APPENDIX A
METHODOLOGY REPORT

QUANTITATIVE CONSUMER SURVEY ON ALLERGEN LABELLING: BENCHMARK 2003

REPORT ON SURVEY DESIGN

C02039 March 2003

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Prepared by

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1 BACKGROUND

1.1. Introduction

Anaphylactic reaction to allergens in food products is a serious health issue that affects around one percent of adults and less than ten percent of young children (FSANZ 2002).

Such a reaction can occur as a result of exposure to substances such as:

- Crustacea and their products;
- Egg and egg products;
- Fish and fish products;
- Milk and milk products;
- Nuts and sesame seeds and their products; and
- Peanuts and soybeans and their products.

The new *Australia New Zealand Food Standards Code* (the Code) was fully effective from 20 December 2002, and specifies three levels of advice for consumers:

- Mandatory warning statements;
- Mandatory advisory statements; and
- Mandatory declarations of certain substances in food (allergen labels are an example of this requirement) that apply when the sorts of particular ingredients defined above are present as:
  - an ingredient;
  - an ingredient of a compound ingredient;
  - a food additive or component of a food additive; or
  - a processing aid or a component of a processing aid.

The objective of the mandatory declarations, warning statements and advisory statements are to provide consumers with sufficient information such that they and / or their carers can avoid potentially life-threatening adverse reactions to food or an ingredient in food.

Many food manufacturers have been in the process of bringing their food product labels into alignment with the new Code since it was first introduced in December 2000.

Food Standards Australia New Zealand (FSANZ), through its established Evaluation Strategy 2001-03, is therefore in the process of assessing through this research, how well the regulatory arrangements of the Code are working in terms of the allergen labelling requirements (*Standard 1.2.3)*.

This research with consumers is to collect baseline data against which comparisons can later be made, in charting the effects of the introduction of the labelling changes for allergens on those 'at risk' of anaphylactic reaction to foods.

Research objectives

The research aims outlined in the Request for Tender (RFT) were to:

- **Assess the level of awareness and knowledge of consumers** 'at risk' of an anaphylactic reaction and their carers (if relevant) of the labelling provisions that cover allergens;
- **Assess the ability** of those 'at risk' (if relevant) or their carers **to successfully identify those foods** that contain the pertinent allergens;
- **Understand the existing behaviours** of 'at risk' consumers (where relevant) or their carers in regard to food selection; and
- Identify whether a **lack of understanding of the allergen labelling** of foods contributes to the occurrence of anaphylactic reaction in those affected, and to what degree.

The evaluation described herein is the first part of what is intended to be a two-part process to measure the impact of the new labelling requirements.

This first phase is described as the **benchmark survey.** The survey is therefore referred to throughout as the Quantitative Consumer Survey on Allergen Labelling: Benchmark 2003.

It is planned to conduct a second phase of research at some time in the future to track changes in awareness, knowledge and behaviours when compared to the measures that are established by the benchmark survey based on the aims listed above.

This has an implication for the methodology selected in that it must be able to be replicated, a key requirement for ensuring reliability.

1.2. Target groups

The target groups for the proposed research were originally identified as:

- those at risk of anaphylactic reaction to certain foods or food ingredients; and
- their carers.

Food-induced anaphylactic reaction was defined in the RFT as a 'reaction that involves one or more of the following symptoms: difficulty breathing or throat swelling, generalised urticaria (hives) and/or faintness or collapse (FSANZ 2002).

Originally, participants to be included in the research were those who have already had an anaphylactic reaction, or who have been identified as 'at risk' of food allergies by medical specialists, or their carers in those instances where the person is a child aged 14 or under.

However, during the development of the questionnaire, the defined target group was broadened to the following definition:

By serious food allergy we mean a reaction that involves one or more of the following symptoms due to exposure to a particular food or food ingredient:

- **difficulty breathing or throat swelling,**
- **swelling or itching of lips or tongue,**
- **hives, skin rashes or eczema,**
- **stomach cramps, vomiting or diarrhoea, or**
- **faintness or collapse**

This broader definition was adopted in order to attain a wider cross-section of participants who may be assessing food labels critically, because of concerns about the presence of allergens, so it is not canvassing a truly anaphylactic population.

It should be noted that this survey is <u>not</u> intended to measure the prevalence of food anaphylaxis in Australia and / or New Zealand.

The questionnaire was eventually designed to be answered by the **main grocery buyer**, as it was deemed that they would be the most knowledgeable and appropriate person in the household to answer questions about food labels and food selection.

