FSAI Scientific Committee Recommendations of Sodium Content of Bottled Water suitable for Infant Feeding:

Corrigendum: Section 4.8.3 Scientific Recommendations for a National Infant Feeding Policy 2nd Edition

BACKGROUND

In July 2014 the Scientific Committee received correspondence from the HSE National Drinking Water Group (NDWG) (see Annex 1). The role of the NDWG includes development of generic advice and guidelines for HSE staff involved in advising Irish Water and its agents on health related aspects of drinking water quality. The NDWG considered the advice in Chapter 4, Section 4.8.3 of the FSAI scientific Committee report: Scientific Recommendations for a National Infant feeding Policy 2nd Edition. In doing so, the NDWG disagreed with the Scientific Committee advice and laid out their rationale. The FSAI asked the Scientific Committee to consider the rationale from the NDWG and decide if any amendments to the advice contained in the Scientific Committee report were necessary.

SCIENTIFIC COMMITTEE OPINION

The Scientific Committee has considered the correspondence from the HSE NDWG and has also reviewed the advice on water used in the preparation of powdered infant formula (Scientific Recommendations for a National Infant feeding Policy 2nd Edition, Section 4.8.3, page 69). It is the view of the Scientific Committee that amendment of the advice contained in the report is necessary as follows:

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Water used in the preparation of powdered infant formula

Boiled tap water should be used to prepare powdered infant formula. If this is not available, boiled bottled water[1] should be used.

Tap water which has been boiled on only one occasion is recommended for preparation of powdered infant formula feeds (FSAI, 2007). Using fluoridated tap water to prepare powdered infant formula is safe, and tap water should be used to prepare powdered infant formula (Forum on Fluoridation, 2002), unless specific advice not to use tap water has been given. In the event that tap water is not available, or when it has been advised that tap water should not be used, boiled bottled water should be used. Bottled water is not sterile, and should be brought to the boil prior to use in preparing powdered infant formula feeds. If boiling water on the hob, water should be brought to a rolling boil for at least one minute before being used (WHO, 2005).

The concentration of several minerals in bottled water, particularly sodium, has been an issue of some concern. Infants and children, the elderly, and people with compromised renal systems are more susceptible than healthy adults to the harmful effects of high sodium intakes.

Based on the EU legislation on infant formula, it has been recommended that all infant formula should contain a maximum of 60mg sodium/100kcal as reconstituted (Directive 2006/141/EC) which is equivalent to about 400mg sodium/l. The highest labelled sodium concentration in infant formula on the Irish market is 270mg/l as reconstituted (see Annex 1). Assuming this only takes account of sodium in formula powder (and not water used for preparing the formula) this allows for up to 130mg sodium/l in water used for preparing the formula. The sodium concentration of practically all public drinking water supplies in Ireland is less than 130mg/l (see Annex 1) while the sodium concentration of bottled waters available in Ireland does not exceed 40mg/l (see Annex 1). Thus, boiled tap water or boiled bottled water may be safely used to prepare powdered infant formula. It is best not to use bottled water labelled as 'Natural Mineral Water' as it can have higher levels of sodium and other minerals. It can be used if no other water is available, for as short a time as possible, as it is important to keep babies hydrated.

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ANNEX 1. REPRODUCTION OF CORRESPONDENCE FROM THE HSE NATIONAL DRINKING WATER GROUP

The HSE National Drinking Water Group has had to advise on using bottled water for the preparation of infant formula. This becomes relevant if a household cannot use their tap water because of elevated lead (Pb) levels. The parametric value for lead in drinking water was reduced on December 25th 2013 from 25 micrograms per litre to 10 micrograms per litre. More people will therefore be using bottle water for the preparation of infant feeds long-term. Another long-term use of bottled water to reconstitute infant formula is where there might be elevated nitrates in a small private supply, although this is now rare. The public tends to ask about bottled water if there is *Cryptosporidium* detected in their water although it is not necessary to use bottled water in these circumstances if tap water is boiled. Sometimes advice is needed during flooding, but this tends to be about the use of bottled water in the short-term not long-term.

Current FSAI advice [before corrigendum]

From the FSAI Scientific Recommendations for a National Infant Feeding Policy, it appears that the advice is based on the assumption that some infant formulas will contain the maximum permitted sodium content of infant formula by EC Regulations and that there is no allowance for added sodium from the water used to reconstitute the formula.

