to existing chemicals which are subsequently released in nano form. The purpose of the working definition of nanomaterial is to put business on notice that after reforms are implemented existing chemicals which fall within the working definition may be subject to the regulatory scrutiny of NICNAS.
- The process of reform for existing chemicals is much more complicated.
- Chemical powders will contain a tiny percentage of nano sized particles which occur naturally or accidentally as a result of the production process. The NICNAS working definition expressly excludes accidentally or non intentionally produced nano sized particles.
- In powder form, the chemical's components may range from micro size to nano size. Therefore, the ISO definition of nano is looking at the distribution of components not their size. The reason for this is that if only a small amount of nano particles are present this is unlikely to cause health problems.
- As NMI has shown, there is a problem that conventional sunscreens may all have nano particles in them which occurred accidentally. Therefore, strictly speaking, no brand may be able to call their sunscreens nano-free.
- Measuring of nano particles can be problematic, especially when looking for small numbers of particles. The NICNAS working definition applies only where the material includes 10% or more nanomaterial.
- The EU definition contains a similar threshold because of problems of measuring small proportions of material. What the threshold level should be is the current debate. The EU currently has a 50% threshold level.

- There is also controversy about the cut off point for the size of nano particles subject to regulation. Some people argue particles greater than 100 nanometres should be classified as nano.
- NICNAS publishes information sheets about nano measurement on its website as well as recommended testing methods. NICNAS recommends that different production methods should use different testing methods as appropriate for the individual product.
- There is some criticism about the light scattering testing method because small particles are disguised and difficult to identify when large particles are present.
- There is no one methodology that can measure particle distribution when in a powder or when in a product.
- There are three concerns with agglomerates;
  - Larger clumps made up of nano particles may still have different properties that may have health impacts;
  - larger clusters may still have nanoscale features on the surface; and
  - loosely bound particles, whereby small amounts of nano particles can possibly break off.
- The NICNAS working definition captures aggregates. However, claims that the products are non-nano (given concerns that agglomerates can be made up of nano sized particles) is not misleading given the current legislation. This is because most of the sunscreens, even if containing nano sized particles, are made from existing chemicals.
- There is a difference between the scientific and regulatory definitions. Internationally, the scientific definition of "nano" or "nanoparticle" is agreed (ie less than 100 nanometres ( $10^{-9}$ m)). Definitions of "nanomaterial" for regulatory purposes (such as the NICNAS and EU definitions) are problematic. These regulatory definitions are designed to capture materials which have some nano attributes that may have the potential to change the properties of the compound. For example, the NICNAS definition includes unique nanoscale properties.
- The ISO nanomaterial definition does not carry any weight in Australia. Controversy exists for Standards Australia about whether they should adopt the ISO standards.
- The current controversy is that the ISO definition is more a legal definition rather than a chemical definition. A scientific definition is only interested in the size of a particle and not some legal definition.
- The EU definition is a regulatory, not scientific, definition. While having a regulatory definition, the EU concedes that the definition may alter on whether the product is chemical or therapeutic.
- The TGA does not have a definition of nano material.
- There is not one single method for testing different products and sensitivities.



## Enforcement Committee Submission

<b>Title</b>	Antaria Ltd and Ross Cosmetics Aust. Pty Ltd - Nano Claims
<b>TrackIt</b>	50985
<b>Description</b>	Friends of the Earth Australia Inc allege that Antaria Ltd and Ross Cosmetics Aust. Pty Ltd made false and misleading representations that their zinc oxide formulations used in the manufacturing of sunscreens were free of nano particles.
<b>Purpose</b>	To update the Committee on the progress of the investigation to date and to seek direction as to whether the investigation should be discontinued.
<b>Recommendation</b>	The Committee direct staff to discontinue investigation of this matter.
<b>Status</b>	In-depth investigation - information gathering
<b>Office</b>	Enforcement Operations – WA
<b>Project staff</b>	Bettella, Adrian; Cromwell, Peter; Beigel, Murray
<b>Economists</b>	N/A
<b>CCLU</b>	Tim Massey
<b>External Legal team</b>	N/A
<b>Commencement date</b>	16 July 2012
<b>Last EC date</b>	N/A
<b>Last EC decision</b>	N/A
<b>Previous EC Papers</b>	N/A
<b>Proposed return date</b>	N/A
<b>Legal costs to date</b>	\$0
<b>Legal advice</b>	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Contains confidential & privileged material (shaded)
<b>Staff have considered ACCC's strategic priorities:</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not relevant

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## 1. Alleged conduct

- 1.1 Friends of the Earth Australia Inc (FoE) allege that Antaria Ltd (Antaria) and Ross Cosmetics Aust. Pty Ltd (Ross Cosmetics) made false and misleading claims that their zinc oxide formulations were free of nano particles.

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## 2. Potential contravention/s

- 2.1 s.18 Misleading or deceptive conduct
- 2.2 s. 29(1)(g) False or misleading representation that goods have performance characteristics, uses or benefits

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## 3. Context of conduct and investigation

### Relevant Parties

#### Friends of the Earth Australia Inc

- 3.1 FoE is an incorporated association promoting environmental, health and social issues. Since 2005, FoE has promoted a campaign about the risks associated with nanotechnology.
- 3.2 As part of that campaign, FoE has focused attention on the use of nano-scale zinc oxide and titanium dioxide material in the manufacture of sunscreens and cosmetics. Manufacturers<sup>1</sup> of “nano-sunscreens” use this product as they consider it provides a more desirable product for consumers as these lotions become transparent when applied to the skin whilst other sunscreens tend to leave a whitish appearance on the skin.
- 3.3 Since 2008, FoE has published its annual Sunscreen Guide to inform the public about sunscreen brands in Australia which FoE claims do not contain manufactured nanomaterial. A copy of the 2011/12 Sunscreen Guide is attached (**Attachment 1**).
- 3.4 The Sunscreen Guide is produced on the basis of responses from sunscreen manufacturers to a questionnaire prepared and distributed by FoE. Some of those responses are supplemented by additional technical information provided by Antaria and Ross Cosmetics who were the manufacturer or supplier of those zinc oxide formulations.
- 3.5 FoE advised that findings by the National Measurement Institute<sup>2</sup> (NMI) presented at a conference in Perth on 6 February 2012, indicated some nano-free sunscreens listed in the Sunscreen Guide contained nanomaterial.
- 3.6 After further enquiries by FoE, it concluded the Sunscreen Guide was inaccurate by wrongly identifying some sunscreens as nano-free and withdrew and destroyed 45,000 printed copies of the Sunscreen Guide.
- 3.7 FoE claim that as a result of Antaria and Ross Cosmetics providing false and misleading information to sunscreen manufacturers, FoE suffered serious reputational damage and costs of about \$73,000, in relation to printing of the Sunscreen Guide.

