

APPENDIX 7.0

TIME TEMPERATURE PROFILING OF RECONSTITUTED POWDERED INFANT FORMULAE FEEDS PREPARED AND FED IN DAY NURSERIES AND INSIDE / OUTSIDE OF PARENT HOMES.

Appendix 7.1 Day Nursery Participant Information Sheets, Consent Forms and Additional Information sheets

Instructions for Day Nursery Staff: Reconstitution of powdered infant formula feeds by parents

Additional Information sheet completed by Day Nursery Staff: Reconstitution of powdered infant formula feeds by parents

Instructions for Day Nursery Staff: Reconstitution of powdered infant formula feeds in nursery

Additional Information sheet completed by Day Nursery Staff: Reconstitution of powdered infant formula feeds in nursery

Day Nursery Consent Form

Appendix 7.2 Parent Documentation for Time Temperature Profiling

Parent Recruitment Questionnaire

Parent Confirmation Letter

Parent Participant Information Sheet (page 1 and 2)

Parent Consent Form

Parent Instructions

Parent Additional Information Sheet

Appendix 7.1: Day Nursery Documentation for Time Temperature Profiling

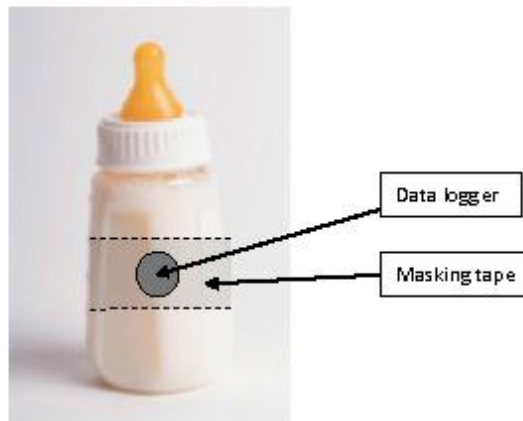
Instructions for Day Nursery Staff: Reconstitution of powdered infant formula feeds by parents

DAY NURSERY DATALOGGER RESEARCH

May-June, 2009

Instructions

1. Using the masking tape, attach one data logger half way down the side of each made-up bottle of powdered infant formula (see image below) as soon as it is brought into your nursery.



2. **Write down the time when the data logger is attached to the bottle** of made-up powdered formula on the attached form. In addition, please note on the form whether the made-up feed feels cold, room temperature, luke warm or very warm. Where possible please record approximately when the feeds were made-up and in what sort of bag they were brought to the nursery in.
3. **Store and handle the bottle of made-up powdered formula with attached data logger** (as shown above) **exactly as you would do normally**.
4. Immediately before feeding, remove the data logger from the bottle and place in plastic storage tube ready for collection. **Write down the time of feeding** (and removal of data logger from bottle) on the attached sheet.

Please do not let the data loggers get wet!

Your nursery will be provided with a £3 supermarket voucher of your choice for each bottle of powdered infant formula that you attach a data logger to.

**PLEASE ENSURE THAT DATA LOGGERS
ARE STORED AND KEPT AWAY FROM ALL
INFANTS AND CHILDREN AT ALL TIMES.**

Additional Information sheet completed by Day Nursery Staff: Reconstitution of powdered infant formula feeds by parents

Please record the following information for each bottle of made-up powdered infant formula that has a data logger attached.