This report details the survey design and data collection procedures for the Quantitative Consumer Survey on Allergen Labelling: Benchmark 2003.

2 SURVEY DESIGN

2.1. Overall survey design

To address the requirements of the project in the most cost-efficient and appropriate manner possible whilst maximising the participation rate, a **self-completion** methodology was designed.

The methodology adopted comprises three data collection avenues:

- Medical institutions (clinics at hospitals);
- Private specialists in private practice; and
- Support groups.

The first two of these avenues are expected to provide a more 'balanced' sample in that those who are invited to participate will be selected by allergy specialists/immunologists according to an established selection protocol. Participants attained via the allergy support groups will be self-selecting and hence are likely to have a particular interest in or concern with the topic through their own or a family member being affected.

Each of these individual collection avenues is further discussed in sections 3 and 4, however the following note is made about a significant variation to the methodology as defined in the RFT documents:

The prescribed methodology was based on getting personnel from medical clinics to administer questionnaires to patients. It was suggested by NFO Donovan Research that a more appropriate (less onerous) approach would be to pay medical institutions a nominal amount to distribute the questionnaires to selected patients. This was subsequently the methodology adopted, and that is what is described herein.

The rationale for utilising this particular methodology (over the original one) was that:

- It minimised the level of involvement, or burden, required by selected hospitals or clinics with the aim of increasing their likelihood to participate;
- It had the capacity to include a larger proportion of respondents who have been aware of their own or their child's condition for a longer period, and hence have been exposed to labelling issues for a longer period;
- It minimised the potential muddying of data by having a relatively short data collection period;
- It preserved the privacy of respondents because the research agency does not come in contact with their contact details, and responses would be truly anonymous;
- It increased the randomness of the sample by reducing potential selection bias;

- It increased the representativeness of the sample by allowing more medical institutions across Australia and NZ to be included;
- It preserved quality standards; and
- It was cost-effective in that the cost of getting the agency to mail out the questionnaires is markedly reduced compared to having hospital personnel administer it (adjusted to compensate for non-responses with the preferred method).

A note on benchmarking

Ideally benchmark data should have been obtained prior to any changes to food labelling regulations. As it is, the new Code was in the process of implementation from December 2000 to December 2002, and hence some manufacturers had made changes to their labels in line with the new Code prior to December 2002. The data collected therefore cannot be truly defined as 'benchmark', but are really a snapshot of the situation at the time of recording.

2.2. Sample size

Sample size is usually based on the level of sub-group analysis that is required. In this instance FSANZ indicated that they would not be seeking the provision of detailed sub-group analysis, and hence a total sample size of n=500 is the target. Of this total, n=400 questionnaires will be sought via 'official' sources such as medical institutions and specialists, and n=100 will be sought via support groups.

The RFT specified that the data should deliver results to a 95% confidence level. Based on the projected population of probable anaphylactics[1], a sample of n=400[2] will allow for variations of 10% (+/- 5%). This means that there is a 95% probability (ie. 95% confidence) that the actual population percentage will not vary by any more than 5% in either direction from that recorded by the sample.

The number to be distributed was calculated based on an estimated response rate of 50%. Mailing out n=1000 self-completion questionnaires (n=800 via official sources and n=200 via support groups), and achieving n=500 returns.

The sample distribution is shown in Tables 2.2a – 2.2f.

1 *Based on the incidence statistics provided by FSANZ in the RFT (FSANZ 2002).*

2 *The calculation is based solely on the proportion of the sample that is attained via 'official' sources due to concerns about the representativeness of those who respond via support groups.*

The calculations of sample size are based on the Australian and New Zealand population statistics shown in Table 2.2a.

Table 2.2a Population characteristics for Australia and New Zealand

		Australia	New Zealand
Population (million)	June 2000	19.2	3.8
0-14 years (%)	June 2000	20.5	22.9
15-64 years (%)	June 2000	67.2	65.3
65 years and over (%)	June 2000	12.3	11.8

Sources: Australian Demographic Statistics, June 2000 (Cat. no. 3101.0); Statistics New Zealand, Demographic Trends, 2000, Wellington.

To spread the sample required across Australia and New Zealand in the correct proportions, the total population of both countries must be considered.

Based on these population figures and the prevalence rates provided in the RFT (FSANZ 2002), the proportions for the total sample required in each of the countries are shown in the following tables.

