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## **Supporting document 4**

Consumer research in relation to safe preparation and use of infant formula

Safety & food technology Consultation paper

Proposal P1028—Review of the regulation of infant formula products

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This is a targeted review of consumer research related to the labelling of infant formula products relevant to food safety. Findings from this review inform FSANZ’s assessment in the Consultation paper on Safety & Food Technology for Proposal P1028 – Infant Formula.

The consumer evidence reported on in this review is not restricted to peer-reviewed published research. Given there is an evidence gap in recent published research examining Australian and New Zealand caregivers’ use and understanding of infant formula, this review incorporates primary research commissioned by FSANZ to address this information gap and inform P1028. Furthermore, grey literature also addressing the subject matter has been included.

Consumer research included in this review has sought to address a set of research questions relevant to: preparation instructions, warning and advisory labelling, and protein source information. The gathered consumer research while varied in research techniques (e.g. qualitative focus group and quantitative cross sectional survey design) offers insight into the nature of labelling of infant formula where findings align.

Findings from the research indicate that preparation instructions are primarily viewed during initial use of formula products with attention toward the instructions declining over time. Caregivers who use infant formula are not always aware of the health risks associated with not adhering to the preparation instructions. Research suggests many users of infant formula have not noticed or read the on-label warning to follow instructions as directed.

Users of infant formula report deviations from the preparation instructions for a number of reasons including; increasing efficiency when preparing formula, maximising formula longevity by using less powder, believing certain steps are not necessary for older infants. However, caregiver knowledge of correct preparation can be improved with changes to the instructions.

Most caregivers do not use protein source information, but they believe it would be helpful for caregivers of infants with known health concerns (e.g. allergies and intolerances). Evidence suggests that in the event the protein source is not clearly labelled on the front of an infant formula caregivers may seek this information using the ingredient list on infant formula products.

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# Introduction

## Objectives

This review informs FSANZ's consideration of issues related to safety labelling elements for infant formula products as part of the Consultation paper on Safety and Food Technology for P1028. The objective is to review evidence on consumer use and understanding of current infant formula safety labelling (e.g. preparation instructions).

## Background

This review builds on the previous rapid assessment of consumer research prepared by FSANZ as part of initial consultations to date as part of P1028 (refer [to SD2 Attachment A2.2](#) – Rapid evidence assessment on infant formula preparation, perceptions and label use pp. 85).

In 2016, FSANZ noted there was limited published literature which investigated infant feeding practices and specifically use of infant formula. This led FSANZ to commission several research studies over the subsequent years.

## Method

The review includes FSANZ-commissioned research, peer-reviewed literature, and grey literature. Peer reviewed research was identified by searching six online research databases for studies published between 2003 and September 2019. More detail on the literature search and review methods are provided in Appendix A.

## Scope

This review is structured around the following research questions:

- How do carers for infants follow and comprehend preparation instructions on infant formula products?
- How does the presentation of warning and advisory statements on infant formula influence consumer's awareness of the statement?
- Does the placement of the protein source statement required on infant formula influence consumer purchase decisions?

For each question a summary of evidence from FSANZ research is provided, followed by a summary of additional literature, and then conclusions.

# Findings

## 1. Use and comprehension of preparation instructions

This section addresses the research question - “How do carers for infants follow and comprehend preparation instructions on infant formula products”.

### 1.1 *FSANZ-commissioned research*

Consumer research previously identified by FSANZ (2016a) concerning the use and comprehension of preparation instructions on formula products has primarily relied on self-report measures rather than objective observational techniques. Additionally, FSANZ identified an information gap concerning research examining Australian and New Zealand caregivers. In light of this evidence gap and a lack of objective evidence, FSANZ commissioned a study to examine how Australian caregivers use and understand label information related to preparation and storage of infant formula.

#### ***Malek 2016b Infant Formula Use and Decision Making Study (InFormD) Australian and New Zealand consumers’ perceptions, understanding and use of labelling information on infant formula products. Part B: Infant formula preparation<sup>1</sup>***

This study consisted of a formula preparation task utilising eye-tracking equipment that was followed by an interview. Participants (n=30) were caregivers from Adelaide, South Australia who were responsible for an infant aged up to 12 months<sup>2</sup>. Participants were required to comprehend English, and be using infant or follow-on powdered formula (either exclusively or in conjunction with breast milk and/or solids). The study was conducted in participants’ homes. Participants were asked to prepare an unfamiliar infant formula<sup>3</sup> while wearing eye-tracking equipment that measured their visual attention toward the product. The objective of the study was to increase understanding of how caregivers perceive, interpret and use mandatory and voluntary labelling when preparing and storing infant formula. The eye-tracking equipment recorded where participants looked, and for how long at the infant formula product (examples shown in Figure 1).

Immediate follow-up retrospective ‘think-aloud’ and semi-structured in-depth interviews occurred after the eye-tracking task. The interviews served to align and validate eye-tracking data with participants’ understanding and use of preparation instructions. The retrospective think-aloud interviews consisted of participants viewing playback footage of their completion of the preparation task while narrating what they were thinking and doing during the task. The in-depth interviews which followed the think-aloud interviews examined comprehension of the step-by-step preparation instruction, discard instruction, warning (discussed further in section 2 of this report), use by/best before date and the feeding guide. The interview findings were consolidated and reported on against the aforementioned label elements.

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<sup>1</sup> Aspects of this study are published in Malek et al. (2020).

<sup>2</sup> A sample quota was established for infant age. Half of the study cohort cared for an infant aged ≤6 months.

<sup>3</sup> Participants were instructed: “Imagine that you are running low on formula at home, so next time you go shopping you plan to buy some more. When you get to the shops and are in the formula aisle, you discover that the product you usually buy is out of stock. So you end up buying this one [*unfamiliar product presented*] instead. You get home, and [*name of infant*] is crying and ready for a feed, so you go into the kitchen and prepare a feed using this new product that you haven’t used before. Once you have prepared the feed, pretend that [*name of infant*] drinks about half and then do what you normally would do with the rest of the feed and then place the tin where you would normally keep it.”



### *Key findings from the eye-tracking glasses*

Participants took between 1.36 and 5.75 minutes, with a median time of 2.78 minutes, to complete the preparation task. The areas of interest on the infant formula label that were assessed using the eye-tracking data were; step-by-step preparation instructions, the instruction to discard unfinished feeds, warning to follow preparation instructions exactly and the storage instructions for the formula. Of the 30 caregivers; 28 visually attended to the preparation instructions, seven attended to the discard feed instruction<sup>4</sup>, 13 attended to the warning, and eight attended to product storage instructions.

Of the participants who viewed the discard instruction, warning and the product storage instructions; they did so once for half a second on average. In comparison, participants visually attended to the step-by-step instruction multiple times (four times on average) and for a substantially longer period of time (21 seconds on average per visual visit).

The eye-tracking data in this study demonstrates that most participants did not thoroughly look at information related to the preparation of infant formula (e.g. the warning and the discard instruction). Less than a third of participants looked at the 'discard unfinished feeds' (part of the last instruction on both infant formula labels). This indicates most participants did not read the step-by-step preparation instructions in full. Furthermore, the warning was not visually attended to by most participants. The warning instructs caregivers to follow preparation instructions and advises that incorrect preparation can make their baby ill. This finding suggests some caregivers are missing out on this information and, consequently, may not be aware of the seriousness of failing to follow the instructions correctly.

### *Key findings from the playback and interviews*

Most caregivers reported reading the step-by-step preparation instructions only the first few times they used a formula product. Some caregivers mentioned this was the only time they ever read the instructions carefully. Caregivers reported that once they felt confident and knew the process they no longer felt the need to refer to the instructions again. Only a few reported rereading preparation instructions when using a new or unfamiliar formula product. This finding from the interviews provides one explanation for why less than a third of participants looked at the discard instruction. It is plausible that participants did not look at the preparation instructions in full due to a confidence in their own abilities, having read other preparation instructions on prior occasions.

While most participants looked at the preparation instructions and indicated they understood and were confident using them, most participants did not follow all the preparation steps as written. The three main parts of the instructions caregivers did not follow were; handwashing, bottle sterilisation and water preparation. From the interviews it was found that failing to notice specific steps, the desire to increase preparation efficiency, low perceived risk from deviating from the instructions, and the infant's age (older infants were considered less vulnerable) were factors that influenced caregivers adherence to the preparation instructions.

Handwashing was generally not adhered to as caregivers either did not notice the instruction or did not consider it an essential step (e.g. they believed their hands were already clean). Caregivers generally did not sterilise bottles directly before preparing formula (i.e. did not prepare them on a feed-by-feed basis). Instead, they sterilised bottles in batches to save time. Caregivers were less likely to sterilise bottles for older infants as they believed this was unnecessary, particularly once complementary foods were introduced.

