OMBUDSMAN'S OPINION

Request for regulatory cosmetic ingredient nanomaterial notifications
Refusal by the Environmental Protection Authority
Complaint by the Sustainability Council of New Zealand

Background

On behalf of the Sustainability Council of New Zealand, Ms Stephanie Howard wrote to the (then) Environmental Risk Management Authority (ERMA) seeking:

> *"all notifications filed up until July 6 2010 that relate to the use of nanoparticles/material in cosmetics, as required under the Cosmetics Group Standard."*

By letter dated 2 August 2010, Andrea Eng (General Manger, Hazardous Substances) replied releasing one of two notifications held.[1] The second document was withheld pursuant to section 9(2)(b)(i) and (ii) of the Official Information Act (the OIA).[2]

Ms Howard responded seeking a reconsideration of that decision by email dated 17 August 2010, in which she stated:

> *"We do not believe that the response – withholding all content of the notification in question – conforms to s17 of the Act in particular, when 'there is good reason for withholding some of the information; contained in a document, the other information in that document may be made available by making a copy of that document available with such deletions or alterations as are necessary'.*
>
> *(...)*
>
> *Under s 17(2) we further request that if the revised version does not already make clear the grounds which part of s9(2) is grounds for withholding the information, then can you please identify which of 9(2)(b)(i) or 9(2)(b)(ii) is being relied on."*

Ms Eng responded and confirmed the withholding, and added:

> *"The notifier concerned has provided sufficient justification for withholding the information under both s9(2)(b)(i) and (ii)."*

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[1] Consultation had established that the third party consented to release.

[2] This section provides for the protection of information where making it available would disclose a trade secret (9(2)(b)(i)) or be likely to unreasonably prejudice the commercial position of the person who supplied or is the subject of the information (9(2)(b)(ii)).

(I interpolate here that the test in the OIA for withholding information is not whether or not the notifier has provided "*sufficient justification*", but whether the holder of the information, in this case the EPA, has "*good reason for withholding the information*".)

Ms Howard sent a further and final email to ERMA on this issue on 9 September 2010, and provided a detailed explanation of the background to and reason for her request. This is reproduced for completeness and ease of reference:

> *"The HSNO notification requirement for nanoscale cosmetic ingredients is a provision that the Sustainability Council is very keen to see working effectively until full regulatory scrutiny of such materials is introduced. This was the main focus of our submission to the ERMA committee hearing on the Cosmetic Group Standards last month.*
>
> *In addition to poor monitoring for compliance and enforcement, we are concerned that the notification policy supports the lack of transparency about the commercial use of nanoscale cosmetic ingredients as the approach adopted by ERMA presumes all details provided in notifications are confidential unless released under the Official Information Act.*
>
> *This does not allow New Zealanders to make an informed decision as to whether to use or avoid products containing such ingredients and places a heavy burden on ERMA staff to manually consider each notification should OIA requests come forward.*
>
> *This is unfortunate for the ERMA staff who will need to process these requests and for the Council: the public right to know about the use of such novel particles in high exposure products is such that we intend to lodge regular OIA requests to ensure that information about the use of nanoscale cosmetics ingredients is available.*
>
> *The presumption of confidentiality is not a necessary interpretation of the notification regulations and we believe there is a way forward that will allow ERMA to ensure that commercially sensitive information can be withheld while providing a basis for New Zealanders to make informed decisions until such time as greater regulatory scrutiny is brought to bear. This can be achieved by changes to the notification form, by making certain details publicly available as a matter of course. Based on the current form, the details that should be made publicly available as a matter of course are:*
>
> *Name of company*
>
> *Name of product*

> *Type of nanomaterial used*
>
> *Commercially sensitive information or information that might constitute a trade secret includes formulation, concentration and purpose of nanomaterials. It would be reasonable, in our view, for ERMA to withhold this information as a rule, and consider its release on a case-by-case basis in response to specific OIA requests. (This is not information that the Council would seek as a matter of course, but might choose to obtain as a result of developments in nanosafety.)*
>
> *We understand that there may be some resistance by the industry to such a move, but developments in other jurisdictions make transparency by way of labelling and public registers inevitable in New Zealand. The case for public right to know about the use of nanomaterials in cosmetics has been affirmed in the new European Union directive, which New Zealand Group Standards is tagged to, and will see many products labelled and a comprehensive public register once it enters into force. You may also be aware that the primary Australian cosmetics trade association (ACCORD) has just announced its support for labelling of nanotech ingredients".*

I am not aware that any reply to that email and suggestion was received prior to my investigation commencing.