Table 2.2b Preliminary calculations for sample proportions

PROJECTED ANAPHYLACTICS	TOTAL	Australia	New Zealand
Total population	23,000,000	19,200,000	3,800,000
0-14 years	4,770,000	3,900,000	870,000
5% of children aged 0-14 (10% of children aged up to 7)	238,500	195,000	43,500
15+ years	18,230,000	15,300,000	2,930,000
1% of those aged 15+	182,300	153,000	29,300
Estimated anaphylactic population	420,800	348,000	72,800
Proportion of population by country		**83%**	**17%**

Of the total sample (n=500), 83% needs to be derived from Australia and 17% from New Zealand, as shown in Table 2.2c.

Table 2.2c How the sample is to be divided between the two countries (proportional)

SAMPLE SOURCE	TOTAL TO BE ACHIEVED	Australia	New Zealand
% of total required	**100%**	**83%**	**17%**
	n	**n**	**n**
Official sources (ie medical institutions, private clinicians)	400	332	68
Support groups	100	83	17
	500	415	85

When the sample is drawn from each Country, State and Territory in the correct proportion, it is not possible to compare between locations because the sample size is insufficient. A minimum of n=100 per location is recommended for sub-group comparisons.

Therefore, in order to enable some cross-country comparisons, albeit at a decreased level of confidence, it was suggested that the sample from 'official' sources be boosted for New Zealand. This involves shifting fifteen questionnaires from Australia to New Zealand, as shown in Table 2.2d.

Table 2.2d Proposed boosted sample for New Zealand

SAMPLE SOURCE	TOTAL TO BE ACHIEVED	Australia	New Zealand
% of total required	**100%**	**79% (adjusted)**	**21% (adjusted)**
	n	n	n
Official sources (ie medical institutions, private clinicians)	400	332-15 **=317**	68+15 **=83**
Support groups	100	83	17
	500	400	100

As shown above, this would mean that when the official and support group samples were combined, a total of n=100 responses would be obtained from New Zealand.

To attain the specified sample, and based on an estimated response rate of 50%, the number of questionnaire packs mailed out must be doubled, and this is shown in Table 2.2e.

Table 2.2e Calculations for 'boosted' sample from official sources

	TOTAL	Total sample required	Total mail out required	To be mailed out via medical institutions	To be mailed out via private clinicians
	%	n	n	n	n
TOTAL	100%	400	800	400	400
Australia	**79%**	317	634	317	317
New South Wales	*28.0%*	*100*	*200*	*100*	*100*
Victoria	*20.6%*	*80*	*160*	*80*	*80*
Queensland	*15.4%*	*60*	*120*	*60*	*60*
South Australia	*6.5%*	*26*	*52*	*26*	*26*
Western Australia	*8.2%*	*33*	*66*	*33*	*33*
Tasmania	*2.0%*	*10*	*20*	*10*	*10*
Northern Territory	*0.8%*	*NA*	*NA*	*NA*	*NA*
Australian Capital Territory	*1.3%*	*8*	*16*	*8*	*8*
New Zealand	**21%**	83	166	83	83

It should be noted that the Northern Territory, although comprising 0.8% of the total sample, is not included in the figures, since it was not possible to locate any official organisations (or private clinicians) that were suitable to take part. Hence their allocations of questionnaires have been redistributed to Tasmania and Australian Capital Territory.

Note: The final mail out sample size for each individual recruiter depends upon the number of collection points eventually arranged in each location (Country, State or Territory).

The number of questionnaires to be obtained from support groups is shown in Table 2.2f.

Table 2.2f Calculations for proportional sample from support groups

	TOTAL	Total sample required	Total mail out via support groups
	%	n	n
TOTAL REQUIRED	100%	100	200
Australia	**83%**	**83**	**166**
New South Wales	*28.0%*	*28*	*56*
Victoria	*20.6%*	*21*	*42*
Queensland	*15.4%*	*15*	*30*
South Australia	*6.5%*	*7*	*14*
Western Australia	*8.2%*	*8*	*16*
Tasmania	*2.0%*	*2*	*4*
Northern Territory	*0.8%*	*NA*	*NA*
Australian Capital Territory	*1.3%*	*1+1*	*2+2*
New Zealand	**17%**	**17**	**34**

When the completed questionnaires are returned and the information they contain has been entered, the data will then be weighted to represent their proper proportions in the sample as shown in Table 2.2e.

Due to uncertainty about the likely response rates utilising the methods specified, it is impossible to predict the actual final sample size that will be achieved with any degree of accuracy, and hence the calculations shown in the tables are estimates only.