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<sup>1</sup> Sunscreen suppliers are referred to as “manufacturers” in the Paper. Generally these companies have a sunscreen product manufactured for them under contract by an unrelated third party business. The manufacturers sell those products under their own brand eg Coles’ “Sports” sunscreens are manufactured for Coles by Ross Cosmetics.

<sup>2</sup> NMI is the peak Australian measurement body responsible for biological, chemical, legal, physical and trade measurement division within the Department of Industry, Innovation, Science, Research and Tertiary Education. It develops measurement infrastructure, expertise and standards for nanotechnology.

### **Antaria**

- 3.8 Antaria is an ASX listed company based in Western Australia which describes itself as a “specialist developer of advanced intermediate materials used by the industrial, chemical and cosmetic sector”. The major shareholder of Antaria is the University of Western Australia (19.5% shareholding).
- 3.9 Antaria manufactures and supplies zinc oxide under the ZinClear-IM brand for use in sun care, skincare and cosmetic products.
- 3.10 ZinClear-IM is used in a variety of sunscreen products including the Cancer Council, Woolworths, ChemMart, and Invisible Zinc brands.

### **Ross Cosmetics**

- 3.11 Ross Cosmetics, based in Tullamarine, Victoria, is a manufacturer of private label cosmetics, toiletries and therapeutic goods. Ross Cosmetics manufactures both its own “Auscreen” brand of sunscreen and sunscreens under contract for other companies that include the brands Coles “Sports”, Sun Zapper and Coco Island.
- 3.12 A component of some sunscreens produced by Ross Cosmetics is a zinc oxide formulation manufactured by Symrise ([www.symrise.com](http://www.symrise.com)). This formulation is marketed under the name “Zinc Oxide Neutral” and has been available in Australia since at least 2008.
- 3.13 Symrise is a global supplier of fragrances, flavourings and cosmetic active ingredients. Its headquarters is in Germany and they have an office in Sydney.

### **Basis of FoE’s Allegation**

- 3.14 The basis of FoE’s allegation is its belief that zinc oxide formulations supplied by Antaria and Ross Cosmetics for use in manufacturing sunscreens do contain “nanomaterial” as defined by “official” or “major” definitions in Australia and internationally. FoE’s concerns relate to the theoretical possibility that if nanoparticles were to be absorbed into skin cells, they could possibly interact with sunlight to increase the risk of damage to these cells.
- 3.15 The official definitions noted by FoE are those issued by the National Industrial Chemicals Notification and Assessment Scheme<sup>3</sup> (NICNAS), the International Standardization Organization (ISO), the European Union and the US National Nanotechnology Initiative.
- 3.16 NICNAS describes its definition of nanomaterial as a “working definition”. However, it acknowledges there is no current internationally agreed definition of nanomaterials.
- 3.17 Common to these “official” definitions is the concept that nanomaterial includes not only particles which are less than 100 nanometres in size, but also aggregates / agglomerates (ie clusters) of nano-scale particles.
- 3.18 FoE states that because the Antaria and Ross Cosmetics formulations are comprised of large zinc oxide particles made up of clusters of nano-scale primary particles, those formulations should be regarded as “nanomaterial” in terms of the “official” definitions. This leads FoE to conclude that it is misleading to describe those formulations or sunscreens containing those compounds as “nano-free”.
- 3.19 FoE also includes independent opinions in its submissions to the ACCC to support its conclusions that Antaria and Ross Cosmetics’ formulations are nanomaterials according to NICAS and ISO definitions.

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<sup>3</sup> NICNAS is the Commonwealth regulatory authority responsible for industrial chemicals. It provides a national notification and assessment scheme for industrial chemicals introduced to Australia, and aims to protect the public and the environment of the harmful effects of these chemicals.



### Antaria and Ross Cosmetics' Position

- 3.20 Both Antaria and Ross Cosmetics acknowledge their zinc oxide formulations contain "aggregates" or clusters of nano-scale primary particles but state that their respective formulations are not nanomaterial because the bound zinc oxide aggregates are greater than 100 nanometres, thereby, making it non-nano. They do not agree with FoE's allegation that their "nano-free" representations are misleading.
- 3.21 Testing methods used or reported by Antaria and Ross Cosmetics for their zinc oxide products find the formulations do not contain particles less than 100 nanometres in size (ie the cluster particles are not nano sized).
- 3.22 Furthermore, Antaria and Ross Cosmetics do not agree with FoE's premise that there is an "official" definition of nanomaterial in Australia.

### Definition of "Nano"

- 3.23 As part of the investigation, staff sought the assistance of NICNAS in understanding the definition of nanomaterial and the legal basis of any definitions in Australia.
- 3.24 Dr Matthew Gredley, Head of the Reform Program at NICNAS, advised staff that there is both a scientific and regulatory definition of "nano" (usually "nanomaterial" in the case of regulatory definitions). Dr Gredley advised that the scientific definition of "nano" is not disputed and universally accepted (ie particles less than  $10^{-9}$ m in size (100 nanometres)).
- 3.25 Dr Gredley advised that regulatory definitions are devised on the basis of the underlying regulatory purpose and in light of measurement limitations, are only applicable in the jurisdiction in which the definitions have legal enforceability. Dr Gredley further advised that regulatory definitions typically extend the scientific definition to include larger non-nano sized particles with nanostructures (eg an internal or surface feature of nanoscale, or agglomerates and aggregates). Dr Gredley advised that the reason for this is the regulatory concern that nanostructures may change the properties of a particle in such a way as to create a health or other hazard and accordingly, regulators want to be advised when those type particles are released.
- 3.26 Dr Gredley advised that NICNAS' "working definition" has no basis in law. Staff also confirmed that there is no legal or mandated definition of "nano" or "nanomaterial" in Australia. Dr Gredley also advised that the ISO and EU definitions of nanomaterial (which are both regulatory definitions) have no legal standing in Australia.
- 3.27 Dr Gredley also advised NICNAS had met with FoE in November 2012 for a general discussion about nano issues. FoE was advised of NICNAS's views, as outlined above, in relation to the lack of a mandate for the definition of "nano" in Australia.