Since Ms Howard's request, the Environmental Protection Authority (the EPA) has been formed, succeeding to this outstanding matter. The EPA has reviewed whether nanomaterials ought to be compulsorily identified in product labels. I understand that compulsory identification will be introduced in 2015. However, until then, the issue of whether notifications may justifiably be withheld under the OIA – or not – remains open.

The complaint

Ms Howard (on behalf of the Sustainability Council of New Zealand) made a complaint about the refusal of the request.

By way of background, Ms Howard explained:

> *"Under the Hazardous Substances and New Organisms Act, the use of certain nanoscale ingredients in cosmetic products triggers a requirement for importers and manufacturers to notify ERMA."*

In her complaint, Ms Howard made the following comments:

> *"We do not believe it reasonable for ERMA to withhold all details of the notification in question. We have made the case to ERMA at a hearing on the Cosmetic Products Group Standard and in a subsequent letter*

(see attached correspondence, No. 5) that while some information (such as concentrations or exact composition) might be commercially sensitive or constitute a trade secret, it is difficult to see how other information required in a notification – such as product name and type of nanomaterial – would be sufficiently commercially sensitive or constituted a trade secret that outweighed the public right to know.

Of note, ERMA made a similar distinction in response to a subsequent request (August 13 2010) for any new notifications, choosing to release the notification but withholding details concerning the concentrations:

> "ERMA New Zealand has withheld some information relating to the concentrations of the nanomaterials in the finished products, as well as information relating to the concentrations of the components making up the nanomaterials under s 18(a) of the OIA." *(ERMA, Response to the Sustainability Council, September 17 2010, File Ref: ENQ-08474-HYVWMG)*

*The public right to know about the use of nanomaterials in cosmetic products is the basis of consumer choice. This was affirmed last year by the then Minister for Consumer Affairs, who stated that consumers should "*have ingredient information that enables them to make informed personal choices about products.*" (Roy H, "*Effective Market And Consumer Choice*" ...).*

At present, there is no regulatory requirement for manufacturers to inform their customers as to the use of nanomaterials in product lines (e.g., by way of labelling). Our own research has indicated that manufacturers are generally unwilling to confirm the use of nanomaterials. At present, therefore, the notification requirement can provide an important source of information about whether nanoscale ingredients are present in cosmetic products.

Release of information will also help ascertain whether the notification scheme is working.

In a report we released in June[3] ..., we identified a number of cosmetic products that appear to contain nanoscale ingredients that would require notification to ERMA. However, when the report was released, there had been no notifications, suggesting that the notification regime was not functioning effectively. Knowing what products have been notified since then will help determine whether regulatory agencies are following through, and which companies are complying."

[3] *http://www.sustainabilitynz.org/docs/TheInvisibleRevolutionJune2010.pdf*

ERMA's comments

Following the notification of this investigation, ERMA provided the following response:

> *"In accordance with section 57 of the Hazardous Substances and New Organisms Act 1996, if ERMA New Zealand receives a request for information that they believe may be able to be withheld under s 9(2)(b) of the OIA, ERMA New Zealand must notify the applicant of that request. The applicant is then given 10 working days to respond to ERMA New Zealand stating whether they believe that the information should be withheld, and if so, on what grounds.*
>
> *In this case ERMA New Zealand considered that the information may be able to be withheld under s 9(2)(b). Therefore, ERMA New Zealand notified the applicant (Key Pharmaceuticals Pty Limited) on 12 July 2010.*
>
> *The applicant responded on 28 July 2010. They expressed the belief that the information should be withheld on the grounds set out in both s 9(2)(b)(i) and 9(2)(b)(ii) of the OIA.*
>
> *The response included a document entitled* "Justification for the withholding of confidential information"*. ERMA New Zealand considered the information that Key Pharmaceuticals provided and determined that there was sufficient justification for withholding the information. ERMA New Zealand subsequently refused Ms Howard's request for a copy of that information.*
>
> *As explained in the justification document, the specific prejudice or harm that is likely to occur if the information is disclosed is that competitors of Blistex would denigrate the brand to the consumer and the applicant would lose market share, potentially across the full brand and not only the two products that contain the nanoparticle material.*
>
> *ERMA New Zealand considered the proposed alternative to release of the full document but considered that to release even part of the document would not be an appropriate course of action.*
>
> *ERMA New Zealand considers that all of the information provided in the document in question is confidential information, and to disclose even part of it would be prejudicial to the applicant."*