2.3. Validity and reliability

The issues of validity and reliability were addressed by:

- Adopting a methodology that can be replicated;
- Having a widespread number of sample collection points (allowing collection of information proportionally by state and country);
- Pre-testing the questionnaire with actual respondents meeting the survey selection criteria to ensure the issues are clearly understood; and
- Maintaining quality standards such as:
  - Controlling the questionnaire distribution process to the greatest degree that is possible under the circumstances;
  - Ensuring that the completed questionnaires are handled properly on receipt;
  - Ensuring that appropriate code frames are developed from a sound proportion of open-ended responses;
  - Ensuring that all open-ended responses are coded by an experienced coder;
  - Ensuring that questionnaire checking is conducted prior to data entry; and
  - Employing double-punch techniques to provide an accurate data file.

3 FINDING PARTICIPANTS

Because the prevalence in the general population of those at risk of an anaphylactic reaction is very small (FSANZ 2002), the more usual means of surveying (ie telephone or intercept) were not viable options for this study. Potential respondents were therefore accessed via alternative, targeted sources.

To ensure that the survey is as representative as possible, the research design incorporated many **distribution points**, attempting coverage of every State and Territory in Australia and both islands of New Zealand.

Whilst this involved a large amount of liaison and administration time, it also enabled a smaller impost on medical establishment staff, by spreading the required sample across locations.

The methodology was therefore designed to include the following distribution points in both Australia and New Zealand:

- **Major hospitals or medical institutions** in Australia and New Zealand (one adult hospital and one children's hospital in each location, where possible);
- All of those **allergy specialists or immunologists** who consent to be involved (accessed via their professional association Australasian Society of Clinical Immunology and Allergy Inc [ASCIA]); and
- The major **relevant support groups** such as Food Anaphylaxis Children's Training and Support (FACTS) and Allergy New Zealand (Allergy NZ).

3.1. Contact procedures

Different procedures were required for each of the different types of questionnaire distribution points.

Medical institutions

Initial contact was made by NFO Donovan Research to obtain information on how to make submissions to each respective hospital / regional ethics committee, and to identify the appropriate person to approach within each hospital, to support the survey at that location.

The relevant ethics applications were completed by Ms Shareen Lata at FSANZ and submitted to each committee by the established deadlines. FSANZ also addressed the follow-up queries and requests for additional information from each committee.

Private specialists

Private specialists were approached via an email that was distributed by ASCIA. The email, similar to the letter that was sent to medical institutions, explained the purpose of the survey and requested the medical specialists support for the survey.

The response received was minimal. Hence, the FSANZ project officer subsequently initiated a follow-up call and email distributed via ASCIA in an attempt to increase the participation rate.

Support groups

One large support group was located in each country to provide broad coverage in their respective countries. Only n=100 completed questionnaires in total were required from support groups and it was initially deemed unnecessary to contact more than two support groups.

NFO Donovan Research approached the support groups. For Allergy NZ, a paid advertisement was placed in their newsletter: *Allergy Today (Issue 103, Summer 2002)*. A copy of this advertisement is included in Appendix B.

For FACTS, a donation was made to the organisation for them to insert a similar advertisement in their newsletter *News Facts (December 2002)*.

Each organisation had the opportunity to review the questionnaire before the advertising was placed in their newsletter. Both organisations were very supportive of the survey, and their assistance is greatly appreciated by the Project Team.

In addition, members of the Australian Food and Grocery Council (i.e. large manufacturing firms such as Nestle, Kraft, Unilever, Cerebos, etc) volunteered to inform consumers calling for product information about the survey, and to give them the NFO Donovan free call phone number for them to request a questionnaire.

3.2. Criteria for selecting participants

Official data sources (i.e. medical institutions and private specialists)

For each of the official data collection avenues, participants (patients or clients) are to be selected by the appropriate medical specialists (hereinafter referred to as recruiter) based on selection criteria developed in consultation with the FSANZ project team and other allergy specialists.

Clients to be included are to:

- Be aged over 1 year old;
- Be ‘at risk’ of anaphylactic reaction to certain foods or food ingredients;
- Have been seen at the clinic in the past 2 years; and
- Comply with the definition of anaphylaxis to ensure consistency,

To ensure that a broad cross-section of food allergies are covered, recruiters are to be asked to select clients that roughly represent the proportion of each allergy typically seen at their clinic. This should reduce the likelihood of attaining participants with the most common of food allergies, such as peanut allergies.