The maximum permitted sodium content of infant formula by EC Regulations is 60mg Na per 100kcal of made-up formula (equivalent to 60mg Na per 154mls of made-up formula. 40mg Na per 100mls of made-up formula, 400mg Na/L of made-up formula, 41.96mg Na/L is used in Table 4.5 on page 69 of the FSAI scientific feeding policy document[1]).

It is important to note that these are not the levels permitted in the formula powder. They are the levels permitted in made-up formula. If any formula powder contained the maximum sodium allowable under the Regulation, then only water with no sodium could be added to reconstitute formula. Powdered formula is not sold at these maximum concentrations of sodium. Powdered formula is sold at lower concentrations.

The highest sodium concentration in infant formula we could find on the supermarket shelves was 27mg Na/L per 100mls of made up formula. The lowest was 17mg Na/L. There may be some error either side of this (+/-1mg). It appears, although it is not certain, that the formula companies allow for added sodium from water, with the aim that the finished product does not exceed the legal limit of 400mg Na/L. As so much formula is manufactured in Ireland and exported, it makes sense that they would allow for a wide range of sodium concentration in drinking water, ensuring that Directive 2006/141/EC is not breached.

What is the evidence that only water with 20mg Na/L should be used for the preparation of infant feeds?

The evidence cited by the FSAI comes from a WHO document[2]. This document discusses the mineral composition of drinking water and the variation that is possible in prepared feeds given the infant formula EC Regulations and the possible range of mineral concentration in drinking water used to reconstitute infant formula.

It states that this recommendation, i.e. using only bottled water with <20mg Na/L for reconstituting baby formula, 'was set'. It cites the decision of the Committee on Nutrition, German Society of Pediatrics to adopt this lower level of sodium in bottled water. Two references are provided to support this. Both references are in German. I have been in contact with the author, months ago, and have requested copies of these documents, translated into English if possible, but have not yet received them. There may be a scientific justification in for 20mg Na/L in these papers.

This chapter does not state that this is a WHO guideline value. In fact, it unequivocally states that the WHO drinking water guideline value for sodium is drinking water is 200mg/l. To some extent, it assumes that the German position has been adopted everywhere else. It also assumes that water with less than 20mg Na/L is labelled as 'suitable for the preparation of infant formula. This is not the case in Ireland. This 'set level' does not appear to be used or cited internationally as accepted practice or as a WHO recommendation. The chapter does acknowledge the discrepancy between this 'set level' and the EU drinking water Regulations and states that it is not of practical relevance in Germany. It is however, of practical relevance in Ireland.

This chapter also provides a practical example of the variation in sodium content in made-up infant feed using a regular German formula and using water with 20mg Na/L and water with 200mg Na/L. The total sodium in the made-up feed using water with 200mg Na/L was 366mg Na/L, below the EU limit. The essence of this chapter is that there is large variation in mineral concentration in water and that the optimal composition of water remains undefined. It also points out that infant formula (and desalinated waters) is (are) a manufactured product and offers the potential of influencing the final nutrient mineral supply to the infant. Tap water is a natural resource and altering the sodium content is less likely to be feasible.

How much sodium does an infant need?

The adequate intake (AI) of sodium for infants less than six months of age is 120mg per day[3]. The adequate intake is the *mean* intake of a healthy breast-fed baby[4]. This is not a maximum. There is currently insufficient evidence to calculate a recommended daily allowance or an upper limit of sodium for an infant[3].

What is the concentration of sodium in human breast milk?

The concentration of sodium in mature human breast milk is between 170mg Na/L[4] and 180mg Na/L[2]. The mineral content of human milk varies considerably both with mother/baby environment but mostly as a result of a baby's needs.

What is the range of sodium in prepared formula feeds?

The range of sodium in prepared infant formula feeds is between 130mg Na/L and 390mg Na/L[2]. Others (Australia) estimate it to be 125mg Na/L to 532mg Na/L[4]. For the purpose of this discussion, it is reasonable to work to a maximum of 400mg Na/L as in EC Directive 2006/141/EC.

What is the range of sodium in regulated drinking water supplies in Ireland?

An analysis of all audit samples from public water supplies (874) and private water supplies (1029) from 2006 to 2012 is shown in Table I below.