Further meetings and discussion on this matter have taken place between the EPA and my staff.

Wyeth[4]

ERMA referred to the Supreme Court judgment in *Wyeth* - in particular to the application of section 57 of the Hazardous Substances and New Organisms Act (the HASNO Act), and its relationship with section 9(2)(b)(ii) of the OIA. I note that prior to that decision, the original request for information and the refusal by ERMA to release the requested information was considered by my colleague, Dame Beverley Wakem (now Chief Ombudsman). I have referred to her investigation into the matter, and reviewed *Wyeth.*

Context of Wyeth
In *Wyeth,* the context of the request was that a competing provider of veterinary medicine products used the OIA to request information that identified the formulation of a medicine that had been submitted to ERMA for approval. The submitter's vested commercial interest in keeping the formulation secret from a competitor was clear. The main argument advanced in support of release was that it was impossible for the requester to make a fully-informed submission, for the purposes of the hearing to approve (or not) the product, without the secret information at issue being released either publicly, or to the requester with conditions. It was also argued that it was in the public interest for the requester to have the information in order for the decision-makers appointed to oversee the approval process to benefit from its specialist expertise and opinion. This argument was not successful.

Context of this matter
The context of this matter differs from *Wyeth.* There is no application for a new product; no submissions called for; and no approval hearing scheduled. Rather, this request is for copies of notifications that had been provided to ERMA (now the EPA) in compliance with its *Cosmetic Products Group Standard* (the *CPGS*) and that relate to an existing product on the market.

I note that the requester does not have a commercial interest in the release of the information, but seeks to inform public debate and promote informed choice by consumers. I agree with a point made to me by the EPA that the latter, in itself, does not remove the possibility of unreasonable commercial prejudice arising, though it is clearly a relevant factor in any consideration of where the public interest lies in release.

Comparison of Wyeth *with this request*
The issue of unreasonable commercial prejudice is a common factor in both *Wyeth* and the matter at hand. But the circumstances in which this prejudice is alleged differ markedly. In *Wyeth,* a competitor sought access to a unique and secret formula. The alleged prejudice was that publication of the formula would allow duplication and the manufacturer would no longer be the exclusive provider of the product. Thus the manufacturer would lose an existing market advantage due to the disclosure of the information. This request is not for the identity of a unique and

[4] *Wyeth (NZ) Limited v Ancare New Zealand Limited and Anor* [2010] 3 NZLR 569.

secret formula. The ingredients present in the *Blistex* lipbalm are already known. It is the *form* of one ingredient – in this case, as a nanomaterial – that is sought to be identified. It is not what it is, but the way in which it is being used that is at the heart of this matter. In this case, the alleged prejudice is not exposure of a secret formula to commercial duplication creating a likelihood of commercial prejudice, as in *Wyeth*, but instead the unreasonable prejudice alleged is exposure to, and the manipulation of, public opinion. The considerations of prejudice differ and this matter cannot be resolved on the same basis as *Wyeth.*

Section 9(2)(b)(i)

The EPA refused the request on 2 August 2010, relying on section 9(2)(b) of the OIA. It was noted in its report to me of 6 December 2010, that the supplier of the information (Key Pharmaceuticals Pty Ltd) considered that section 9(2)(b)(i) of the OIA applied to the requested information. However, the EPA has not advanced any further arguments in support of this ground and it has not been further considered.