Recruiters will be also asked to address the questionnaire pack to the parent or next-of-kin / carer where the client is aged 14 or less.

A copy of the detailed selection criteria (Questionnaire Pack Instructions) is included in Appendix B.

Support groups

The use of advertisements in the support group magazines yielded fewer responses than expected, with a total of 75 calls received (53 from Australia and 22 from NZ). It is assumed that the NZ calls derived from Allergy NZ members and the Australian calls derived from FACTS members.

To supplement the numbers attained via the advertisements in the support group publications, the editor of News Facts (Australia) was asked to select an additional n=116 members at random. They were sent the requisite number of questionnaires to be distributed to each State and Territory and asked to mail the pre-paid questionnaires.

The additional numbers required from each State were:

New South Wales	*24*
Victoria	*35*
Queensland	*24*
South Australia	*12*
Western Australia	*15*
Tasmania	*5*
Australian Capital Territory	*1*

For the New Zealand sample an additional n=14 were required. Some of the potential support group participants who had phoned and left their contact number were called and asked to distribute one extra questionnaire to an eligible friend or acquaintance, where possible.

Randomising is a technique to ensure representativeness, however since the sampling method for the support group sample was self-selecting anyway (people called the helpline in response to an ad), it was not deemed essential to specify a randomising procedure to attain the remainder. It was not possible to make this sample representative, because the nature of the membership of the support groups (ie whether actually at risk of anaphylaxis) is not known.

Note that the support group sample will be analysed separately from that achieved via medical institutions.

4 DATA COLLECTION PROCEDURE

Each medical establishment or private specialist will be paid a set fee ($10) per questionnaire distributed, for:

- selecting the names of potential respondents from their patient lists,
- mailing them a questionnaire, and then
- mailing them a reminder card two weeks later.

The number of questionnaires to be mailed out by each organisation will be determined by the number of organisations who agree to participate and the size of the target population for each location (State or Territory in Australia[3]).

For the two support groups, a payment was made for the insertion of an advertisement into their respective newsletters asking for participants to call a FREECALL 1800 number (in Australia) or FREECALL 0800 (in New Zealand). NFO Donovan Research will then send them a questionnaire pack. All contact details will be destroyed once the questionnaire is despatched, in accordance with the project's ethics in human research requirements (NHMRC, 2002).

4.1. Distribution of questionnaires

Once the number of collection points and the sample mail out required from each have been decided, the contact person at each distribution point will be sent a *distribution point kit* that contains:

- A **step-by-step checklist** for how to do what is required (including how to select potential respondents using the definition detailed herein);
- The required number of sealed **questionnaire packs** (plus one unsealed for their records);
- Blank postage-paid **reminder cards** for each questionnaire mailed out (the contact person is advised to address these at the same time as the questionnaire, but to mail them out two weeks later); and
- A **reply-paid notification card** for use when the recruiter has completed mailing out their quota of questionnaires. This notification card serves as a trigger to generate the payment of $AUD/NZD10 per questionnaire, once they have completed each of the steps requested.

[3] *The New Zealand sample was approached as one unit, because of its small sample size overall and the limited availability of appropriate hospitals and medical specialists.*

Each *questionnaire pack* will comprise a pre-stamped, sealed envelope that contains:

- The questionnaire;
- A reply-paid envelope addressed to NFO Donovan Research;
- A letter from FSANZ explaining that the packages were sent out blind (ie that the patient's contact details were not released to us) and encouraging them to participate.
- Two parental consent forms, one for retention by the participant and the other to be returned with the questionnaire by those aged 15 to 18 years old who are main grocery buyers.

All questionnaires are numbered and NFO Donovan Research holds a record of the range of questionnaire numbers that are sent to each participating organisation. This provides an audit mechanism as a form of quality control. The reader is reminded however, that for this aspect of the survey, the researchers cannot at any point identify individual participants and hence this process provides only limited control.

4.2. Delivery of distribution packs

The distribution packs are to be sent by express post or air courier to the nominated contact person or recruiter at each distribution point.

4.3. Data collection period

Whilst at the inception of this project we sought to shorten the data collection period to a single exercise to enable as much data as possible to be collected prior to 20 December 2002, as the project progressed it became exceedingly difficult to meet this proposed deadline, due to the delays in getting the necessary approvals from the relevant ethics bodies. This will need to be taken into account for any follow-up survey.