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<sup>4</sup> The authors note that a limitation of the eye-tracking equipment is to accurately measure visual attention in very small areas of interest (i.e. small fine print). The authors note that caution should be taken when interpreting the 'discard feed' eye-tracking data.

Some caregivers noted that solids are not sterile and therefore bottle sterilisation is less important for infants who have started solids.

Caregivers considered that boiling water and waiting for it to cool each time they prepared formula was inefficient. Caregivers either used cold pre-boiled water from the kettle or pre-filled bottles with boiled water then kept these in the fridge or on the kitchen bench. Some caregivers reported using filtered tap water rather than boiled water. A common practice amongst caregivers was to heat up the water they planned to use in the microwave before adding powdered formula. The findings suggest that caregivers misinterpret the instructions or do not understand the risks of deviating from them.

Thirteen caregivers in this study reported they hadn't ever noticed the 'discard' instruction on any infant formula tins. This finding is consistent with the eye-tracking results which showed only seven of the 30 caregivers attended to this instruction. When the instruction was drawn to their attention most understood it meant to throw out any leftover feed immediately. However, many mentioned that no timeframe for following this instruction is specified. They were uncertain whether feeds needed to be discarded as soon as feeding finished or whether there was some leeway (e.g. 30 minutes) in which the feed could be given to the infant again. Of the 30 participants in this study, 13 reported discarding unfinished feeds immediately after feeding. Twelve reported usually waiting between 30 minutes to an hour before discarding unused formula in case their infant wanted more later. Five reported saving left over formula by storing it in the fridge and keeping it for a few hours, or a couple days in some instances.

The main reason for discarding unused feeds immediately by some caregivers (n=13) was personal choice. Caregivers indicated that cleanliness and hygiene were primary motivators for throwing out unused formula immediately. Of those who discarded unused feeds right after use, the majority reported having seen the discard instruction on formula before.

Of the participants (n=12) who reported waiting 30 to 60 minutes before discarding unused feeds, only two reported having ever seen the discard instruction. Most reported using their own judgment to decide when to discard unused feeds. Decisions to discard were based on information sources such as family and friends, or online information. Some caregivers had been told that leftover breastmilk could be stored and reused and assumed the same applied to infant formula. Given that most of these caregivers reported not having seen the discard instruction, it is possible they had overlooked the instruction when preparing infant formula in the past.

The few caregivers (n=5) who kept unused feeds for later use did not understand why infant formula should be discarded. Three of the five were confused as they believed the discard instruction conflicted with advice that feeds could be prepared in advance and refrigerated. Amongst these caregivers, risk perception was low and they were confident in their own abilities to assess whether a feed was spoiled (e.g. by smell) and personal practices to overcome perceived risks (e.g. changing a bottle's teat).

Two caregivers reported adding other substances when preparing infant formula (e.g. chocolate powder, crushed biscuits, vanilla essence). In both instances the rationale was to encourage their infant to feed. One of the caregivers justified the addition of these substances by noting the product does not explicitly stipulate not to do so. Warning labels instruct caregivers not to change proportions of powder except on medical advice and that incorrect preparation can make your baby very ill. International research (particularly from the United States) has also found caregivers add substances like cereal and sweeteners to bottles of infant formula and follow-on formula (Ellison et al., 2017; Gross, Mendelsohn, Fierman, Hauser, & Messito, 2014; Hurley, Black, Merry, & Caulfield, 2015; Thompson & Bentley, 2013; Toh et al., 2016). The addition of extra substances/foods to infant feeds may

be a consequence of parents attempting to introduce solids into their child's diet.

The findings of this study suggest that some caregivers do not abide by the discard feed instruction on account of never having read the instruction, or that they do not believe storing and reusing leftover feeds is risky. The discard instruction is generally at the very end of the step-by-step preparation instructions, after the instruction to test the temperature of the feed before feeding the infant. Once they have tested the temperature of the feed, caregivers may assume they have completed all the step-by-step instructions and therefore don't need to check for any further steps. This is one possible explanation for why so many caregivers did not attend to the discard instruction in this study and why many caregivers did not recall ever reading it before.

### ***Malek 2017. Infant formula information use and preferences: an online survey of Australian and New Zealand caregivers***

An online survey commissioned by FSANZ and conducted by the Centre for Global Food and Resources at the University of Adelaide examined caregivers' use and preferences toward information on infant formula products in Australia and New Zealand (Malek, 2017). Australian (n=285) and New Zealand (n=341) caregivers of infants aged up to 18 months took part in the survey.

Within the survey respondents were asked 'where did you go or who did you talk to when you had questions about how to prepare or store infant formula?'. From a list of information sources the majority of respondents (57% of Australian and 62% of New Zealand respondents) selected 'infant formula product label'. Respondents were also presented with a series of statements and questions related to preparation and storage of infant formula and asked whether they had ever wanted to know the answers to the questions:

- 67% of Australian and 72% of New Zealand caregivers wanted to know 'the potential consequences if each preparation step isn't followed exactly as stated on the label'.
- 62% of Australian and 71% of New Zealand caregivers wanted to know 'Can I feed left-over/unfinished formula at the next feed if it has been refrigerated?'
- 64% of Australian and 68% of New Zealand caregivers wanted to know 'How long can I continue using a tin of infant formula after opening it?'
- 54% of Australian and 62% of NZ respondents wanted to know 'Can I feed left-over/unfinished formula at the next feed if it was kept at room temperature?'
- 64% of Australian and 70% of NZ respondents wanted to know 'how long can I keep any left-over/unfinished formula before I have to throw it away?'
- 55% of Australian and 58% of New Zealand wanted to know 'Why must left-over/unfinished formula be thrown away?'

These findings suggest that caregivers may not have seen, recalled, or understood the warning statement, instruction to discard unfinished feeds, or the storage instructions on formula products.

### ***1.2 New Zealand Ministry for Primary Industries commissioned research***

An online survey commissioned by the Ministry for Primary Industries New Zealand (Magill, Kalafatelis, & Wallace, 2020) in collaboration with FSANZ examined caregivers' use and understanding of preparation instructions on infant formula labels. Participants were caregivers of a child up to 18 months of age who had received some infant or follow-on formula before the age of 12 months. The survey was carried out in both Australia (n=600) and New Zealand (n=733). The sample included caregivers for whom English was not their first language (n=82 in Australia, n=131 in New Zealand).

### *Importance of preparation instructions*

Respondents were asked how important they thought a range of label elements on infant formula products were<sup>5</sup>. The instructions on how to prepare formula were considered important or extremely important by the greatest proportion of respondents (92%). This was followed by the feeding guide (89%), warning notice about following instructions exactly (89%), and information about the type of formula to use and when (89%). The storage instructions were rated as important or extremely important by 88% of respondents, and the warning statement by 70% of respondents.

Respondents were also asked how important they believed it was to follow the preparation and storage instructions on a tin exactly. Fifty seven percent of respondents believed it was extremely important to follow the instructions exactly, and a further 30% believed this was very important. Only 11% of respondents thought it was not at all or only somewhat important to follow the instructions exactly.

### *Perceived risks of incorrect formula preparation*

The researchers then examined caregivers' understanding of the risks of incorrect formula preparation. Respondents were asked a follow-up question about why they felt it was (or was not) important to follow the preparation and storage instructions. Respondents' free text responses were used to identify common types of explanations for the importance of following instructions. The most common response was 'Don't know' (27%). Of respondents who attempted to provide an explanation, the most frequent was a general comment about the importance of following the instructions (15%), followed by 'Baby can become ill/sick' (i.e. the respondent did not mention a specific illness) (13%), 'Safety reasons/to prevent harm/avoid risk' (12%). Very few respondents were able to mention a specific health condition or symptom that could arise from incorrect preparation, such as a sore tummy for the infant (three percent), constipation (one percent), diarrhoea (zero percent), or vomiting (zero percent). Eleven percent of explanations were categorised as 'To get the amount/proportion/ratio of formula right/to avoid under or over feeding' and six percent were categorised as 'For baby's nutrition/to get the nutrients baby needs'.

Respondents' awareness of the risks of incorrect preparation was higher when they were prompted with particular risks. Respondents were asked to indicate whether they had heard of any of a range of things that could happen as a result of not following the instructions on infant formula products. The percentage of respondents that had heard of each risk was as follows:

- Not get enough nutrition (51%)
- Constipation (50%)
- Diarrhoea (43%)
- Have too little weight gain (39%)
- Have too much weight gain (33%)
- Get a bacterial infection (33%)
- Get burns on their mouth or throat (30%)
- Choke (14%)

Fifteen percent of respondents answered that they had not heard of any of the listed risks of

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<sup>5</sup> Respondents were asked how important they thought the following label elements were: instructions on how to prepare the formula; the feeding guide; information about the type of formula to use and when (e.g. infant formula from birth); the warning notice about following instructions exactly; storage instructions (i.e. where to store the tin, and how long to keep it for); and the warning statement regarding consulting a health professional before using the product.

not follow preparation instructions.