Table I

	Geometric mean mg Na/L	% ≥20mg Na/L	% ≥130mg Na/L	% ≥200mg Na/L
Public Water Supplies (874)	14.6mg Na/L (95% Cl 14. 2 to 15.1)	22.5%	0.11%	none
Public Group Water Schemes (263)	14.6 mg Na/L (95% Cl 13.6 to 15.6)	24.7%	0.38%	0.38%
Private Group Water Schemes (433)	14. 8 mg Na/L (95% Cl 14.0 to 15.7)	20.6%	1.15%	0.23%
Small Private Supplies (333) Regulated Wells	39.4 mg Na/L (95% Cl 34.6 to 44.9)	62.5%	29.1%	8.4%

Source of data all audit samples 2006 to 2012 – The Environmental Protection Agency
The mean sodium over five years in each supply was first calculated. The mean of the means is presented here.

Between 20 and 25% of public and private water supplies exceed 20mg Na/L. Only a small percentage of supplies had a mean sodium of greater than 130mg Na/L over the six year period. Many of these supplies have been taken over, amalgamated and decommissioned in the intervening years.

Small private supplies are mostly individual wells. They have a higher concentration of sodium than either public or private supplies. They are subject to the drinking water Regulations if they serve the public; hotels, shops, GAA clubs, schools etc. They are not usually domestic household wells, where you expect baby formula to be prepared, although they could be. Private domestic household wells are not regulated in Ireland and therefore, there are no sodium levels available for them. About 13% of the Irish population is on an unregulated water supply for which there is no information on quality available.

What is the range of sodium in bottle water in Ireland?

From work that the FSAI has done and work that we have done it does not appear that the sodium concentration of bottled water on the supermarket shelves in Ireland exceeds 40mg Na/L. Several are around 25mg Na/L and most are <20mg Na/L. It is legally possible for mineral waters to have a sodium level that exceeds the drinking water parameter of 200mg Na/L but none of the four products marketed as Mineral Waters in Ireland do and they are all ≤ 25mg Na/L.

Brand	Na (mg/L)
Nestle Pure Life Water	40.4
Tipperary Still Water (mineral)	25
Tipperary Kids	25
Deep River Rock	24.7
Crystal Spring Water	20
Ballygowan (mineral)	15
Volvic Still	11.6
Evian	6.5
Highland Spring	5.6
Tesco Every Day Value	trace
Tesco Irish Spring Natural Mineral Water	trace

What level of sodium is allowable in drinking water in order not to exceed sodium levels laid down in EC Directive 2006/141/EC)?

The enclosed Excel sheet[2] shows the concentration of sodium in prepared infant feed using different concentrations of sodium in powdered formula and using different concentrations of sodium in water. It shows that at the highest sodium concentration in infant formula available in Irish supermarkets, water sodium concentrations would have to reach 130mg Na/L before EC Directive 2006/141/EC is (40mg/100mls) is exceeded. This is highlighted in red. This spreadsheet also shows that water used to reconstitute infant feeds contributes a small proportion of sodium to the prepared feed, in comparison to the contribution of the formula itself.

CONCLUSION OF THE HSE DRINKING WATER GROUP

- Overall, the water used to reconstitute infant feeds contributes a small proportion of sodium to the prepared feed in comparison to the contribution of the formula itself.
- 20 to 25% of public and private tap water supplies in Ireland exceed the FSAI sodium guideline value for water used for reconstituting infant formula.
- It may well be that water with a concentration of 200mg Na/L is too high for the preparation of infant feeds but we do not think the evidence supports only using water at a sodium concentration of less than 20mg Na/L. Considering the highest sodium in infant formula (27mg/1OOmls), water with a concentration of up to 130mg Na/L, theoretically could be used before exceeding the EC Direction for sodium concentration in made-up infant formula (400mg Na/L). However, the impact of choosing a lower sodium formula is greater than choosing a lower sodium water.
- Bottled water available in Irish retail outlets currently does not appear to exceed 40mg Na/L. Therefore, based on these calculations, we see no indication to instruct buyers of bottled water to check the label to see if sodium is below 20mg Na/l before using that water to reconstitute infant formula.
- The sodium concentration in the majority of public drinking water supplies (99.9%) and in the majority of public (99.6%) and private (98.9%) group water schemes is, by these calculations, suitable (<130mg Na/L) for the preparation of infant formula. Small private supplies (private wells with a public function) have a considerably higher sodium level, possibly because of water softeners, but these tend to be businesses and do not tend to be homes where infant formula is habitually prepared.

REFERENCES

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[2] This is not available.