BOTTLE / DATALOGGER: DATE:

Bottle of powdered infant formula is brought to nursery *(please tick)*

Size of bottle and Volume of milk *(please state)*

Time when bottle of made-up formula arrives at the nursery *(please write time)*

Time when datalogger is attached to the bottle of made-up formula *(please write time)*

When parents arrive at the nursery with bottles of made-up powdered formula feeds, do the feeds feel.... *(please tick one option per bottle)*

... cold	<input type="checkbox"/>
... room temperature	<input type="checkbox"/>
... lukewarm	<input type="checkbox"/>
... very warm	<input type="checkbox"/>

When bottle of powdered infant formula was 'made-up'? *(please tick one option per bottle)*

Previous day	<input type="checkbox"/>
Previous evening	<input type="checkbox"/>
Morning of arrival at nursery	<input type="checkbox"/>
Don't know	<input type="checkbox"/>

How was the bottle of made-up powdered infant formula brought into your to your nursery? *(please tick as many as applicable)*

In insulated bag / part of baby bag to keep bottle warm	<input type="checkbox"/>
In a cool bag / part of baby bag with frozen cool packs	<input type="checkbox"/>
In a cool bag / part of baby bag (no frozen cool packs)	<input type="checkbox"/>
In the bottle holder on a pushchair / pram	<input type="checkbox"/>
In a carrier bag / other general bag / handbag / rucksack/ general compartment of baby bag	<input type="checkbox"/>
Other <i>(please state)</i>	

Please note how the made-up bottle of formula has been handled / stored once arrived at the nursery: *(please note details per bottle) (please include where in the fridge the formula was stored – e.g. door, top, middle, bottom shelf, back / front of fridge.)*

Time of feeding, when datalogger is removed to the bottle of made-up formula *(please write time)*

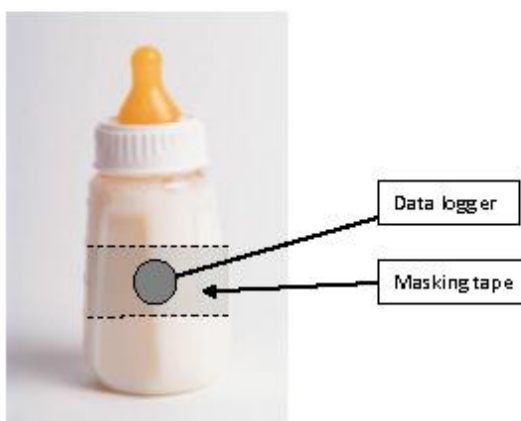
Instructions for Day Nursery Staff: Reconstitution of powdered infant formula feeds in nursery

DAY NURSERY DATALOGGER RESEARCH

May-June, 2009

Instructions

5. Using the masking tape, attach one data logger half way down the side of each made-up bottle of powdered infant formula (see image below) as soon as the water is added to the powdered formula in your nursery.



6. **Write down the time when the data logger is attached to the bottle** / time water is added to the powdered formula.
7. **Store and handle the bottle of made-up powdered formula with attached data logger** (as shown above) **exactly as you would do normally.**
8. Immediately before feeding, remove the data logger from the bottle and place in plastic storage tube ready for collection. **Write down the time of feeding** (and removal of data logger from bottle) on the attached sheet.

Please do not let the data loggers get wet!

Your nursery will be provided with £3 supermarket voucher of your choice for each bottle of powdered infant formula that you attach a data logger to.

**PLEASE ENSURE THAT DATA LOGGERS
ARE STORED AND KEPT AWAY FROM ALL
INFANTS AND CHILDREN AT ALL TIMES.**

Additional Information sheet completed by Day Nursery Staff: Reconstitution of powdered infant formula feeds in nursery

Please record the following information for each bottle of made-up powdered infant formula that has a data logger attached.

BOTTLE / DATALOGGER:

DATE

Bottle of powdered infant formula is made-up in the nursery *(please tick)*

Time when bottle of formula is made-up (i.e. powdered formula is added to water) in the nursery *(please write time)*

.....

Time when datalogger is attached to the bottle of made-up formula *(write time)*

.....