### *Use of preparation instructions*

Despite the importance respondents placed on the preparation and use instructions, only 72% indicated they had referred to these when they first started preparing infant formula. The proportion of respondents who referred to these instructions was lower in the other situations listed: 'When I change the stage of formula I'm using' (43%), 'When I change the brand of formula I'm using' (41%), 'Once in a while, when I need a reminder' (32%), 'When my baby gets older and needs bigger feeds' (28%), 'When someone else prepares the formula (e.g. a babysitter)' (22%), 'Every time I prepare it now' (16%). One percent of respondents said they had never used the preparation instructions on the tin.

### *Comprehension of preparation instructions*

The researchers tested respondents' understanding of preparation instructions. Respondents were presented with a set of instructions and asked to indicate whether various statements about infant formula preparation were true or false. Half of respondents saw instructions that represented the status quo (i.e. were based on current requirements in the Code and common practice in the market).

#### Status quo instructions:

1. Wash hands before preparing the feed. Clean and then sterilise all feeding equipment by boiling, for 5 minutes, or using an approved steriliser.
2. Boil drinking water and allow to cool.
3. Measure the required volume of water (consult FEEDING GUIDE for quantity of water) into the sterilised bottle.
4. Use only the enclosed scoop, fill scoop and level off using inner rim. Measure the correct quantity of formula (consult FEEDING GUIDE ) into the bottle.
5. Cap the bottle and shake briskly to dissolve the powder.
6. Test the temperature on your wrist and feed immediately. Discard unfinished feeds.

Prepare each bottle individually. If a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours.

The other half of respondents saw a set of instructions ('potentially improved') that had been altered in an attempt to make some of the steps easier to understand.

Potentially improved instructions:

1. Wash hands before preparing the feed. Clean and then sterilise all utensils by boiling, for 5 minutes, or using an approved steriliser.
2. Boil safe drinking water and allow to cool until lukewarm.
3. Prepare each bottle individually. Measure the required volume of water (consult FEEDING GUIDE for quantity of water) into the sterilised bottle. Always put the water into the bottle first, before adding the powder.
4. Use only the enclosed scoop, fill scoop and level off using inner rim. Always add 1 level scoop of powder for each 50mL of water. Never add more or less formula powder or water than recommended unless directed by a healthcare professional. Do not add any other food (e.g. cereal) or flavouring to the feed.
5. Cap the bottle and shake briskly to dissolve the powder.
6. Once prepared, formula can spoil quickly. Discard any formula left in the bottle after a feed.
7. Test the temperature on your wrist. It should feel warm, but cool is better than too hot. Feed your baby immediately.

*Preparing feeds in advance*

It is safer to prepare each bottle as needed. If a bottle of formula is made up prior to use, it must be refrigerated and used within 24 hours.

In addition to the preparation instructions, respondents were shown the feeding guide and the warning to follow instructions exactly:

*Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill*

Understanding of some aspects of the instructions was relatively high regardless of which preparation instructions respondents were shown. For example, 84% of respondents who saw the status quo instructions correctly answered that the statement 'You need to sterilise the bottle you're using every time you make up formula' was true. However, this still means a substantial proportion of respondents either incorrectly believed the statement was false (nine percent) or did not know (seven percent) whether it was true or false.

The proportion of respondents providing correct true/false answers to the statements when shown the status quo instructions was as follows:

- 'You need to sterilise the bottle you're using every time you make up formula' (correct answer true) – 84%
- 'You can add an extra scoop of formula powder if your baby is really hungry' (correct answer false) – 81%
- 'You need to let the boiled water cool down before mixing it with the formula powder, rather than mixing it when it is still hot' (correct answer true) – 80%
- 'Any scoop is the same as the scoop that's provided in the tin to measure the formula powder with' (correct answer false) – 78%
- 'To make 100ml of formula, use two levelled scoops of formula powder' (correct answer true) – 77%
- 'It's OK to add other flavourings or foods to made-up formula' (correct answer false) – 72%
- 'Any formula left over after a feed can be put in the fridge and reheated' (correct answer false) – 68%

- 'It's OK to store made-up formula in the fridge for 24 hours' (correct answer true<sup>6</sup>) – 66%
- 'It doesn't matter if the water or the formula powder is put in the bottle first, as long as it's mixed well'<sup>7</sup> (correct answer false) – 58%
- 'It's OK to prepare a few bottles or a 'batch' of formula at once, rather than just preparing each bottle as you need individually' (correct answer false<sup>8</sup>) – 57%

Some of the above results are concerning as they suggest many caregivers in Australia and New Zealand do not understand the current instructions on infant formula labels. For example, only 68% of respondents understood leftover formula should *not* be reused (i.e. refrigerated and reheated later). However, nineteen percent incorrectly believed leftover formula *could* be reused and 12% didn't know.

The following changes were made to the status quo instructions to create the 'potentially improved' instructions:

- 'until lukewarm' was added to the end of the instruction about boiling and cooling water.
- 'Always put the water into the bottle first, before adding the powder' was added to the instruction on measuring water into the bottle.
- 'Always add 1 level scoop of powder for each 50mL of water. Never add more or less formula powder or water than recommended unless directed by a healthcare professional. Do not add any other food (e.g. cereal) or flavouring to the feed' was added to the instruction on measuring powder into the bottle.
- An additional instruction 'Once prepared, formula can spoil quickly. Discard any formula left in the bottle after a feed' was added.
- 'It should feel warm, but cool is better than too hot' was added to the instruction on testing the temperature of the feed.
- The heading 'Preparing feeds in advance', followed by the text 'It is safer to prepare each bottle as needed' was added at the end of the step by step instruction.

As a result, respondents who saw the 'potentially improved' instructions performed better than those who saw the status quo instructions on three statements. These differences were statistically significant. The three statements that showed improved performance were:

- 'It's OK to add other flavourings or foods to made-up formula' (correct answer false) – 81% correct compared to 72% for status quo
- 'Any formula left over after a feed can be put in the fridge and reheated' (correct answer false) – 74% correct compared to 68% for status quo
- 'It doesn't matter if the water or the formula powder is put in the bottle first, as long as it's mixed well' (correct answer false) – 71% correct compared to 58% for status quo

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<sup>6</sup> Both the status quo and potentially improved instructions suggest it is preferable to prepare feeds as needed. However, they also both provide instructions on how to safely prepare feeds ahead of time and store them for up to 24 hours.

<sup>7</sup> Preparation instructions tell caregivers to add water to the bottle first, followed by powder. This is because water is usually measured in the bottle using the volume markers on the side. If powder is added to the bottle first, the volume markers will no longer be an accurate measure of the water being added (as the powder is contributing to the total volume). As a result, the formula will be too concentrated.

<sup>8</sup> The Code currently requires an instruction that each bottle should be prepared individually. The intention of this instruction is that caregivers who are preparing multiple feeds at the same time (e.g. when they are preparing feeds in advance) measure the water and formula powder into each bottle. I.e. that they do not measure all the water and formula powder needed into one large container, mix it and then divide it between the bottles.

These findings suggest that changes to the preparation and use instructions on infant formula labels could improve caregivers' understanding of some of the instructions. As discussed above, Malek (2017) found a lack of understanding of instructions was one reason some caregivers were preparing or using infant formula incorrectly.

#### *Self-reported preparation practices*

Respondents were asked how often they follow a series of practices when they prepare formula feeds. Some of the practices listed were 'correct' (i.e. caregivers should ideally follow this practice every time they prepare formula feeds), and some were 'incorrect'. The percentage of respondents who reported 'always' following the correct practices were as follows:

- Check the temperature of the made-up formula before giving it to the child – 73%
- Level the scoop of formula powder – 69%
- Use only boiled water to make formula – 63%
- Sterilise/boil the bottles and teats – 59%
- Wash your hands before starting to prepare the formula – 53%
- Use cool or lukewarm water to make formula – 33%

The percentage of respondents who reported 'never' following the incorrect practices were as follows:

- Warm the formula up in the microwave – 39%
- Add the formula powder to the bottle before you add the water – 57%
- Make up a number of bottles of formula at the same time to use for later feeds – 53%
- Add more (or less) formula powder to the bottle than the instructions say – 62%
- After a feed, save any left-over formula in the fridge to reuse later – 52%
- Use something other than the measuring scoop that comes in the tin to measure the formula powder – 74%
- Add extra flavourings or foods to the bottle – 75%

This means a significant proportion of these caregivers are incorrectly reconstituting infant formula, and for many this is something they do 'always' or 'most times'. Fourteen percent of respondents reported always adding powder to the bottle before they added water, and nine percent did this most times. Seven percent always add more (or less) formula powder than instructions say, and a further seven percent do this most times. Some respondents always use something other than the measuring scoop that comes with the tin (six percent), and six percent do this most times. These deviations from the instructions can result in infant formula that is over- or under-concentrated. This can be harmful for infants, particularly when it is done regularly.