Section 9(2)(b)(ii) - prejudice to commercial position

This section reads:

> *"9 **Other reasons for withholding official information***
>
> *(1) Where this section applies, good reason for withholding official information exists, for the purpose of section 5, unless, in the circumstances of the particular case, the withholding of that information is outweighed by other considerations which render it desirable, in the public interest, to make that information available.*
> *(2) Subject to sections 6, 7, 10, and 18, this section applies if, and only if, the withholding of the information is necessary to— ...*
> *(b) protect information where the making available of the information— ...*
> *(ii) would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information; ..."*

I take the following approach:

- *Is there a commercial position? If so, what?*
- *Is there a prejudice/disadvantage? If so, what?*
- *Is that prejudice or disadvantage unreasonable? If so, why?*
- *If the above is so, then is it "*necessary*" to withhold the information?*

Is there a commercial position? If so, what is it?

I have referred to the previous Ombudsman investigation which preceded the Court's judgment in *Wyeth* on the request for information held by ERMA. In that investigation the Ombudsman concluded that the company which had provided the

information to ERMA self-evidently had a commercial position. Having read the information provided to me by ERMA on this matter, I similarly conclude that the provider of *Blistex* (the product containing a nanomaterial) has a commercial position.

Is there a prejudice/disadvantage? If so, what is it?

Key Pharmaceuticals Pty Ltd (the provider of the notification to ERMA), argued that the release of the requested information would result in commercial prejudice in the form of adverse consumer reaction. It argued as follows:

> *" ... the disclosure of confidential formulation data would be misused by the competitors to denigrate the brand to the consumer either via the media or sales staff ... (o)ur competitors which use this knowledge to denigrate the brand and we would lose market share, potentially across the full brand and not only the two products that contain the nano-particle material. It is unlikely our competitors or the Sustainability Council would clearly spell out exactly which two products in the* Blistex *range contained the nano-particles and it is believed the full range of* Blistex *products may well be implicated in the media attention that may eventuate ... (a)s nano-technology and nano-particles are a topic of speculation in New Zealand and to the best of our knowledge, we are the only company in the lip care market to have listed with ERMA, we would be adversely affected if the confidential data relating to the formulations was to be made public ... disclosure of the formulation details would cause our competitors to denigrate our brand and this would be unreasonable as only two of the products contain nano-particles, which are only a topic of speculation in New Zealand - there has been no proven risk of the particular materials in the* Blistex *products - they are allowed in all other International Markets (i.e.: no restriction in other countries or need to report information on packaging). It therefore seems unreasonable that the confidential information be made public ... The Sustainability Council has recently published an article titled '*Nanotech Commercialisation Racing Ahead of Safety Regulation*' in which they broad-brush cosmetic products containing nano-particles advising consumers that there is no safety assessment conducted on the products before they are marketed. Should they have access to the data on* Blistex *products, it is apparent that they would tarnish the* Blistex *brand with the same brush, and thus cause major harm to the brand in the commercial world. Only 2 of 8 Blistex products in NZ contain nano-particles, and this particular ingredient has been in use for many years, in many products throughout the world with a good safety profile. Similarly, if the information were to be made public our competitors would use the information to denigrate the entire brand of* Blistex *- it is highly unlikely that they would clarify the two individual products that contain the nano-particles, nor explain that the particular material has in fact been used over many*

> *years without any safety issues. Nano-particles are a current topic of interest in the media with unwarranted hype for many of the materials - there may be safety concerns with some nano-particles, but not with those used on* Blistex *products."*

As I understand it, the argument is that were the information advising of the presence of nanomaterial in products to be released, it will be publicised by the requester and accompanied with its views that a product containing nanomaterials is capable of having potential adverse effects, or is unsafe to use, or unproven to be safe. These views will be used to convey the impression of a safety threat to consumers, who, taking note of this campaign, will be influenced to avoid the product, causing a decline in sales. In essence, Key Pharmaceuticals argues that a likelihood of misuse of information is a reason for withholding information.

The requested information is factual information. If released, persons who are interested in the information may choose to comment on it. Such comment may include adverse criticism. However, information is not generally withholdable under the OIA simply to avoid adverse criticism being generated. If it were, much information with political implications, for example, would not be released. Generally speaking, in situations where releasing information is likely to generate public criticism (fairly or unfairly), then it is open to the supplier of the information (or any other interested party) to release an explanatory or contextual statement along with the information, setting out the factual matters at issue and stating its position with regard to those matters.[5]

I do not consider criticism to be a prejudice in and of itself. People and organisations are entitled to express their opinions, and it is an object of the OIA to allow them to do so on the basis of a fuller access to the relevant information than might otherwise be the case. I further note that in the manufacturer's view quoted above, the creation of the predicted prejudice depends on the alleged misuse of the factual information.