Is the powdered formula made-up with..... *(please tick as many as applicable per bottle)*

- ... boiled water, cooled for more than 30mins in the kettle
- ... boiled water, cooled for less than 30mins in the kettle
- ... boiled water, cooled for more than 30mins in the bottle
- ... boiled water, cooled for less than 30mins in the bottle
- ... refrigerated water
- ... tap water
- ... water at room temperature
- ... commercial presterilised water

When bottle of powdered formula is made up, does **the feed** feed.... *(please tick one option per bottle)*

- ... cold
- ... room temperature
- ... like warm
- ... very warm

Where is the made-up bottle of formula stored IMMEDIATELY after being made up? *(please tick one only)*

- Kitchen work surface
- Fridge
- Other *(please state)*.....

Time when bottle of made-up formula is placed in the fridge *(please write time)*

.....

Please note how the made-up bottle of formula has been handled / stored once arrived at the nursery: *(note details per bottle) (please include where in the fridge the formula was stored - e.g. door, top, middle, bottom shelf, back or front of fridge)*

Time of feeding, when datalogger is removed to the bottle of made-up formula *(please write time)*

.....

Day Nursery Consent Form



DAY NURSERY DATALOGGER RESEARCH

CONSENT FORM

Please tick each box

1. I confirm that I have agreed to attach data loggers provided by UWIC to bottles of made up powdered infant formula in my nursery.
2. I have received and understand the instructions required to participate in this datalogger study and agree to carry out such methods.
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
4. I understand that all information gathered from the study will remain confidential and data reported will be anonymous.
5. I agree to be responsible for safe keeping of the dataloggers and will ensure that dataloggers will be kept away from infants and children in the nursery. I agree to remove each data logger from feeding bottles BEFORE feeding any infant with the bottle.
6. I agree to take part in the above study.

.....
Name of Day Nursery Manager

.....
Date

.....
Signature

.....
Name of Researcher


.....
Date

.....
Signature

Appendix 7.2 Parent Documentation for Time Temperature Profiling

Parent Recruitment Questionnaire


PSA Study E13000201r.E.Redmond.FIC.UWIC.000610 Version 1



**PREPARATION, STORAGE AND HANDLING
OF POWDERED INFANT FORMULA -
PARENTS**

**PHASE 3.2 DATALOGGER
RECRUITMENT QUESTIONNAIRE**

APRIL, 2010



Q1 INTERVIEWER RECORD GENDER

Male → CONTINUE
Female → CONTINUE

Q2 HOW OLD ARE YOU?

Under 18 → CLOSE
18 - 24 → CONTINUE
25-34 → CONTINUE
35-45 → CONTINUE
46 or over → CLOSE

Q3 HOW OLD IS YOUR BABY?

1-2 months (0-4 weeks) → CONTINUE
3-4 months (5-8 weeks) → CONTINUE
5-6 months (9-12 weeks) → CONTINUE
7-8 months (13-16 weeks) → CONTINUE
9-10 months (17-20 weeks) → CONTINUE
11-12 months (21-24 weeks) → CONTINUE
12 months + (25+ weeks) → CLOSE

SHOWCARD

Q4 HOW DO YOU CURRENTLY FEED YOUR BABY?

Breast Feeding Only → THANK & CLOSE
Mix of powdered formula & breast milk → CONTINUE
Powdered Formula only → CONTINUE

Q5 YOU SAY THAT YOU CURRENTLY / SOMETIMES USE POWDERED FORMULA MILK TO FEED YOUR BABY. CAN YOU PLEASE TELL ME APPROXIMATELY HOW OFTEN YOU USE POWDERED FORMULA?

All or most feeds → CONTINUE
At least once a day → CONTINUE
Other → THANK & CLOSE

PSA Study E13000201r.E.Redmond.FIC.UWIC.000610 Version 1

Q5 DO YOU EVER MIX THE POWDERED FORMULA WITH WATER MORE THAN 2 HOURS BEFORE FEEDING?