Also of concern is the percentage of respondents reusing left-over formula. Six percent reported always saving left-over formula to reuse later, and 11% said they did this most times. Bacteria can grow in reconstituted formula, particularly when it is being held at room temperature for a feed. As a consequence, caregivers may expose their infants to high levels of bacteria if they reuse leftover feeds, potentially making them sick.

Some caregivers were regularly adding extra flavourings or other foods, such as cereal to bottles. Five percent reported always doing this and six percent did this most times. As noted earlier, this behaviour has been found in other countries (particularly the United States). However, until recently very little Australian or New Zealand evidence has been available on this practice. This finding (combined with that from Malek 2016b) suggests this is also a problem in the Australian/New Zealand context.

These findings suggest caregivers' compliance with the preparation instructions varies. Some correct practices are followed by a high proportion (but not all) of caregivers. Others (e.g. washing hands) are often not followed.

### *Confidence about preparing infant formula*

Interestingly, caregivers reported a very high level of confidence in preparing formula feeds. Sixty percent of respondents reported feeling 'extremely confident' and 24% reported feeling 'very confident' about preparing formula. This suggests that changing the practices of caregivers who already have experience preparing infant formula may be a challenge. Their confidence may make them unlikely to seek new information on how to prepare infant formula safely.

### **1.3 Additional literature search findings**

One American study used a combination of observation of infant formula preparation and semi-structured interviews to examine mothers' preparation practices (Ellison et al., 2017). Thirteen low income mothers with an infant aged three months or younger were recruited. All participants (n=13) were in low income households and their infants were predominantly fed infant formula. In the observational component of the study, participants were asked to make one bottle using their own formula and equipment. They then made a bottle of unfamiliar infant formula. Following the observational component, participants completed an in-depth semi-structured interview.

Only six of 13 participants looked at the preparation instructions on the packaging of the unfamiliar infant formula product before preparing the bottle. Participants were not asked why they did or did not look at the instructions. It is possible that some participants assumed the instructions would be the same on all brands of infant formula, so they could rely on their previous experience.

Some of the participants did not follow recommended practices when preparing the infant formula. For example, no participants were observed washing their hands before preparing formula and two of the 13 participants added infant cereal. However, because of the study design it was unclear to what extent this was due to participants not reading the instructions, or reading but not understanding them.

Some participants were aware of the recommended practices and were deliberately deviating from them. In these cases they explained to the interviewer this was because changes needed to be made for their infant. For example, some participants reported adding infant cereal to reduce spitting up, to keep the infant full for longer, to reduce the amount of formula they used and to help the infant sleep longer. It is unclear how much of their knowledge of recommended preparation practices was from the preparation instructions and how much was from other sources (e.g. family and friends, health professionals).

In some cases participants believed they were using the correct proportions of formula powder and water when preparing the unfamiliar product, but were actually over- or under-diluting it. This suggests they either didn't read this part of the instructions, or read but did not understand it.

Participants reported feeling anxious and lacking confidence when they first started preparing infant formula. However, some appeared reluctant to discuss infant formula preparation with health professionals because they didn't want to appear unintelligent. Over time as they gained experience with preparing formula, they gained confidence in their abilities.

A qualitative Australian study (Appleton et al., 2018) of 24 caregivers of infants aged

between nine and 11 months receiving formula investigated caregivers' use of infant formula. Respondents were initially recruited online and asked to complete a series of online surveys before receiving a semi-structured telephone interview. Caregivers during the interview described how they prepare formula products.

Caregivers reported preparing formula for their infant as per labelled instructions on formula products. Most caregivers reported following the preparation instructions in conjunction with the feeding guide. How closely caregivers followed the step-by-step instructions was not measured. Some caregivers reported deviating from the instructions by using a microwave or not sterilising feeding bottles, for example. Two respondents indicated they deviate from the instructions based on professional health advice (e.g. adding more water to assist infant constipation).

Using data from *The Infant Feeding Practices Study (IFPS) II* Gafney et al. (2014) examined postpartum depression (PPD) as a potential risk factor for non-adherence to infant feeding guidelines, including the addition of baby cereal to their baby bottle at age 2 months. Of the 4902 mother-infant dyads included in the IFPS II, 1447 had sufficient data to be included in Gafney's et al (2014) analysis. They found that 11.7% reported adding baby cereal to their baby bottle. However the survey did not distinguish between adding cereal to infant formula and adding cereal to expressed milk and the proportion covers both practices. Among participants with post-partum depression 16.6% reported adding cereal to baby bottle. Mothers with PPD were 1.77 times more likely to add cereal to baby bottle than mothers who did not have PPD (Gafney et al 2014).

A cross-sectional survey (Kumar et al., 2010) of 182 American caregivers of infants across three paediatric centres tested caregiver numeracy and literacy skills. Specifically, caregivers' numeracy and literacy skills were tested using a validated questionnaire assessing parental health literacy. Contained in the questionnaire were questions related to the preparation of powdered and concentrated formula.

The study found caregivers' accuracy in mixing the formula varied depending on the wording of the instructions. When researchers asked caregivers to prepare 4 fluid ounces of powdered formula using a numeric chart illustrating how much water and scoops of formula to use, 90% gave correct responses. By contrast, when asked to prepare the same amount of concentrated formula with the written instruction to '*mix equal amounts of concentrated formula and warm water*' only 47% of respondents provided correct answers. The finding suggests caregivers may face difficulties converting written instructions into numeric ratios to follow when preparing formula products.

A systematic review (Lakshman, Ogilvie, & Ong, 2009) into mothers' experiences of formula feeding included research examining hygiene and safety during formula preparation. The review found that recommendations regarding hygiene and safety in relation to formula preparation were often not followed. Common practices associated with poor safety and hygiene outcomes related to over or under concentrating formula feeds during preparation, improper water preparation (e.g. not boiling water), and heating prepared feeds in the microwave. The authors did not elaborate on whether the caregivers in these studies were inadvertently or deliberately not following the instructions.

A focus group study (Winstanley & Cressey, 2008) of 14 New Zealand mothers spread across three focus groups explored aspects of the preparation of infant formula. Mothers ranged in age from 20 to 41 years of age and all had an infant aged between 1 to 11 months. Participants in the focus groups were identified and recruited by local child birth educators who had conducted antenatal classes and kept contact with caregivers postnatally.

Participants were asked to describe in detail how they usually prepared powdered infant

formula. Participants demonstrated a good appreciation of the importance of correct preparation. However, in most cases they did not know why particular preparation practices were important. Aspects of formula preparation discussed with caregivers included: hygiene, sterilising equipment, preparing water, adding formula, reheating, unfinished feeds, night-time/away from home feeds.

Hygiene (handwashing and cleanliness of preparation areas) was considered by most caregivers to be so obvious that it often was not mentioned in focus groups until participants were prompted. Mothers were less likely to follow these practices with older infants (who were considered less vulnerable). Mothers reported they were fastidious with handwashing and cleaning preparation areas with their first child and became less careful with subsequent children.

A number of sterilisation practices were discussed and reported including: chemical sterilisation (sterilising tablets), boiling in water, adding boiling water to overflow, microwave sterilisation. Overall there was a reasonable level of understanding that sterilisation was most important during the first three months, although most mothers expressed a tendency to err on the side of caution.

Caregivers generally used boiled water when preparing feeds for infants up to (and often exceeding) three months. The authors noted this was in accordance with many guidelines. Many caregivers boiled water ahead of time to make preparation of feeds quicker. For example, they would put boiled water into a number of bottles, so they were 'ready to go', or pour it into a container for future use. Pre-boiled water was stored either on the bench or in the refrigerator. Boiling water for each individual feed was uncommon. Mothers tended to stop boiling water for feeds at a particular age (e.g. six months) or when they believe the infant would be encountering bacteria from other sources (e.g. complementary foods).

Mothers reported high levels of compliance with manufacturers' instructions regarding the ratio of formula to water when preparing formula. However some deviations to instructions were reported. One participant reported adding water to formula, rather than formula to water. One more reported their partner did not level the scoops. As this was a focus group study, the researchers relied on mothers' self-report for this practice. However, as highlighted by Ellison et al. (2017) caregivers may believe they are using the correct proportions, but actually be over- or under-concentrating the formula.