The length of time taken by some agencies in approving the ethics submissions meant that the mail-outs to recruiters were staggered, with materials being sent to each institution as their ethics approvals were advised. This process commenced in mid-March 2003.

Although a 6-week in-field period was originally allocated it is anticipated that overall, this will not be sufficient, due to the staggered mail-outs. Each progressive mail-out will therefore need to have a notification attached that advises of any extension to the deadline. The total data collection period required is therefore not known at the time this report was prepared.

Recruiters are instructed to mail out the reminder cards 2 weeks after the questionnaires are mailed.

4.4. Support services for participants

FREECALL helpline

In order to provide some assistance to participants, the questionnaire contains details of a FREECALL number that can be used in Australia - 1800 688 122 and 0800 230 012 in New Zealand.

NO translation services are available for those from a Culturally and Linguistically Diverse (CALD) background. CALD groups require specific provisions for their inclusion in such a survey and this was not defined in the RFT. However, there are instructions on the front of the questionnaire to the effect that participants can seek the help of their family or friends to complete the survey.

New Zealand

A Maori contact person was provided by NFO Donovan Research in New Zealand to deal with particular inquiries. Contact with this person will be facilitated through a call to the 0800 number provided.

FSANZ contact details

The name, contact number and email address for the relevant FSANZ project officer was also provided to provide an additional access point for any queries about the validity or authenticity of the survey, or to request further information about the survey and subsequently, its findings.

5 ETHICS APPROVALS

This project was somewhat unusual in that it required approvals from several hospital or regional ethics committees, as it involved a health issue, food anaphylaxis and required the cooperation of staff (medical specialists or recruiters) based within medical institutions. Accordingly, the questionnaire and research parameters had to be approved by every institution involved.

The Commonwealth Department of Health and Ageing Ethics Committee initially approved the survey. Once approval was obtained from the Commonwealth Ethics Committee, submissions were made to individual hospital and regional ethics committees.

This clearance process took a considerable amount of time and ultimately resulted in a delay in the start date.

5.1. Ethics applications submitted

Institutions from which approvals were required are shown in the Table following.

AUSTRALIA: **1. Department of Health and Ageing Ethics Committee**
New South Wales *2. Central Sydney Area Health Service Ethics Review Committee (The Royal Prince Alfred Hospital)* *3. The Children's Hospital at Westmead Ethics Committee (The Children's Hospital at Westmead)*
Victoria *4. Royal Children's Hospital Campus Ethic in Human Research Committee (The Royal Children's Hospital)*
Queensland *5. Royal Children's Hospital and Health Service District Ethics Committee (The Royal Children's Hospital)*
South Australia *6. Flinders Clinical Research Ethics Committee (Flinders Medical Centre)* *7. Women and Children's Hospital Research Ethics Committee (The Women and Children's Hospital)*
Western Australia *8. Princess Margaret Hospital Ethics Committee (Princess Margaret Hospital)* *9. Sir Charles Gairdner Human Research Ethics Committee (Sir Charles Gairdner Hospital)*

Tasmania

10. Southern Tasmanian Health and Medical Research Ethics Committee (The Royal Hobart Hospital)

Australian Capital Territory

11. ACT Health and Community Care Human Research Ethics Committee (The Canberra Hospital)

No medical establishment that treats allergies could be located in the Northern Territory and hence it is not included in the research. However, Northern Territory respondents may be picked up via newsletters in the support group sample or in the institutional sample where they may have attended a clinic in another State.

NEW ZEALAND:

12. Auckland Ethics Committee (Auckland Hospital and Starship Children's Hospital)

13. Canterbury Ethics Committee (Christchurch Hospital)

14. Auckland District Health Board Maori Research Review Committee and Te Committee Whakarite

Only four hospitals in NZ were identified as offering allergy or immunology services in NZ. However, only 3 New Zealand hospitals were recruited as the fourth hospital, Wellington Hospital did not have an Immunologist/Allergist at the time of this survey.

5.2. Clinician support for the ethics applications

Prior to submitting applications for ethics approvals, it was necessary for the Project team to identify specialist clinicians within each medical establishment and seek their support for the project. This was largely undertaken by NFO Donovan Research in the first instance, and was taken over by FSANZ in the latter stages.

The Project Research Team would particularly like to express thanks to the supporting clinicians in each of the medical institutions, without whose support the study could never have been completed.

6 PRIVACY ISSUES

In accordance with the *Privacy Act 1988 (Australia)* and the *Privacy Act 1993 (New Zealand)*, the survey methodology that was adopted was designed to ensure the privacy of all participants.