By way of noting the consumer response to the presence of nanomaterials, I note that the EPA did release one of the two notifications within the scope of the request (as the supplier of the notification agreed to its release) and as far as I am aware the second product remains available for purchase. Criticism or consumer disaffection does not appear to have followed the information release.

Thus, I am not convinced a prejudice exists. However, for the purposes of argument, I adopt a cautious and speculative approach and assume that criticism can create an identifiable prejudice which, for present purposes, I take to be the negative effect on the reputation of *Blistex* in the New Zealand market, caused by adverse criticism that is made as a result of the public identification of *Blistex* as having nanomaterials in it.

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[5] I also note that lip balm as a product is not immune from criticism (http://www.radionz.co.nz/national/programmes/thiswayup/audio/2498101/lip-balm-support-group) and *Blistex* itself has received such criticism (various websites). Therefore, given the existence of criticism of this product, whether the release of information would further add to any existing prejudice would need to be sufficiently established.

Is that prejudice or disadvantage unreasonable? If so, why?

The argument put forward is that a prejudice (if established) is unreasonable because the released notification could be used by the requester to make misleading or incorrect adverse statements about the product, attempting to influence consumers to consider the product unsafe, thus detrimentally affecting the reputation of *Blistex* and reducing market share. It is argued that to expose *Blistex* to the predicted behaviour of the requester is unreasonable because it is simply not true that the presence of nanomaterials in *Blistex* is unsafe. Specifically, it was stated *"there has been no proven risk of the particular materials in the* Blistex *products"*.

In choosing to put nanomaterial into its product, a manufacturer may be presumed to take the view that the material is a necessary ingredient in that product. If that is the case, I do not consider that it is unreasonable for it to explain, if necessary, the reasons why this is so for the benefit of consumers. I would note, as above, that the supplier of the product can take steps to prepare for release of such information, including provision of information as to why the nanomaterial does not cause harm given that it asserts this is so.[6]

I appreciate that bad publicity about a product will be viewed as unreasonable by any manufacturer. But I consider a more objective consideration (though not uninfluenced by the manufacturer's perspective) is called for.

The simple fact of the matter is that, once informed that the nanomaterial is present, if consumers have no concerns about purchasing a product with the nanomaterial, they will do so and sales will continue unaffected.

However if, in light of the information being released, consumers choose to avoid a product on the basis that it contains nanomaterials (and regardless of whether this choice is influenced by the opinion of the Sustainability Council or made independently), then I fail to see why an impact on sales that is due to a more informed consumer choice can be classed as unreasonable.

I consider that no unreasonable prejudice is established. I thus conclude that section 9(2)(b)(ii) is not a valid basis for withholding.

Section 9(2)(ba)

In the course of the investigation, the EPA indicated that it considered that withholding the information is justified based on an obligation of confidence. Although no detailed submissions have been made on construction of such an obligation, and any associated consequences of breaching it, this issue is one of significance for the EPA and the requester, and it is appropriate that I consider this ground so that all the relevant issues in this matter are addressed.

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[6] Noting also section 24 of the *CPGS* which requires that cosmetic products must not cause harm.

Section 9(2)(ba) states:

> ***"9 Other reasons for withholding official information***
>
> *Subject to sections 6, 7, 10, and 18, this section applies if, and only if, the withholding of the information is necessary to—*
>
> *...*
>
> *(ba) protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information—*
>
> *(i) would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied; or*
> *(ii) would be likely otherwise to damage the public interest."*

Compulsory provision

Section 9(2)(ba) applies to both information that is subject to an obligation of confidence, and equally to information " *... which any person has been or could be compelled to provide under the authority of any enactment".*

As the notification requirement is a component of the *CPGS*, which itself has been created under the authority of the HASNO Act,[7] I accept that the information has been provided under the authority of an enactment. Further, the *CPGS* states that:[8]

> *"Notification of nanomaterials in cosmetics*
>
> *Any person intending to import or manufacture a cosmetic product containing nanoparticles other than zinc oxide or titanium dioxide* ***must****, at the time they first import or manufacture the substance, notify ERMA New Zealand. Manufacturers or importers notifying us of nanomaterials in their products must use the following form: ... ."*
>
> (emphasis added).