Heating formula in the microwave was widespread amongst participants. The risk of uneven heating and the need to shake microwave heated formula before feeding was generally understood. This was only raised spontaneously by one participant. However, upon prompting, this appeared to be generally known. Approximately one-quarter of the participants did not bring the formula to body temperature, either feeding formula hot or cold. The common rationale for this deviation was that the baby preferred formula hot/cold to warm.

There were generally high rates of compliance with guidelines for discarding unfinished feeds. However, two (out of 14) participants reported that if the infant wouldn't finish a feed it would be stored in the refrigerator for later use. One participant reported that they would reheat formula feeds while feeding if feeding time lasted a significant amount of time. The cost of formula, particularly for those using 'premium' formulas was a major driver for participants deviating from discard instructions. The decision to discard unused feeds appeared to involve a personal cost-benefit decision in these instances.

Caregivers had to adapt their preparation methods for night-time feeds and feeds away from home. Caregivers preparing feeds away from home may not have access to their usual facilities (e.g. sterilisation equipment, a jug to boil water). Night-time feeds needed to be

prepared quickly to feed a crying infant and because the caregiver wanted to return to bed as soon as possible.

Reported behaviours covered a wide range of approaches. Some caregivers used pre-measured water in a bottle with formula set aside ready to add when required. Other caregivers reported having pre-mixed formula ready to go. There was a reasonable level of awareness that prepared feeds could be stored in the refrigerator.

Overall, self-reported compliance with the preparation instructions varied. Mothers tended to become more relaxed with many of the steps (e.g. handwashing, sterilising, boiling water) as their infant grew older. Of particular concern were the two mothers who reported reusing leftover feeds, the participant who added formula powder to the bottle before water (which results in over-concentrated formula), and the participant with a partner that did not level scoops. It is notable that although the study only included 14 participants and relied on self-report, it did identify some caregivers not following these important instructions.

The New Zealand Ministry for Primary Industries commissioned a study (Yockney & Comfort, 2013) seeking to examine consumer understanding, perceptions and uses of follow-on formulas (six to 12 months) and toddler milks (12 up 36 months). The qualitative research was conducted using online forums with a total of 137 caregivers in Australia and New Zealand. Three online forum groups were created consisting of: caregivers who use formula in Australia, formula users in New Zealand, and caregivers who don't use formula in both Australia and New Zealand. Caregivers in the study had at least one child aged between six and 36 months.

The study found caregivers consider the preparation instructions on formula products include three key instructions: how to sterilise bottles, to use cooled boiled water, and the powder to water ratio required. These key instructions were considered particularly important for caregivers who are new or unfamiliar with the process of preparing formula products. The preparation guide gives caregivers reassurance that they are preparing the formula as they are meant to, and as such that it is safe for infant consumption. However, caregivers reported that once having prepared formula a few times they no longer felt the need to refer to the preparation instructions.

Caregiver input to the online forums also identified the preparation instructions are considered useful in other circumstances, such as: changing brands or stages of formula, or for parents who do not prepare formula products often. In general, caregivers felt instructions about sterilising and using cooled boiled water are more important when the child is younger. As their child gets older they are less particular about ensuring bottles are sterilised and whether boiled water is used.

Most caregivers reported following the ratio of powder to water consistently. One caregiver (of a child aged between 12 and 24 months) sometimes reduced the quantity of powder in an attempt to make the formula last until she could afford more. However, as Ellison et al. (2017) found, caregivers may not be aware they are using the incorrect ratio of powder to water.

The online study also analysed caregiver use of the feeding guide in tandem with the preparation instructions. It was found that similar to the preparation guide, most caregivers refer to the feeding guide when they are new to preparing follow-up formula and toddler milks. At first they find the feeding guide useful to provide them with an idea about the quantity they should be offering their child.

Initially, some caregivers reported becoming anxious when their child consumed more or less than the amount stated on the feeding guide. At first, these caregivers did not realise that the feeding guide is only a guideline of the quantities the child might consume. Once caregivers became more familiar and confident with preparing formula products, they were guided by their child's appetite.

Caregivers who mix fed were unlikely to refer to the feeding guide. This is because they perceived the feeding guide serves those who are solely using formula, rather than as a supplement to other dietary sources such as breastmilk and solids. Finally, some caregivers were slightly sceptical of the feeding guide. These caregivers felt it might be a marketing tactic to encourage caregivers to provide more product to their child, and thereby purchase more.

A report published by Food Standards Agency<sup>9</sup> (FSA) (Redmond & Griffith, 2013a, 2013b, 2013c, 2013d) presents consolidated findings from a series of qualitative and quantitative research conducted in the United Kingdom. The research investigated attitudes and behaviours of consumers and caregivers in the preparation, handling and storage of powdered infant formula inside and outside the home.

The research found that parents in the UK reported and demonstrated a variety of methods for the preparation, handling and storage of infant formula inside and outside of the home. While all feeds that were reported and observed being prepared as part of the research were done so with boiled water, many methods and practices involved in formula preparation were not in accordance with guidance from the UK Department of Health or the FSA.

Parents generally expressed positive attitudes toward the preparation of safe powdered infant formula for their children. However, parents also expressed negative attitudes toward practices (e.g. bottle sterilisation) required to achieve this. These negative attitudes were a consequence of caregivers finding preparation tasks inconvenient, and appeared to contribute to non-compliance preparation instructions leading to microbiological safety issues (e.g. not sterilising feeding bottles).

Many parents prepared infant formula ahead of time for convenience, for feeds both inside and out of the home. Of the 200 parents interviewed, 35% reported they sometimes or always prepare feeds in advance. Six percent of parents interviewed reported preparing enough feeds for 12 hours of feeding. A further six percent reported preparing enough feeds for 24 hours. For feeds away from home, 45% of parents reported preparing the feed (i.e. mixing the powder with the water) at home and taking the prepared feed out with them. Modelling of time temperature data from reconstituted feeds stored for 12 to 24 hours indicated high levels of predicted growth of *Cronobacter sakazakii* in made-up feeds stored at an ambient temperature.

Many parents were aware of the recommendation to prepare infant formula feeds on an individual basis for immediate feeding. However, almost all caregivers considered this was difficult and impractical to implement consistently. Caregivers reported not understanding why the preparation of individual feeds is recommended. They considered preparing feeds in advance acceptable and more practical to implement.

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<sup>9</sup> Full report available at: <https://www.food.gov.uk/research/microbial-risk-assessment-b13/an-investigation-into-the-attitudes-and-behaviours-of-consumers-and-caregivers-in-the-preparation-handling-storage-and-feeding>

Most caregivers considered determining an appropriate temperature for cooled boiled water was difficult<sup>10</sup>. Leaving water for longer than 30 minutes after boiling was frequently self-reported, as well as observed in model kitchen study. Many parents believe the temperature recommendation from the UK NHS and Food Standards Agency is intended to prevent scalding infants from feeding feeds that were too hot as opposed to other food safety reasons associated with boiling water.

A common practice reported and observed during the preparation of powdered infant formula feeds involved leaving pre-boiled tap water in cleaned bottles. These were then stored at refrigerated or room temperature with powdered formula being added later for immediate feeding. The majority of parents reported they believed this practice was following guidelines by making 'one feed at a time'. Similarly, this practice was reportedly advocated by many community midwives and health visitors and day nursery staff.

Findings from the research illustrate a diversity of attitudes and perceptions that parents have toward specific handling, preparation and storage behaviours and microbial safety of powdered infant formula use inside and outside the home.

Results indicate that parents deviate from required preparation practices in order to make preparation more convenient, especially as infant age increases. Results from qualitative components in the research revealed that nearly half of parents reported they were more careful with how they prepared their infants' feeds when they first started preparing powdered formula.

The most common observed cleaning malpractices implemented by parents included the failure to rinse all bottles and components after washing in hot water and detergent. In addition, the vast majority of parents did not clean the inside and outside of the screwcap, outside teat and around the outer rim of a feeding bottle. From testing it is known that the screwcap and outer rim threads on feeding bottles are known to collect food residues and micro-organisms if inadequately cleaned.

When caregivers used sterilisation equipment for baby bottles (e.g. steam sterilisers) it was common for caregivers to not follow manufacturer's instructions for the equipment. Examples of caregivers not using sterilisation equipment as instructed included not loading equipment properly and not allowing for bottles to cool before removing them.

Most caregivers observed preparing infant formula did not wash and dry their hands adequately during preparation and while handling baby bottles. It is noted that this could lead to the contamination of formula feeds during the preparation process.