Although from the outset it was intended that the survey be repeated at some future time, it was not deemed imperative that the same participants be included in any follow-up research. It was therefore not necessary to develop procedures to facilitate longitudinal surveying.

Accordingly, institutions and private clinicians who participate are not required to keep the contact details of those who are surveyed. Any future survey will therefore need to be undertaken with fresh participants.

6.1. Distribution points

Strategies to preserve the privacy of participants were devised for each avenue. Each is discussed in turn:

- **Medical institutions**
  Initial distribution points were largely identified using publicly available information, and hence there are no specific requirements in terms of the Privacy Principles in relation to the organisation.
- **Private specialists**
  The specialists who were included were first contacted via ASCIA and given the opportunity to have their clients (patients) participate.
- **Support groups**
  Initial distribution points were largely identified using publicly available information, and hence there are no specific requirements in terms of the Privacy Principles in relation to the organisation.

6.2. Participants who are patients

Of most pressing concern for official sources was the issue of **patient privacy and the preservation of doctor – patient confidentiality**, as patients are understandably sensitive about the release of their medical details to third parties.

The methodology described herein was designed to minimise any concerns in this regard. Patient confidentiality is preserved because no individual person's details are passed to NFO Donovan Research by the nominating organisation[4].

[4] *The one exception to this is when a mailed-out package may be returned to NFO Donovan Research (return to sender) due to incorrect address details, in which case the personal details are incorrect and hence not subject to any special provisions. In this case, the address label will be destroyed on receipt or shortly thereafter, and no record made of the name or other details.*

6.3. All participants

In accordance with the relevant Privacy Acts and Principles, the letter to be contained in the questionnaire pack to participants included statements to the effect that:

- Their participation is voluntary;
- Their personal details have not been passed on from the medical agency to the research company (patients only);
- Any information collected for the survey will be used for research purposes only;
- Their responses will be anonymous; and
- There are clearly stated mechanisms for complaints.

Copies of the field stationery are included in Appendix B.

7 THE QUESTIONNAIRE

7.1. Development

The questionnaire was developed primarily NFO Donovan Research, in consultation with the FSANZ Project Team.

NFO Donovan Research had retained two specialist consultants (Ms Vicki Dalton, who is a dietitian specialising in paediatric allergens, employed at the Royal Children's Hospital in Melbourne, and Ms Judith Myers, a dietetic allergen specialist at the Royal Children's Hospital in Melbourne) for the purpose of assisting with the process of questionnaire design and analysis and interpretation of the results.

7.2. Pre-testing of instrument

Once the questionnaire had been developed to a suitably advanced stage it was tested initially by individual researchers unconnected to the project and then in a group situation with either those with serious food allergy (in accordance with the definition provided earlier) or parents of children with such an allergy.

7.2.1. Procedure

The pre-test was conducted at the offices of NFO Donovan Research in Perth (Australia) amongst one focus group of seven potential respondents. Participants were recruited by word of mouth networking amongst the friends of staff and snowballing to their friends. All potential respondents were asked to volunteer themselves for inclusion if they were interested in taking part. Thus all participants were aware of the voluntary nature of the research.

Each participant was posted a package containing the materials that would be sent in the final mailout to consumers (i.e. questionnaire, information letter, two copies of the consent form). They were requested to complete the questionnaire and then bring it along to the discussion.

Participants were paid $40 for their time and input.

7.2.2. Outcome

The focus group was well attended and yielded useful information to further refine the questionnaire.

Overall there were no major problems, with most participants indicating that the questionnaire was comprehensive and easy to complete.

The main area of concern was the misinterpretation of the meaning of the word 'diagnosis'. Some participants took it to mean a formal medical opinion whereas others thought of it more generally as an issue of identification. This caused *some* to give different answers than they would have if they had adopted the other meaning.

There were several areas of confusion:

- The limited pre-codes available for adults whose allergies were discovered by parents;
- Participants from households where they were one of multiple sufferers had difficulty in knowing from whose perspective they were answering at each point; and
- Participants from households where they were the only sufferer found it confusing where the questionnaire asked for all the allergies in the household (some answered correctly and some did not).