Yes → CONTINUE
No → THANK & CLOSE

Q6 OCCUPATION OF CHIEF INCOME EARNER IN THE HOUSEHOLD

Job Title: _____ → CONTINUE

Position/Rank/Grade: _____ → CONTINUE

Refused _____ → THANK & CLOSE

IF SUCCESSFULLY SCREENED INVITE RESPONDENT TO PARENT IN THE STUDY:
As I said before, we are conducting a research study concerning different aspects of feeding babies under 12 months old with powdered infant formula, and would like to invite you to attend.
The research involves attaching a datalogger to powdered infant formula feeds that you prepare at home for the duration of storage time (2 hours or more).
The datalogger will be delivered and collected from your home.
You will receive a £3 supermarket voucher per feed.

IF PARENT IS WILLING TO ATTEND PREPARATION SESSION IN UWIC:
Arrange convenient time for attendance to UWIC for participation (Date, time etc).
Record contact details below, then hand them invitation (with date of arranged attendance to uwic), participant information sheet and consent form.

Day/Date: _____
Time: _____

PARTICIPANT DETAILS:

Name: _____

Address: _____

Postcode: _____

Telephone Number: _____

PSA Study E13000201r.E.Redmond.FIC.UWIC.000610 Version 1

SHOWCARD

Breast Feeding Only

Mix of powdered formula &
breast milk

Powdered Formula only

Parent Confirmation Letter

Participant confirmation letter : Phase 3.2 Datalogger Study FSA B13R0002 06/06/2010 Version 1

Headed paper

.....[insert date].....

Dear[insert name].....

On behalf of the Cardiff School of Health Sciences in the University of Wales Institute, Cardiff (UWIC), I would like to thank-you for agreeing to participate in the 2007-2010 Food Standards Agency Powdered Infant Formula Research being undertaken in UWIC.

As discussed on the telephone, this important nationwide study aims to determine how different caregivers, including parents, prepare and store powdered infant formula inside and outside of the home. Cumulatively data will be used to inform the development of powdered infant formula information sources.

As you will recall from our recent *[telephone conversation/meeting at ...[insert location].....]*, we have made the following arrangements for you to participate in the Powdered Infant Formula Datalogger Study. The following arrangements have been made for me to deliver the datalogger to you:

Date: [insert datexx, xxxx, xxxx.....].....

Time: [insert timexx:xx am / pm.....].....

Location: [insert location of delivery ie participant home].....

Arrangements for collection of the datalogger, after use will be made at the time of delivery.

For your reference, I have taken this opportunity to enclose the following:

- Instructions for participation in the Datalogger Study.
- A copy of the form that needs to be completed for each bottle of made-up formula that you attach a data logger to
- The participant information sheet with more information for you about the study
- The participant project consent form. I would be grateful if you could please sign the consent form and give it to me when I deliver the datalogger to you.

I am extremely grateful for your participation with the research, and as a token of my thanks for your help you a £3 supermarket voucher (from Sainsbury's, Marks and Spencers, Tesco's, Boots or Mothercare) for each bottle of formula that you attach a datalogger to.

May I take this opportunity remind you that no special culinary/formula preparation skills are needed to take part in the study and all formula, ingredients, bottles and equipment needed will be provided in the model kitchen. Please be assured that all data collected during the study will remain anonymous and treated in the strictest of confidence.

If you require any further information or for any reason you will be unable to attend the preparation session and interview, please do not hesitate to contact me at UWIC on Cardiff 2041 6452.

I look forward to meeting you.

Yours Sincerely,

Dr Elizabeth Redmond
Research Fellow
redmond@uwic.ac.uk

Powdered Infant Formula Research, 2010
Participant Information: Datalogger Study



For parents feeding their infant(s) aged less than 12 months with powdered infant formula

We would like to invite you to take part in an important Powdered Infant Formula Research Study being carried out at the University of Wales Institute, Cardiff. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. We are happy to provide you with more information or answer anything that is unclear. Thank you for considering this study.

Background and Purpose of the Study

In the UK, 92% of parents use powdered infant formula to feed their baby within 6 months after birth. Given the widespread use of powdered formula, preparation, handling and storage methods used for powdered formula feeds are relevant to many parents and caregivers in homes, hospitals and day nurseries. Currently relatively little is known about (a) how parents or caregivers deal with infant feeds or (b) what information about preparation and storage of powdered infant formula is obtained/give to them and where from.