### Trade or Commerce

- 3.28 The following discussion about whether the potential representations may be misleading in contravention of the ACL includes consideration of the threshold question of whether the representations were made in trade or commerce. In most instances, staff have formed the view that they were not.
- 3.29 The principles governing the construction of the expression "in trade or commerce" in the former section 52 are enunciated in a joint judgement by the High Court in *Concrete Constructions (NSW) Pty Ltd v Nelson* (1990) (**Concrete Constructions (NSW)**). The judgement stated the expression refers to "conduct which is itself an aspect or element of

*activities or transactions which, of their nature, bear a trading or commercial character.....the expression refers to 'the central conception' of trade or commerce and not to the 'immense field of activities' in which corporations may engage in the course of, or for the purposes of, carrying on some overall trading or commercial business".*

#### **Staff Assessment**

- 3.30 Whether the alleged conduct raised in FoE's complaint occurred in trade or commerce is assessed under four categories, namely representations made in:
- 3.30.1 the Sunscreen Guide;
  - 3.30.2 information provided to FoE by sunscreen manufacturers to assist in the production of the Sunscreen Guide;
  - 3.30.3 information about zinc oxide formulations provided to sunscreen manufacturers by Antaria or Ross Cosmetics; and
  - 3.30.4 public statements by Antaria and Ross Cosmetics about the nano-free attributes of their zinc oxide formulations.

#### **Category 1 – 2011/2012 Sunscreen Guide**

- 3.31 The Sunscreen Guide includes details of specific sunscreen brands which their manufacturer or supplier claim are nano free. The FoE Sunscreen Guide was provided to the public free of charge either in hard copy or through FoE's website.
- 3.32 As outlined above, FoE believes its Sunscreen Guide was rendered inaccurate by incorrect information it received from some sunscreen manufacturers about the nano-free status of their products. On the basis of FoE's own reasoning about misleading nano-free claims, it is arguable that FoE's Sunscreen Guide may itself have misled consumers by representing that some sunscreen products were nano-free.
- 3.33 Notwithstanding that concern, staff are of the view that the production and distribution of the Sunscreen Guide by FoE was not in trade or commerce and therefore, the ACL is not applicable. Based on the Court's findings in a number of cases including *"E" v Australian Red Cross Society* [1991] and *Orion Pet Products v RSPCA* (2002), staff consider that the provision of information to the public at large for no charge does not represent conduct of a commercial nature.

#### **Category 2 – Information provided to FoE by sunscreen manufacturers and/or Brands**

##### **FoE Questionnaire**

- 3.34 The primary source of information used by FoE in collating its Sunscreen Guide was responses to its questionnaire from manufacturers.
- 3.35 The key concern for FoE is that manufacturers using either Antaria and Ross Cosmetics zinc oxide responded "No" to the question *"Do any of your brand's products contain manufactured nanoparticles <100nm in size (eg titanium dioxide, zinc oxide), or aggregates or agglomerates that are composed of primary particles that are <100 nm in size."*

- 3.36 Given that it is factually correct that Antaria and Ross Cosmetics formulations are made up of aggregates or “agglomerates”<sup>4</sup> composed of primary nano-scale particles (ie particles <100 nm in size), it is arguable that those responses were false.
- 3.37 FoE relied on these responses as the basis for stating in its Sunscreen Guide that the brands claimed they were nano-free. The brands for which this is a concern are those which use Antaria and Ross Cosmetics zinc oxide formulations (outlined in **Attachment 2**).
- 3.38 Interestingly, the questionnaire does not directly ask whether manufacturer’s products contain nanomaterial (ie it does not use the word “nano”). FoE appears to have extrapolated its assertions of manufacturer “nano-free” claims from responses to question 2 of the questionnaire referred to in paragraph 3.35 above.
- 3.39 Notwithstanding this concern, staff do not consider that responses to a voluntary questionnaire by manufacturers to FoE were in trade or commerce. Relevantly:
- 3.39.1 there is no trading relationship between the manufacturers and FoE;
  - 3.39.2 the questionnaire information was sought by FoE on the basis of furthering its own public information campaign;
  - 3.39.3 manufacturers did not actively seek or otherwise lobby FoE for the opportunity to be included in the sunscreen guide; and
  - 3.39.4 the information was provided by the manufacturers without charge.
- 3.40 In light of those factors, staff are of the view that while responding to the FoE questionnaire may have been viewed by sunscreen manufacturers as providing some collateral sales advantage, the nexus between any perceived collateral sales advantage and filling out a questionnaire is too remote as to make those parties conduct as meeting the legal requirement of being in trade or commerce. This view is supported by the Full Court in *Village Building Company Limited v Canberra International Airport Pty Limited* (2004) where it was held that “*the airport operator’s activities were motivated by a degree of self-interest.....the fact that conduct has the purpose and/or effect of maintaining or protecting a business is not, of itself, enough to ensure that the conduct is ‘in trade or commerce’*”.
- 3.41 Staff also do not consider that conduct can be regarded as referring to the “central conception” of the brands trading activities as discussed in *Concrete Constructions (NSW)*.
- 3.42 Questionnaire responses by Coles and some other manufacturers whose products contained Ross Cosmetics zinc oxide formulation were supplemented by a Particle Graph (**Attachment 3**). The Particle Graph was sourced from a product information brochure issued by Symrise who supplies Zinc Oxide Neutral to Ross Cosmetics.
- 3.43 The Particle Graph appears to signify that the zinc oxide particles are one micron in size on average (i.e. 1,000 nanometres), and never less than 500 nanometres. The Particle Graph indicates the test method used to determine the particle size.
- 3.44 For the same reasons specified at 3.40 above, we do not consider that manufacturers providing information by way of a Particle Graph in response to the questionnaire was in trade or commerce.
- 3.45 Furthermore, staff note that no information has been provided by FoE that suggests the Particle Graph is not factually correct.

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<sup>4</sup> “Agglomerates” are a collection of loosely bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components (definition from ISO TS27687 2008).