There was a lack of knowledge concerning microbiological hazards associated with powdered infant formula amongst caregivers (parents, nursery staff and NHS professionals). Close to three-quarters of parents and between 45 to 77% of nursery and NHS caregivers believed that infant formula was a sterile product prior to opening and using the product.

Parents reported having a general level of confusion concerning the length of time opened ready to use formula and reconstituted powdered infant formula may be kept. Caregivers noted that opened ready to use formula may be kept for a day when refrigerated as per instructions, while instructions for powdered infant formula dictate to feed immediately. Parents' were unsure why there was a difference between storage instructions between the two formula types.

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<sup>10</sup> In the United Kingdom, caregivers are advised to use hot water for reconstituting infant formula. The correct temperature can be reached by boiling water in an electric kettle and allowing it to cool for no more than 30 minutes.

## **1.4 Conclusions**

Caregivers consider preparation instructions an important part of the label. They also say they believe it is important to follow them exactly. However, the research shows that when they are asked about more specific practices, caregivers reveal deviating from the instructions. Common deviations that caregivers self-report include: not washing hands before preparing formula, not boiling water, not sterilising bottles and utensils, microwaving formula, and adding powder to the bottle before water. Some caregivers also report reusing unfinished feeds, altering the ratio of powder to water, and adding flavourings and other foods to bottles.

Research on caregivers' use of the label reveal a range of reasons for these deviations. In some cases caregivers are unaware of particular instructions and so do not follow them (e.g. discarding unfinished feeds rather than reusing them). In other cases caregivers have read the relevant instructions but did not understand them. For example, some caregivers do not understand the instruction to discard unfinished feeds. Observational research also shows that caregivers may believe they have read the instructions and believe they are following them but are actually preparing formula incorrectly. For example, some caregivers use the wrong quantity of powder relative to water.

For some instructions, caregivers report deliberately deviating from the instructions. They have noticed, read, and understood the instructions but have chosen not to follow them. For example, some caregivers self-report altering the proportions of powder to water (e.g. adding an extra scoop), adding flavourings or foods to formula, or reusing leftover feeds despite knowing this went against the preparation instructions. In some cases, caregivers report they are doing this based on advice from health professionals.

Reasons for deliberately deviating from the instructions included: low perceived risk, increasing efficiency when preparing formula, the desire to avoid waste or expense of discarding formula, infant age considerations, and receiving conflicting preparation advice from other sources such as healthcare professionals.

In some cases caregivers reported the lack of detail or explanation made the intent of instructions unclear. For example, they were unclear how long after feeding leftover formula should be discarded. Additionally, some caregivers who reported adding flavourings to formula noted that the instructions did not advise against this.

Caregiver confidence in their abilities appears to also contribute to their adherence to following the instructions. Caregivers report reading the instructions when using infant formula for the first time, and using them less as they become familiar with preparing infant formula. This is consistent with more general research on warnings and instructions (Argo & Main, 2004). In their literature review, Argo and Main (2004) found that as consumers become more familiar with a product they are less likely to notice warnings on the product and are less likely to follow the precautions included in the warning. Some caregivers indicate they do not or would not review the preparation instructions if and when they change brand/product.

The research shows that caregiver understanding of some of the steps can be improved through changes to the instructions. In particular, understanding that flavourings and other foods should not be added to formula, leftover formula should not be reused, and water should be added to the bottle before formula can be improved.

Further highlighting of key steps to follow in the preparation instructions by means of emboldening or colouring, as well as drawing greater attention to the risks associated with not following the preparation instructions may increase adherence to the instructions.

## 2. Presentation of warning and advisory statements

This section addresses the research question - “How does the presentation of warning and advisory statements on infant formula influence consumer’s awareness of the statement”.

### 2.1 FSANZ-commissioned research

#### ***Malek 2016b Infant Formula Use and Decision Making Study (InFormD) Australian and New Zealand consumers’ perceptions, understanding and use of labelling information on infant formula products. Part B: Infant formula preparation***

A study commissioned by FSANZ and mentioned previously in this report (Malek 2016b) investigated caregivers’ use and understanding of infant formula preparation instructions. Caregivers’ visual attention toward infant formula product labelling was measured using eye-tracking equipment. One of the label areas of interest in this study was the ‘Warning’ that instructs caregivers to “*follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill*”.

The eye-tracking data showed that of the 30 participants in the study, 13 visually attended to the warning statement. The follow-up interviews with participants identified that some caregivers were completely unaware that any formula products bear the warning statement. This finding suggests that some caregivers using formula are not aware of the warning label as they have never looked at it. In one instance a caregiver was not aware of the warning label as the notice on infant formula advising that ‘breast is best for babies’ deterred them from looking at other warning and advice label elements. In the instance the ‘warning’ statement follows the ‘important notice’ on infant formula, some caregivers may not attend to the warning statement as the ‘breast is best’ message may elicit a negative response causing them stop reading warning and advisory statements.

When asked directly about the warning label most participants indicated they would comply with the advice and not deviate from the directions given. However, caregivers noted that they believed other formula users must be deviating from the advice to follow the preparation instructions exactly. The main reason participants gave for this suspicion concerned the cost of formula and a belief that caregivers use less powder to maximise the longevity of a tin of formula. In two instances caregivers reported deviating from the instructions by adding flavourings (e.g. chocolate powder) or other foods during formula preparation.

The warning instructs caregivers to follow preparation instructions exactly. Given many participants either did not look at the warning label or were unaware the advice exists, it may partially explain why some caregivers did not follow the preparation instructions as directed in the preparation task of this study (discussed in section 1 of this report).

### 2.2 Additional literature search findings

No literature was identified examining warning and advisory statements on infant or follow-on formula products specifically. However broader literature regarding the presentation of warning and advisory labelling has been identified from prior FSANZ programs of work<sup>11</sup>.

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<sup>11</sup> FSANZ (2019) P1050 - Pregnancy warning labels on packaged alcohol: Supporting Document 1, A review of recent literature. Available at: <http://www.foodstandards.gov.au/code/proposals/Documents/SD1%20PWL%20Literature%20Review.pdf>

## **2.3 Conclusions**

Research suggests that some caregivers using infant formula do not visually attend to the warning statement on infant formula. Furthermore, some caregivers report never having seen warning statements which may lead to a lack of risk perceptions associated with not following preparation instructions as directed (e.g. 'Warning: follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill').

Literature beyond infant formula examining the ergonomics and efficacy of warning labels indicates there are a number of factors (e.g. size, location/placement, colour/contrast) that influence consumer awareness and attention to warning labels (Laughery & Wogalter, 2006; Wogalter, 2006; Wogalter & Leonard, 1999).

For a warning label to be effective it first must be noticed and for the consumer to direct their attention to it. Larger label elements received more attention from consumers. However, there is also likely to be a ceiling effect whereby an increase in the size of a warning label element will only have a marginal additional benefit beyond a certain point in relation to the size of the package it is on. The relative size of the warning to other surrounding label elements is also important. The size and type of font impacts readability with larger fonts being more easily read than smaller fonts. Sentences in all capitals can be harder to read than those in sentence case. A clear and large font is particularly important for the visually impaired.

The location of a warning statement also impacts the attention it receives. Generally labels that are placed centrally with reduced visual clutter are more readily identified on packaging (Graham, Orquin, & Visschers, 2012). Borders may also be used on warning statements to draw attention to them depending on the context of the warning statement in relation to other label elements on a package. Borders may be used to distinguish and separate the warning from other information that competes for attention. Research on pesticide labels shows that people are more likely to comply with warnings when they are incorporated into instructions, rather than placed on a separate part of the label (Edworthy et al., 2004).

Colour in warnings enhances the attention they receive. Using red in a warning can increase the speed at which the warning is identified and also increase the level of attention the warning receives. Colour operates as a cue that in combination with an appropriate signal word (e.g. 'Warning') is perceived as implying a greater hazard than the equivalent signal word in black text. Some colour combinations produce contrast that is difficult to read (e.g. yellow on white), and legibility is reduced when the contrast between characters and the background is low. Dark lettering on a white background, or vice versa, rather than similar shades of a similar colour has been recommended to enhance legibility.

This broader research suggests that modifications to size, placement, and colour/contrast may influence consumer awareness of and compliance with warning statements on infant formula products. For example, locating the warning statement within, immediately above or adjacent to the preparation instructions may increase the proportion of caregivers that notice and read the statement. Increasing the contrast of the warning statement and incorporating colour (e.g. for the signal word 'WARNING') may also increase attention to the warning statement and caregivers' perceptions of the risk of not complying.

No research was identified examining caregiver/consumer identification of advisory/warning statements on infant formula products designed for special dietary purposes. Statements on these products advise that they are not suitable for general use and should be used under medical supervision. While there has been no specific research on these statements, the general findings regarding warnings are likely to apply.