The requested information is supplied in order to comply with a regulation. It is not an optional or voluntary supply of information. I therefore consider it can be compelled, within the terms of this section. Therefore, the threshold for the application of section 9(2)(ba) has been established.

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[7] HASNO Act 1996, section 96B.
[8] http://www.epa.govt.nz/hazardous-substances/approvals/group-standards/Pages/cosmetic.aspx

Prejudice to supply – section 9(2)(ba)(i)

For section 9(2)(ba)(i) to apply, it must be shown that the release of information *"would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied ...".*

Generally speaking, where information is required to be supplied under an enactment it is not likely that supply of information will be prejudiced, as the enactment safeguards and enforces the supply of the information.

This is particularly so where the supplier of the information is seeking approval to access the New Zealand market, as here, and an approval will not be forthcoming if the information is not provided. In this case there is a clear built-in incentive for the information to be provided, even in the absence of utilising an enforcement provision.

Further, it is noted on the notification form for nanomaterials that *"(u)nder the Official Information Act 1982 (OIA) the EPA may be required to release information in response to a request for information".*[9] The supplier of the information is clearly on notice that the OIA applies to information supplied by it to the EPA. There is no evidence that this has caused a problem to the supply of information. In my view, section 9(2)(ba)(i) is not made out as a valid withholding ground.

Damage to the public interest - section 9(2)(ba)(ii)

For section 9(2)(ba)(ii) to apply there must be damage to the public interest. It needs to be shown precisely what the public interest at issue is, and why disclosure of this information would be likely to damage it. I have seen no material suggesting what public interest is served by withholding this information.

However, I note the following:

- The EPA has a role to protect the environment and people of New Zealand from adverse effects of hazardous substances or new organisms.

- The EPA requires notification of nanomaterials in cosmetic ingredients. However, because the nanomaterials are incorporated into products that have already received an approval via the Group Standard process, the EPA does not currently further review or freshly evaluate the risk of each or any product containing a nanomaterial to the environment or people on receipt of the notification.

[9] *Notification of Nanoparticles in Cosmetic products,* page 2.
(http://www.epa.govt.nz/hazardous-substances/approvals/group-standards/Pages/cosmetic.aspx)

- The EPA supplements the notification requirements by way of following international developments on managing nanomaterials.

- Consistent with international developments, the EPA has recently announced that it will require products with nanomaterials in them to be compulsorily labelled as such. This requirement will not apply until 2015. Until that time, manufacturers are not required to inform the public about the presence of nanomaterials in products for sale in New Zealand.

- The public relies on the EPA to evaluate substances and materials that may pose a risk to the environment or people of New Zealand. It is clearly in the public interest that its receipt of this information to assess risk not be undermined.

- While the role of the EPA is as a specialised and expert evaluator of information, this does not prevent the public from undertaking its own evaluation of information and making its own assessment regarding risk and safety.[10] The two are not mutually exclusive.

- I have not identified any likelihood that the release of the information would adversely affect the role of the EPA, as the information at issue is not currently used by the EPA for further evaluations of risk of each material that is the subject of a notification.

- In fact, by empowering the public to make its own decision regarding the degree of risk it will accept in relation to nanomaterials, this would appear to support the EPA's role to manage risk.

Accordingly, I have identified no damage to the public interest that would occur if the requested information were to be released to the public.

Therefore, I do not consider section 9(2)(ba)(ii) to justify withholding the information.

My opinion

I conclude that neither section 9(2)(b) nor section 9(2)(ba) provide good reasons for the EPA to withhold the information. The request should not have been refused.

David McGee
Ombudsman

4 December 2012

[10] Refer to the HASNO Act, section 5(b). It might also be argued that the public are the best judges of their own interest, and, where this is to be abrogated, sufficient justification must exist and must be no more than is necessary.