**Category 3 - Information provided to sunscreen manufacturers by Antaria or Ross Cosmetics about their Zinc Oxide Formulations**

- 3.46 FoE are concerned that zinc oxide suppliers Antaria and Ross Cosmetics engaged in misleading conduct by providing incorrect information about the “nano-free” status of their formulations to their sunscreen manufacturers customers.
- 3.47 In the case of Antaria that information was provided to customers in the form of Product certification documents.
- 3.48 Antaria provided signed product certification documents to its sunscreen customers which set out specifications of its ZinClear-IM dispersions. The sample documents provided by FoE appear in two forms:
- 3.48.1 untitled document dated 5 October 2010 provided to the Invisible Zinc brand (**Attachment 4**), states that Antaria certifies the ZinClear product:
- 3.48.1.1 *is NOT classified as ‘nano material’ and therefore does not require to be labelled as such;*
- 3.48.1.2 *the particle size is above 100 nanometres; and*
- 3.48.1.3 *the average particle size is greater than 1 micron.*
- 3.48.2 certification document entitled “*Certificate of Analysis*” (**Attachment 5**) indicates that particles are greater than one micron in size based on the “laser light scattering” test method.
- 3.49 To the extent that these certificates were provided by Antaria to its existing customers for the purpose of assisting them answer FoE’s Sunscreen Guide questionnaire, staff do not consider that those certificates were provided in trade and commerce. Staff’s reasoning on this point is that same as set out at 3.40 above.
- 3.50 However, staff note that if the certificates had been provided by Antaria to customers as part of it supplying or continuing to supply ZinClear-IM, staff consider that those representations would have been made in trade and commerce. In that circumstance, the question for consideration is whether the certificates are misleading.
- 3.51 In staff’s view, the certification documents are unlikely to be considered misleading. As with the Particle Graph (referred to at 3.43 above), there is no evidence to suggest that information in the document inaccurately reflects Antaria’s tests results. In the case of the “*Certificate of Analysis*” document, the type of testing method used is specifically identified.
- 3.52 The information in the Antaria certification documents also appears supported by independent tests commissioned by the Cancer Council (which staff note were commissioned after the Antaria certification documents were issued and after FoE’s complaint to the ACCC). The Cancer Council published the following comments about these tests on its website:
- “Cancer Council can confirm that the sunscreens referred to, Classic, Sensitive and Day Wear Clear Zinc, contain ZinClear-IM, however our testing shows the bonded particles in these sunscreens are microfine in size, not nanoparticle in size..... Two independent laboratories have tested these sunscreens and in all samples tested, 99.99 per cent of particles were found to be larger than nano size.”*

**Category 4 - Public statements by Antaria and Ross Cosmetics about their Zinc Oxide Formulations.**

**Antaria**

- 3.53 FoE notes that Antaria has made public statements to potential investors claiming or implying its ZinClear-IM formulations are not nanomaterial. FoE refers to:
- 3.53.1 Antaria presentation to BRR Media *"Understanding Antaria's flagship product ZinClear-IM"* (2 February 2011); and
  - 3.53.2 Antaria presentation to ASX *"Antaria Platform for Profitability"* (24 August 2011).
- 3.54 The PowerPoint's for these presentations contain statements in relation to ZinClear-IM such as:
- 3.54.1 *"Micron sized (non-nano)";* and
  - 3.54.2 *"transition from nano to micron size particle".*

**Ross Cosmetics**

- 3.55 Ross Cosmetics, as manufacturer of its own "Auscreen" brand sunscreen, makes the following statements on its Auscreen website about its sunscreens:
- 3.55.1 *"Nano-Particle Free";* and
  - 3.55.2 *"No Auscreen formulation contains nano-particles in zinc-oxide or titanium dioxide form".*
- 3.56 FoE is concerned that those public statements about Antaria and Ross Cosmetics products being "nano-free" are misleading, as it considers particles in these products contain nanomaterial according to a particular "official" definition.
- 3.57 Staff accept that these statements are made in trade or commerce and subject to the ACL provisions. However, staff believe it is arguable that both companies had a reasonable basis for making their "nano-free" statements. To that end, it is noted that both companies have test results supporting their respective positions. Staff also note, as referred to above at 3.51, in the case of Antaria the Cancer Council's two independent tests of its sunscreens containing ZinClear-IM found they were effectively free of nano-particles.
- 3.58 Furthermore, the central question of defining "nano" and "nanomaterial" in Australia is not settled. Despite FoE claiming to the contrary, staff do not consider there is an "official" or legislatively supported definition of these terms in Australia. This position is acknowledged by NICNAS in its 2006 public information sheet on nanomaterials where it states *"...this difficulty is compounded by current lack of uniform internationally accepted nomenclature for nanomaterials, and the absence of standard methods for their characterisation and measurement"*.
- 3.59 Given these factors, staff believe there is considerable doubt over whether it can be shown unequivocally that the components can be characterised as nanoparticles as contended by FoE. On this basis, staff do not believe FoE's allegation that Antaria and Ross Cosmetics have engaged in conduct that misleads the general public can be pursued with any confidence.

**Recent Development – Antaria ASX Announcement**

- 3.60 On 20 December 2012, Antaria announced to the ASX that it had reviewed its ZinClear-IM product line in light of the forthcoming implementation of the European Union Cosmetic Product Regulation (which includes a definition of nanomaterial). The announcement states Antaria has concluded ZinClear-IM will be considered a nanomaterial according to

the definition used in EC and that it will need to comply with the nano-labelling rules in the EU that take effect in 2013.

- 3.61 Staff consider this development indirectly confirms the overall position that there is no official or mandated definition of nanomaterial in Australia, and that the EU and other definitions cited by FoE have no application in Australia for assessing whether “nano” statements are misleading.
- 3.62 On this issue, staff note the following comments made in the EU's Joint Research Centre media release of 17 September 2012 that, despite this new definition, problems with measurement of a nanoparticle still exist.

*“A new report by the European Commission's Joint Research Centre (JRC) presents an in-depth review of methods available to measure the size of nanoparticles. Following the adoption of the definition of the term 'nanomaterial' in October 2011, this report identifies relevant measurement methods and key challenges for measuring nanoparticle size in the regulatory context. The report underlines that no single measurement method can be used for all materials to determine if each of them falls within the regulatory definition. Different methods will be required depending on the material under investigation.”*

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#### 4. Factors that warrant the ACCC's intervention and further action

- 4.1 Action against credence claims is listed as a priority area in the ACCC Compliance & Enforcement Policy, February 2013.
- 4.2 The issue of nano particles and possible detrimental effects to the health of consumers using such products has recently received some media attention. Staff consider the issue raised by FoE is of significant public interest and concern.