### 3. Placement of the protein source statement

This section addresses the research question - “Does the placement of the protein source statement required on infant formula influence consumer purchase decisions”.

#### 3.1 FSANZ-commissioned research

##### ***Malek 2016a. Infant Formula Use and Decision Making Study (InFormD): Australian and New Zealand consumers’ perceptions, understanding and use of labelling information on infant formula products. Part A: Infant formula purchase decisions<sup>12</sup>***

FSANZ commissioned a qualitative study consisting of 136 Australian and New Zealand caregivers spread across 21 focus groups. and examined caregivers’ views and understanding of infant formula labelling. The labelling elements the study examined consisted of the nutrition information statement (NIS), ingredient list, as well as nutrition and health claims labelling on infant formula.

Caregivers from the focus groups reported they would only read the ingredient list when choosing between products if they had a reason to. A main reason for looking at the ingredient list reported by caregivers was whether their infant needed to avoid specific ingredients for health reasons. Caregivers who reported using the ingredients list generally had an infant with an allergy or intolerance. One caregiver explicitly reported looking only looking for protein information in the ingredient list as they felt guilty for using formula.

The focus groups were asked about their use of the protein source statement. Most caregivers did not use (or were unaware) of the protein source statement, and only those whose infant had an allergy or intolerance used this statement. There were generally no issues raised with the location of the statement, though some would prefer to see the protein source statement on the front of the tin.

##### ***Malek 2017. Infant formula information use and preferences: an online survey of Australian and New Zealand caregivers***

An online survey commissioned by FSANZ (Malek, 2017) of Australian and New Zealand caregivers asked respondents to rank the relative importance of information sources and product characteristics<sup>13</sup> when making an infant formula purchase decision. The survey consisted of 285 Australian and 341 New Zealand caregivers (626 total) of infants aged up to 18 months. Participants were primary (or shared responsibility) decision makers concerning the consumption of infant formula. Participants in the survey were required to have an infant who received either infant formula or follow-on formula between birth and 12 months of age.

The results indicated that, on average, the type of protein (e.g. cow’s milk or soy) was the third most important characteristic when making a formula purchase decision. The most important characteristic was nutrition information and the second most important was whether the product was recommended by health professionals. The fourth most important characteristic of relative importance to caregivers was the ingredient list.

Why caregivers ranked these aspects in this order is not explained. However the findings

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<sup>12</sup> Aspects of this study are published in Malek, Fowler, Duffy, & Katzer (2019).

<sup>13</sup> Product characteristics respondents ranked consisted of: Brand, Formula labelled as ‘premium’, Recommendation from health professionals, Country of origin, Type of protein, Recommendation from other parents friends and family, Nutrition information, Appearance of packaging/label, Ingredient list, Price, Organic

partially align with aforementioned focus group research (Malek 2016a). In the focus groups caregivers had a preference toward the NIS when assessing different formula products. Caregivers reported looking at the ingredient list when they had cause to do so primarily on the grounds of health requirements (e.g. allergies). As such, it is understandable that caregivers would rank the protein source statement as of greater importance than the ingredient list.

### ***3.2 Additional literature search findings***

The New Zealand Ministry for Primary Industries commissioned study by Yockney and Comfort (2013) found that generally caregivers do not find the declaration of protein type as useful as other parts of the label. This is often because caregivers do not know what 'protein type' is, and it is therefore meaningless to them. This information is useful if caregivers have a child that has allergies or food intolerances to specific types of proteins. A few Australian caregivers reported specifically searching for whey-based formula, rather than casein-based, as they believed this protein type was easier for their child to digest. In contrast Jigsaw (2015) reported that 74% of respondents said 'the milk source (e.g. from cow's milk or goat milk, etc.)' was useful when making the decision to purchase a particular formula product.

### ***3.3 Conclusions***

Research suggests that protein source information is of most value to caregivers with infants with known health conditions, such as allergies and intolerances. Caregivers with infants suffering from such conditions report sometimes looking for allergen (e.g. specific proteins) information in the ingredient list. When asked to rank different label elements on infant formula products based on importance/usefulness, the protein source statement is considered important by caregivers of infants with allergies more so than the ingredient list. This suggests that the front of package labelling of protein source information assists consumer decisions when they have reason to use it (e.g. health/safety concerns), and that in the event the protein source information is not labelled on the front of package consumers resort to the ingredient list. Finding this information in the ingredient list may be more difficult for caregivers than using a protein source statement on the front of the package.

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## Appendix A: Method

This report reviews the available literature for the following three review questions:

1. How do carers for infants follow and comprehend preparation instructions on infant formula products?
2. How does the presentation of warning and advisory statements on infant formula influence consumer's awareness of the statement?
3. Does the placement of the protein source statement required on infant formula influence consumer purchase decisions?

However this is part of a broader search and identification of literature covering an additional six questions which are not reported in this review and will be reported upon subsequently as part of the 1<sup>st</sup> Call for submissions for P1028:

4. Does the format of the nutrition information statement and ingredient list enable caregivers to make informed choices? If not, what changes would enable them to make informed choices?
5. Does the proxy advertising of later stage formulas (12 months +) on infant or follow-on formula influence perceptions and purchase intentions toward infant formula?
6. How do caregivers perceive and understand nutrient content claims and ingredient claims on infant and follow-on formula?
7. How aware and understanding are consumers of stage identification label elements on infant formula products, including follow-on formula?
8. How do consumers/caregivers perceive and decide to use infant formulas designed for special dietary purposes?
9. Are sources of information beyond 'on tin labelling' helpful in guiding the understanding and use of infant formula?

The above set of nine research questions were used to develop the scope and searches for relevant literature. Accordingly the numbers of studies identified, screened and reviewed etc. here refer to the complete literature search, not to the subset relevant to the first three research questions.

These research questions were responded to using a three-tiered approach to identify relevant research and literature to address the questions: a search of FSANZ accessible online journal articles; relevant grey literature and government reports; and FSANZ-commissioned research conducted to address and inform P1028. The following online journal databases available to FSANZ were searched:

- SocINDEX with full text
- EconLit with Full Text
- Food Science Source
- Food Science and Technology Abstracts
- Medline with full text
- ScienceDirect

Two search strings were used to identify relevant published literature. Searches were for full text peer-reviewed articles published in English since 2003.

- AB (Infant OR baby) AND AB (formula OR powder) AND AB (label\* OR market\* OR promot\* OR advert\* OR warning\*)
- AB (Infant OR baby) AND AB (prep\* OR instruct\*) AND AB (formula\* OR powder)

Initial article returns were 1592 for search string one and 973 for search string two. However, removal of articles not related to the topics below reduced the number of articles to 96 and 483 articles respectively:

- infant formula
- infant formulas
- breast feeding
- infant nutrition
- food labelling
- food handling
- infant care
- health knowledge attitudes practice
- bottle feeding
- milk substitutes
- feeding behaviour

Removal of duplicate articles (n=385) resulted in a final count of 194 potential articles.

Eight additional grey literature reports were identified that directly address the nine research questions and were included. The grey literature included reports published by government bodies (e.g. New Zealand Ministry for Primary Industries and the United Kingdom Food Standards Agency<sup>14</sup>) and work commissioned by industry (e.g. the Infant Nutrition Council).

Five studies commissioned by FSANZ (including two peer-reviewed published articles) were also included in this review search. A previous consumer research review conducted as part of the current proposal (P1028) identified that an evidence gap exists in recent consumer research relevant to Australian and New Zealand populations that directly addresses infant formula labelling. As such, FSANZ invested in primary research to better inform consumer considerations related to the labelling of infant formula.

The quality of each study was assessed against the following criteria to deliver a rating of low, medium or high.

- Theory/Aims/Justification: the study is appropriately justified with clear aims; the study is located in the body of existing theory
- Population/sampling: population being sampled is relevant to the aims of the study; sampling techniques appropriate and clearly detailed
- Methods: methods used are appropriate to the sample and the aims of the study; measures, tools, questionnaires and guides used described
- Analysis: analysis is appropriate to the data collected, details of statistical testing included, qualitative analysis explained, coding frames explained
- Reporting: results reported with appropriate discussion, limitations identified and discussed

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<sup>14</sup> The research commissioned by the Food Standards Agency was published in one report, but contained multiple studies. The four studies relevant to this literature (Redmond and Griffith, 2013a; 2013b; 2013c; 2013d) have counted as four individual studies.