The problems identified above were remedied by:

- Substituting the word 'diagnosis' for more general terms such as when the allergy was first discovered or identified;

Q9 **How was the food allergy first identified for the person with the most serious food allergy? PLEASE TICK ALL THAT APPLY.**

Had a reaction ..... ❑1
From parent (s) ..... ❑2
From an alternative health practitioner (eg Naturopath) ..... ❑3
Worked it out for self..... ❑4
Others (PLEASE WRITE IN).....
.....
Don't know / can't recall ..... ❑9

- Or alternatively, using a more explicit term 'formal medical diagnosis' to indicate which particular circumstance was intended;

Q11a **Has a formal medical diagnosis been made for the person with the most serious food allergy at any time?**
PLEASE TICK ONE BOX ONLY AND FOLLOW DIRECTION TO THE NEXT QUESTION.

Yes..... ❑
No..... ❑2

- Adding suitable pre-codes for adults who have had the allergy since childhood;
- Changing the order of the questions at the start of the questionnaire so that all food allergies in the household was asked first, followed by the most serious food allergies. This allows the respondent to be focussed on the person with the most serious allergies throughout the remaining questions (until directed otherwise);
- Using additional text instructions.

- An additional problem was that where the questionnaire sought to measure the effectiveness of the statements *'may contain traces of nuts'* (Q28a) and *'made in the same premises as products containing nuts'* (Q29a), some conceptual difficulty was experienced in that some seemed to answer from their own perspective rather than from that of a person with a nut allergy, as requested.

This was addressed by making the wording more general:

Q28a **Now consider the statement 'made in the same premises as products containing …'? In your opinion, how useful would this statement be to you if you had an allergy to the particular ingredient listed? Would you say …?" PLEASE TICK ONE BOX ONLY.**

Not very useful because it doesn't say whether the ingredient I am allergic to is definitely in the product or not ..... ❑1

Quite useful because it reminds me I may be eating a product containing the ingredient I am allergic to ..... ❑2

Very useful because I am told that there is a chance that the ingredient I am allergic to is present ..... ❑3

Not sure / don't know ..... ❑9

Although no one expressed any particular difficulty with the labelling exercise (Q30), on examination of the completed questionnaires it was later discovered that one or two had not circled the problem ingredient as they were instructed. It was therefore decided to reword the instructions and rearrange the layout, as shown below, in an attempt to make it easier to follow.

Q30 For this question we would like you to examine each of the labels in turn and do two things:

❶↓

Circle any ingredients that you think might be unsuitable for any person(s) in your household with an allergy. Even if you don't circle any ingredient, please answer part ❷.

❷↓

Indicate your assessment of the product.

LABEL 1: BREAD

INGREDIENTS

UNBLEACHED BAKER'S FLOUR, YEAST, SALT, VEGETABLE OILS, SOYA FLOUR, EMULSIFIERS (481, 472e), PRESERVATIVE (282), VITAMIN (THIAMIN), WATER ADDED. NO ARTIFICIAL FLAVOURS.

(40)

I would avoid this product ..... ❑1

This product is suitable..... ❑2

Don't know..... ❑9

Two questionnaires are used, one for Australia and one for New Zealand. There is very little variation between the two. Different demographic information is collected for each country (location, ethnic origin, and education levels). In the New Zealand questionnaire there is also an additional statement added at Q16 relating to the Manufactured Food Database.

Copies of the questionnaires (Australian and New Zealand versions) are included in Appendix A.

8 FIELD DOCUMENTATION

Various letters and documents had to be devised for the conduct of the survey:

- A letter to medical institutions requesting their support for the survey;
- A letter to private specialists asking them to participate;
- Sampling instructions (instructions for medical institutions and private specialists on how to select participants and manage the paperwork involved);
- A letter to participants (the 'Survey Information Sheet');
- A parental consent form (for where the person answering was the person with an allergy, and aged under 18 but over 14); and
- Reminder cards.

Copies of each of these are included in Appendix B.

9 REFERENCES AND BACKGROUND INFORMATION

Food Standards Australia New Zealand. 2002, Request for Tender 2002/4: Quantitative Consumer Research on Allergen Labelling, [online]. Available: http://www.foodstandards.gov.au/_srcfiles/RFT_Allergy_labelling.pdf. [2002, June 10].

National Health and Medical Research. 2002. 'Human Research Ethic Handbook', AusInfo, Canberra.

Although not referred to explicitly in the text, the following paper also assisted in informing the research design:

Preeti J, Modifi S & Sicherer S. 2002, 'Interpretation of commercial food ingredient labels by parents of food-allergic children', *Journal of Allergy Clinical Immunology*, vol 108, no 8; pp. 1019-1021.