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#### 5. Other considerations

##### **Conflicting views as to the health risks associated with products contain nano-material**

- 5.1 The Sunscreen Guide is founded on the premise that nano-sunscreens are a public health danger. For example, the Sunscreen Guide states *“nano-products pose health risks”* and *“...if nano-sunscreens are absorbed into our skin, they could result in serious damage”*.
- 5.2 However, both the TGA and Cancer Council do not support this view. In early 2009, the Therapeutic Goods Administration (TGA) conducted an updated review of the scientific literature in relation to the use of nano particulate zinc oxide and titanium dioxide in sunscreens.
- 5.3 The TGA review concluded that:
- 5.3.1 *“the potential for titanium dioxide and zinc oxide nano particles in sunscreens to cause adverse effects depends primarily upon the ability of the nano particles to reach viable skin cells”*; and
- 5.3.2 *“to date, the current weight of evidence suggests that titanium dioxide and zinc oxide nanoparticles do not reach viable skin cells; rather, they remain on the surface of the skin and in the outer layer of the skin that is composed of non-viable cells”*.
- 5.4 Similarly, the Cancer Council website states *“...there is no credible evidence sunscreens containing nanoparticles pose a health risk.”*
- 5.5 Staff also note that the view of the TGA is in accordance with similar statements made by the US Food and Drug Administration (FDA).

- 5.6 It is worth noting that in Australia, to help consumers make informed choices, the TGA require all active ingredients, including zinc oxide and titanium dioxide, to be declared on sunscreen labels. However, it is not a requirement for sunscreen labels to list the particle size of those active ingredients. That is, whether a product contains nano-particles or not.

**Other factors in support of discontinuing the investigation**

- 5.7 Despite claims to the contrary by FoE and its supporters, NICNAS acknowledges in its public statements that there is no internationally agreed definition of nanomaterial. Staff note that under the definition used by Antaria and Ross Cosmetics, the claim that their statements that their products are not nanomaterial are correct. FoE, on the other hand, is using a definition that supports their agenda. Therefore, any Enforcement action would be significantly complicated by the lack of an agreed definition of "nanomaterial".
- 5.8 FoE's assertion that it suffered reputational and financial loss as a result of the concern its Sunscreen Guide inaccurately listed some sunscreens as "nano-free" is more appropriately resolved by private action.

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**6. Objectives and case theory**

- 6.1 FoE has promoted a campaign about the health risks associated with nanotechnology. As part of that campaign, FoE has focused attention on the use of nano-scale zinc oxide and titanium dioxide material in the manufacture of sunscreens and cosmetics. FoE allege that by publishing its Sunscreen Guide with incorrect information, primarily provided by the Antaria and Ross Cosmetics, FoE has suffered damage to its reputation and costs associated with printing the Guide.

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**7. Options – with anticipated timeframes and indications as to likely legal costs**

**Option – Discontinue investigation**

- 7.1 In light of the discussion above, staff consider that notwithstanding the issue that much of the alleged conduct may not be in trade and commerce, the evidence available demonstrates that Antaria and Ross Cosmetics have not engaged in misleading conduct and the investigation should now be discontinued. Staff are alive to the need to ensure that any closing letter will need to be carefully drafted given FoE's passionate views on this issue.

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**8. Recommendation and return date**

- 8.1 The EC direct staff to discontinue investigation of this matter and a closing letter be sent to FoE.
- 8.2 **Proposed month of return to EC: N/A**

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**9. Attachments**

- |     |   |        |
|-----|---|--------|
| 9.1 | Copy of the 2011/12 Sunscreen Guide                                 | 1 page |
| 9.2 | Brands which use Antaria and Ross Cosmetics zinc oxide formulations | 1 page |
| 9.3 | Copy of the Zinc Oxide Neutral Particle Distribution Graph          | 1 page |

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9.4	Copy of untitled document dated 5 October 2010 provided to the Invisible Zinc brand	1 page
9.5	Copy of certification document entitled " <i>certificate of analysis</i> "	1 page



Attachment 1

INHALATION OR INGESTION OF SUNSCREENS AND COSMETICS IS ALSO A CONCERN

Respiratory and ingestion of nanoparticles and chemicals from sunscreens and cosmetics is also a concern...

INTERNATIONAL ACTION TO MANAGE NANO RISKS The European Commission has published a report about...

WHAT IS THE AUSTRALIAN GOVERNMENT DOING TO KEEP SUNSCREENS SAFE?

The Australian government has taken steps to ensure the safety of sunscreens...

CHEMICAL UV ABSORBERS IN YOUR SUNSCREEN, MOISTURISER OR MINERAL FOUNDATION

Chemical UV absorbers absorb UV radiation and convert it into heat...

YOUR PART TO PLAY

As part of the national plan, we have developed a range of products to help you make informed choices...

JOIN OUR NANO NETWORK IT'S FREE. Learn about how nanotechnology will affect our lives and what you can do about it...

SAFE SUNSCREEN GUIDE SUMMER 2011/2012. Friends of the Earth Australia. YOUR GUIDE TO NANO-FREE SUNSCREENS. Sunscreens are an essential part of our safety...

SAFE SUNSCREEN GUIDE SUMMER 2011/2012. MANY COMPANIES NOW AVOID USING NANOPARTICLES IN THEIR PRODUCTS BY CHOOSING THESE BRANDS YOU ARE CHOOSING TO AVOID THEM.

SUNSCREENS STAY SUN SAFE. The sun is the most powerful natural source of UV radiation...

COMPANY SUNSCREENS - PRODUCTS DESIGNED PRIMARILY TO PROTECT SUN PROTECTION. Eco Tan, Eco Minerals, Eco Minerals, Eco Minerals...

COSMETICS THAT CONTAIN SUNSCREENS. Sunscreens are an essential part of our safety...

Table with 4 columns: BRANDS, INGREDIENTS, NANO-FREE, and CHEMICAL-FREE. Lists various brands and their product types.

Table with 2 columns: BRANDS and INGREDIENTS. Lists brands and their product types.