## Appendix B: Summary of studies

Table B1: Studies and reports contained in the review

Authors	Country, study population and sample size	Study aim	Design	Key findings	Study quality
<b>FSANZ-commissioned research</b>					
Malek (2016a)	Australia and New Zealand;  Caregivers of formula fed infants  n=136	Increase understanding of caregivers' interpretation and use of formula nutritional labelling	Qualitative – Cross sectional focus groups	Caregivers' do not understand many of the nutrients and ingredients contained in formula, but still use nutritional labelling to compare products (e.g. based on length of nutrients to indicate product quality). Ingredient lists are used to identify potential problem ingredients for health reasons (allergies/intolerances)	High
Malek (2016b)	Australia;  Caregivers of infants <12 months receiving infant or follow-on formula  n=30	Explore caregivers' perceptions, interpretations and use of infant formula preparation and storage instructions.	Observational – Eye-tracking of label use during formula preparation Qualitative – in depth interviews concerning preparation	Time spent visually attending to preparation instructions, storage instructions and warning statement. Warning statements were not attended to.  Having seen instructions before caregivers reported less need to review  Handwashing, Water boiling and sterilisation practices were not uniformly adhered to.  Variance in discarding unused feeds varied from immediately through to storing for later use.	High
Malek (2017)	Australia and New Zealand;  Caregivers of infants <18 months who	Determine use and understanding of nutrition and ingredient labelling. Examine preferences toward formatting of	Quantitative – Online survey with required sample size estimates based on population statistics	Percentages of caregivers who wish to know the adverse outcomes associated with not following prescribed on-label preparation instructions.	High

Authors	Country, study population and sample size	Study aim	Design	Key findings	Study quality
	received formula n=626	preparation and use instructions.		Perceived importance of different label elements on infant formula packaging.	
Additional research					
Appleton et al. (2018)	Australia; Parents of young infants n=24	Explore parents' infant formula feeding practices to understand usage and what factors influence this	Qualitative – In depth semi-structured interviews	Most caregivers report adhering to the preparation instructions provided on formula products. Some caregivers report deviations of instructs based on medical advice.  Caregivers reported receiving primarily informal advice concerning formula use rather than formal (healthcare professionals).	Medium
Ellison et al. (2017)	United States; Low income mothers with an infant ≤3 months born at a normal birth weight. Mothers needed to be predominantly formula feeding their infant. n=13	To observe infant formula preparation and to explore attitudes and beliefs about formula preparation	Qualitative – Observation of infant formula preparation and semi-structured interview	Six out of 13 mothers looked at the preparation instructions on the packaging of the unfamiliar infant formula product before preparing the formula.  Some of the participants did not follow recommended practices when preparing the infant formula. However, because of the study design it was unclear to what extent this was due to not reading the instructions, or reading but not understanding the instructions. Some participants were aware of the recommended practices and were deliberately deviating from them. However, it is unclear how much of their knowledge of recommended preparation practices is from the preparation instructions and how much is from other sources (e.g. family and friends, health professionals).	High

Authors	Country, study population and sample size	Study aim	Design	Key findings	Study quality
Gaffney et al (2014)	United States,  Mother-infant dyads that were included in the IFPS II  N=1447	Examine postpartum depression (PPD) as a potential risk factor for non-adherence to infant feeding guidelines and subsequent infant weight gain	Quantitative – Longitudinal survey study incorporating PPD diagnostic and infant feeding questions	11.7% reported adding baby cereal to their baby bottle. However the survey did not distinguish between adding cereal to infant formula and adding cereal to expressed milk and the proportion covers both practices.  Among participants with post-partum depression 16.6% reported adding cereal to baby bottle.  Mothers with PPD were 1.77 times more likely to add cereal to baby bottle than mothers who did not have PPD	High
Jigsaw (2015)	Australia;  Mothers of young infants  n=501	Identify the key influencers in mothers decisions to use infant formula. Identify sources of information used to make informed decisions and understand the use of formula labelling	Quantitative – Cross section online survey with population confidence intervals developed around results gathered	Mother's use of stage labelling on infant formula.  At what age of infancy mothers reported using different stages of formula.	High
Kumar et al. (2010)	United States;  Caregivers of infants aged <13 months recruited from paediatric clinics  n=182	Assess parental health and numeric literacy skills in understanding instructions for caring for young children	Quantitative – Cross sectional study using a validated Parental Health Literacy Activities Test.	47% of caregivers could correctly describe how to mix infant formula from concentrate instructions  90% of caregivers could correctly describe how to mix infant formula from powdered formula instructions	Medium
Magill et al. (2020)	Australia (n=600) and New Zealand (n=733)  Caregivers of infants or young children ≤18	Gather quantitative data on caregivers' formula preparation practices; their perceptions of the risks of incorrect	Quantitative – Cross sectional online survey, which included a between groups experiment	Caregivers' believe the preparation instructions are important. They are confident in their ability to prepare infant formula.  Caregivers' self-reported preparation	High

Authors	Country, study population and sample size	Study aim	Design	Key findings	Study quality
	months of age. The infant or young child must have received infant formula or follow-on formula between the ages of 0-12 months. The caregiver must have been responsible for preparing formula feeds.	preparation; their understanding of current preparation instructions; and the effect of improved preparation instructions on caregivers' understanding.		practices revealed some instructions were followed by the majority of caregivers. Others (e.g. handwashing) were often not carried out.  Caregivers' had a very poor understanding of the risks of incorrect formula preparation. Caregivers' understanding of the current preparation instructions varied. Understanding for some instructions was improved by some of the changes to instructions.	
Redmond and Griffith (2013a)	United Kingdom;  Parents of infants with infants <12 months.  n=50	Observe parents' hygiene practices and analyse the microbiological quality of 100 feeds and kitchen surfaces, post feed preparation	Observational – Participants filmed while preparing infant formula in a kitchen	100% of parents prepared the feeds used boiled tap water. Large numbers of participants failed to clean bottles correctly with 90% failing to clean the inside and outside of the screwcap, outside of teats and around the outer rim of the feeding bottle.  Failure to adequately wash hands during kitchen practices ongoing at the time of formula preparation was observed on 87% of occasions.	High
Redmond and Griffith (2013b)	United Kingdom;  Parents of infants with infants <12 months.  n=50	Obtain time-temperature data from 'in-use' reconstituted powdered formula feeds	Quantitative – Measurement of temperature of prepared formula	15% of feeds were prepared with boiled water cooled for less than 30 minutes.  85% prepared using boiled water cooled for more than 30 minutes.	High
Redmond and Griffith (2013c)	United Kingdom;  Parents (n=50), Healthcare professionals (n=75),	Obtain information from consumers and relevant caregivers concerning beliefs, attitudes and practices relating to	Qualitative – Moderated Focus groups using specific discussion guides for different groups	Reported preparation methods for infant formula are variable. With many parents reporting practices that are contrary to guidelines/instructions (e.g. reconstitution, water preparation and storage errors) .	High

Authors	Country, study population and sample size	Study aim	Design	Key findings	Study quality
	Day nursery nurses (n=24)  Across 16 focus groups	feeding infant formula	(parents, healthcare professionals and nurses)		
Redmond and Griffith (2013d)	United Kingdom;  Parents of infants <6 months using formula  n=200	Determine parent attitudes and perceptions toward powdered infant formula preparation	Quantitative – Face to face interviews using a self-report questionnaire	Parents expressed negative attitudes toward key risk-reducing behaviours (e.g. single feed preparation and sterilisation practices)  Variable and negative attitudes were expressed toward practices associated with cooling boiled water  Reported confusion regarding storage of prepared formula against instructions to feed immediately	High
Winstanley & Cressey (2008)	New Zealand;  Caregivers of infants <6 months receiving infant formula  n=14  Across 3 focus groups	Obtain information about preparation, use, storage, sources of information and knowledge of product safety.	Qualitative – Focus Group	Parents generally discarded unfinished feeds. Among those who did not, this was generally for cost reasons. Hygiene and adhering to preparation instructions was considered important but not well understood as to why. Parent's reported finding it difficult to obtain information from health professionals.	Medium
Yockney & Comfort (2013)	Australia and New Zealand;  Caregivers of infants aged 6 to 36 months  n=137	Examine consumer understanding, perceptions and uses of infant and follow-on formulas.	Qualitative – Analysis of three online discussion forums developed for research participants	Information caregivers consider most important contained in preparation instructions.  Preparation standards decline as infant age increases  The perceived importance of label elements on formula products	High

<b>Authors</b>	<b>Country, study population and sample size</b>	<b>Study aim</b>	<b>Design</b>	<b>Key findings</b>	<b>Study quality</b>
				Information sources caregivers seek and use.	

**Table B2: Systematic and narrative reviews included**

<b>Authors</b>	<b>Review Type</b>	<b>Content</b>
Lakshman et al. (2009)	Systematic Review	Review of qualitative and quantitative studies examining mothers' experiences of formula feeding.