**Attachment 2**

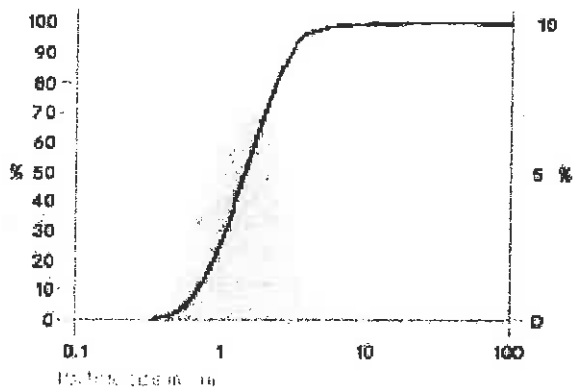
Manufacturers who may have incorrectly responded to the FoE Sunscreen Guide questionnaire:

- Cancer Council
- Woolworths
- Natural Instinct
- WotNot
- ChemMart
- Grahams Sunclear
- White Chemists
- Pharmacy Choice
- Invisible Zinc
- Mukti Botanicals

**Attachment 3**

COIL OXIDE NEUTRAL

PARTICLE SIZE DISTRIBUTION (VOLUME DISTRIBUTION)



■ % of particles below a given size  
■ average distribution in %

Instrument: Malvern Mastersizer (MS 1000/MS 15)  
Scientific principle: Fraunhofer diffraction  
Sample preparation: Ultrasonic horn, 200 W, 2 min.

**Attachment 4**

PC3.24

17



**ZinClear-IM\_50AB**  
**ZinClear-IM\_50CCT**  
**ZinClear-IM\_50JJ**  
**ZinClear-IM\_55L7**

Antaria Limited certifies that the product ZinClear-IM™

- is NOT classified as 'nano material' and therefore does not require to be labelled as such.
- the particle size is above 100 nm.
- the average particle size is greater than 1  $\mu$ m.

5 October 2010

A handwritten signature in black ink that reads "A. K. Hall". The signature is written in a cursive, flowing style.

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Quality Assurance Manager

## Attachment 5

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R6.83\_R2

## Certificate of Analysis



Product Code: ZinClear-IM\_55AB

Product description: ZinClear-IM™ 55 wt % transparent Zinc Oxide dispersed in C12-15 Alkyl Benzoate

Batch: IM430

Test Name	Specification	Test Method	Result
Appearance	Pale yellow to yellow green	Visual	Conforms
ZnO assay, %	Min: 53 – Max: 57	AAS	54.7
Loss on drying, %	Min: 0 – Max: 1	2 hrs 90°C	0.46
Particle size, µm	> 1	Laser light scattering	5.95
Total transmittance (550 nm)	> 90 %	UV Vis, internal method	92.9

Date of Manufacturing: June 2011

Retest Date: June 2013

Issue Date: 16 June 2011

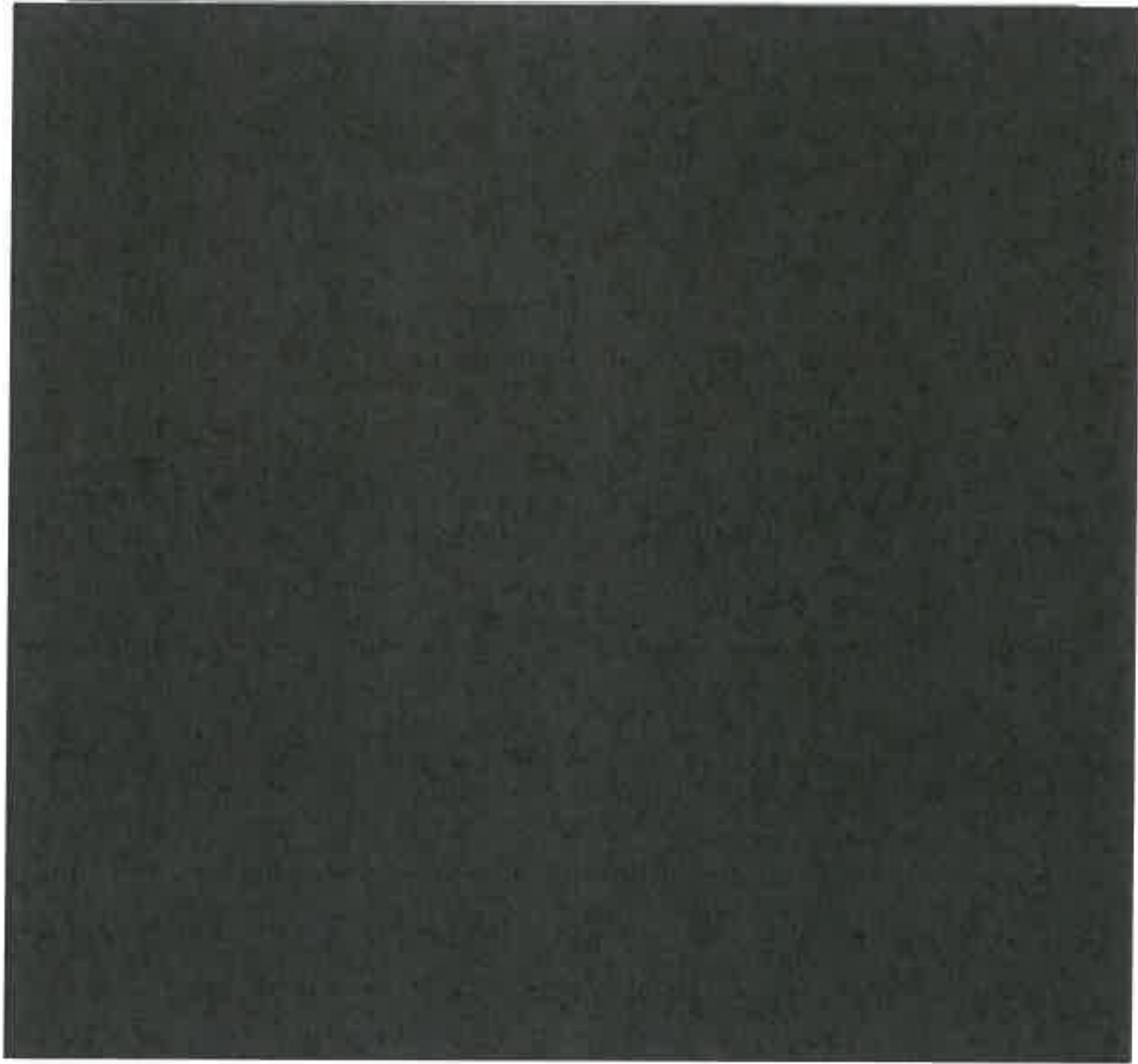
Teresa White, Quality Control

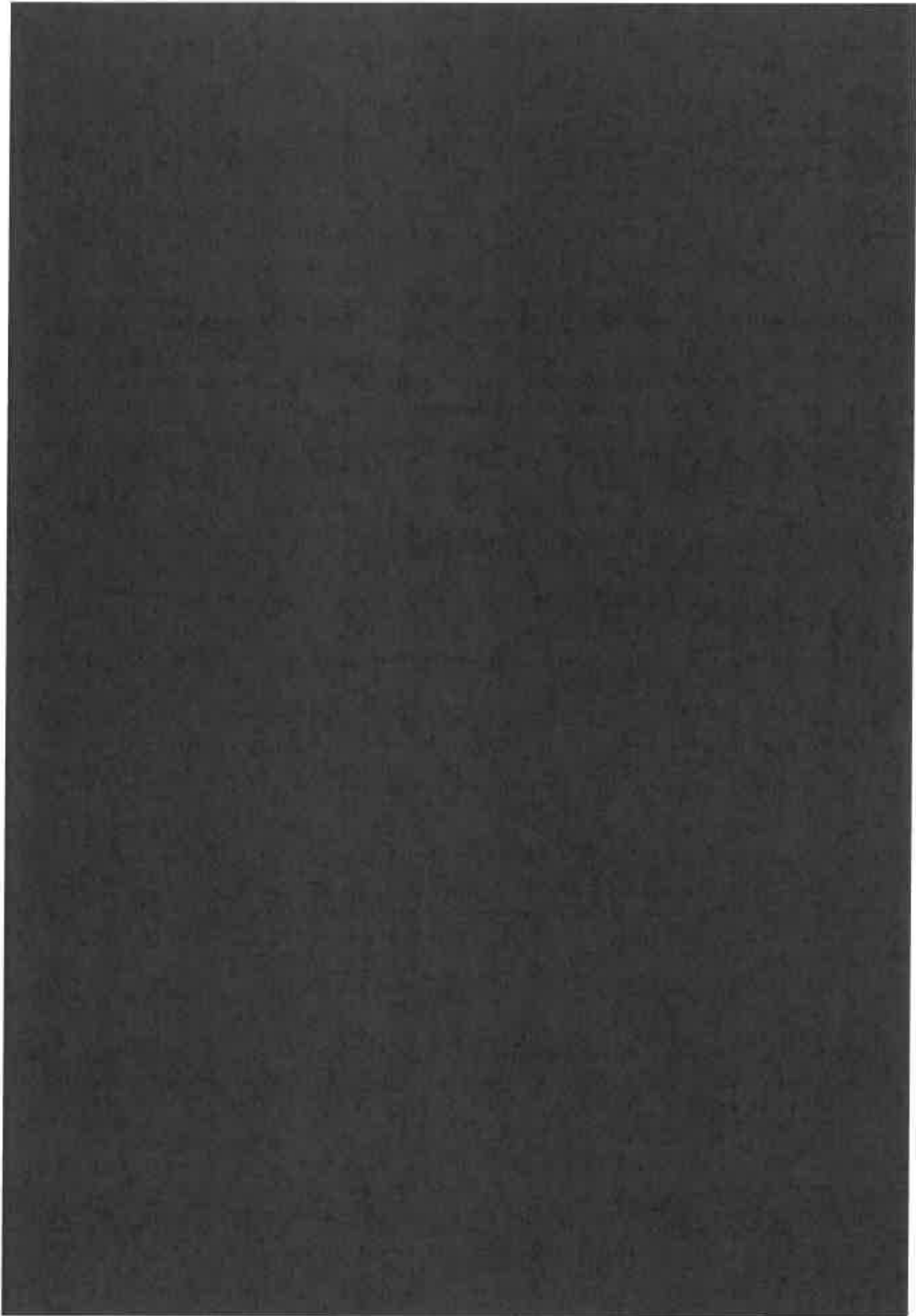
Antaria Ltd and Ross Cosmetics Aust. Pty Ltd  
 100 The Esplanade, West Wyalong, NSW 2590, Australia  
 Tel: 02 6942 1111 Fax: 02 6942 1112

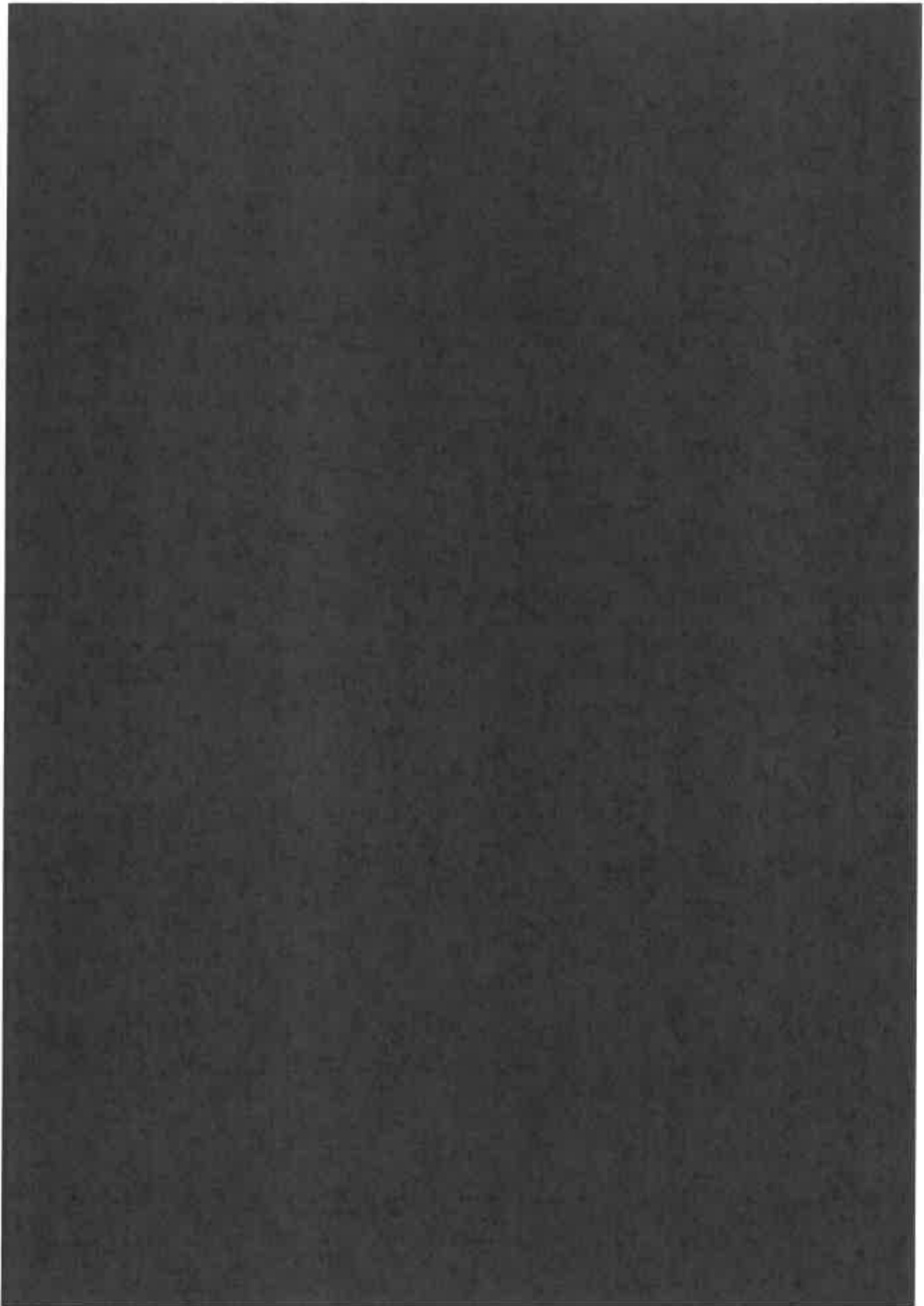


## Enforcement Committee Minutes

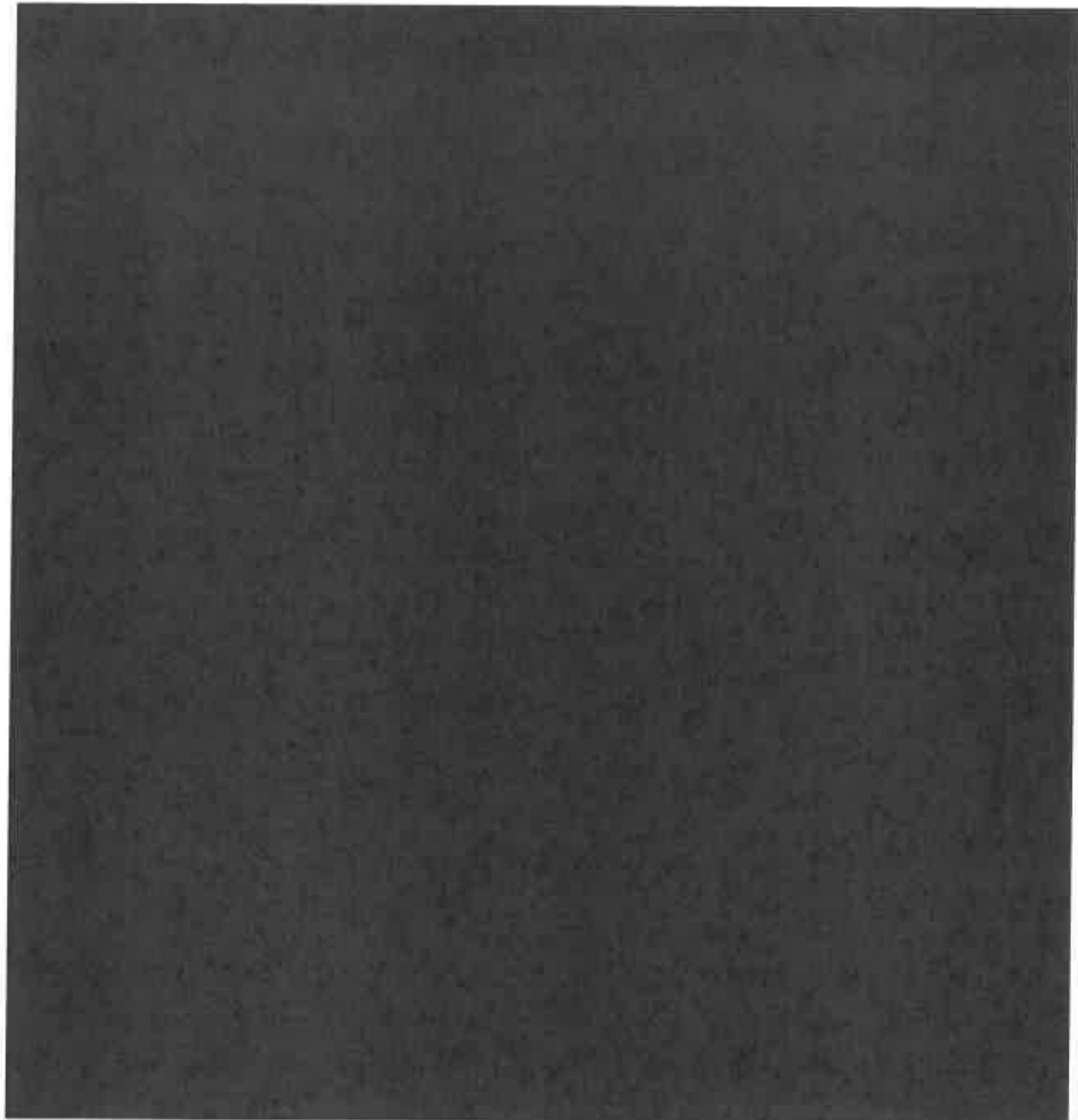
<b>Meeting date</b>	<b>4 April 2013</b>
<b>Meeting number</b>	1213/35
<b>Issue number</b>	1
<b>Locations</b>	All offices
<b>Commissioners</b>	Court (Chair), Sims [REDACTED] Walker, Rickard, Schaper, Dimasi [REDACTED]
<b>Senior managers</b>	Cassidy, de Gruchy, Bezzi, Gregson, King, Peter, Renehan, Cooper, Hannah
<b>Apologies</b>	Grimwade, Ridgway











**Enforcement Operations Western Australia**

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**Antaria Ltd and Ross Cosmetics Aust. Pty Ltd - Nano Claims**      **EC1213/243**

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**Trackit**                      50985

**Decision**                      The Committee directed staff to discontinue the investigation.

**Return date**                      Not scheduled to return

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**Case managers**                      Adrian Bettella, Peter Cromwell, Murray Beigel

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