This cumulative Food Standards Agency funded project (2007-2010) (E13R0002) seeks to address this lack of information and in previous phases of the study has involved participation from NHS Health Visitors, Hospital and Community Midwives, Hospital Nurses and Day Nursery Nurses from Wales, England, Scotland and Northern Ireland.

Ultimately, determining parents' practices, opinions and experiences of using powdered infant formula at home and away from the home is essential. Research findings will inform the development of guidelines and intervention materials for use in the home and in hospitals.

Why have you been invited to take part in this study?

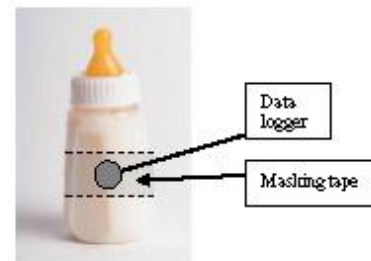
You have been invited to take part because you are an adult living in South Wales and have indicated that you are currently feeding your infant (aged less than 12 months) with powdered infant formula at least once a day. We anticipate that you will be one of 400 parents who will take part in the overall study.

This study has been reviewed and approved by the Ethics Committee of UWIC UREC Reference XXXX Version 1, May, 2010.

Parent Participant Information Sheet (page 2)

What will your participation involve?

If you choose to participate in this part of the study, you will be asked to attach a small datalogger (about the size of a 5p) to a bottle of powdered infant formula (see image) using wide masking tape (supplied). You will be asked to store and handle the bottle of made-up formula with attached data logger exactly as you would do normally before feeding. Immediately before feeding, you will be asked to remove the data logger from the bottle and place in plastic storage tube ready for collection.



You will also be provided with a short form to complete – indicating times when datalogger was attached and removed from the feeding bottle etc.

You will be asked to give your consent to participate in this stage of the study.

As a token of thanks you will be given £3 supermarket voucher for each bottle of formula that you attach a datalogger to (you may do more than 1 if you choose).

Do you have to take part?

Participation in this study is entirely voluntary. If you decide to take part you are still free to withdraw from the study at any time without giving a reason.

How will information be kept confidential?

- All information that is collected from you during the course of study will be kept strictly confidential.
- All data will be securely destroyed after the end of the study or on your withdrawal from the study.
- Your information will not be used or made available for any other purpose than for this research study.
- All of your data will be assigned an ID so that you can not be recognised from it. With your permission, this information will be stored in UWIC on a password protected computer / locked filing cabinet.

What are the benefits of taking part?

- For participating in this part of the study you will be given **£3 voucher of your choice from Tesco's, Sainsbury's, Boots, Mothercare or Marks and Spencers** for each bottle of formula that you attach a datalogger to.
- Whilst there are no immediate benefits for you participating in the project it is hoped that that the study provides the opportunity for you to express your opinions and experiences which will cumulatively contribute to the improvement future powdered infant formula guidelines and intervention materials for use in the home and in hospitals.

Are there any risks or disadvantages for taking part?

All aspects of the project have been risk assessed. Dataloggers used in this study are very small (~size of 5pence) therefore there is a potential risk of losing it and accidental ingestion. All participants are advised to ensure data loggers are securely stored to infant feeds using masking tape during logging time, stored safely in the provided plastic container with secure lid and kept away from all infants and children at all times.

What happens to the results of the research?

All information provided by you will be stored anonymously on a computer, with the analysis of information obtained undertaken by Dr. E Redmond. The results of this study will be presented to the UK Food Standards Agency in a confidential report. Cumulative, non identifiable research findings may be published in peer-reviewed journals and conference presentations.

Who can you contact for more information?

Dr Elizabeth (Liz) Redmond, Research Fellow, Food Industry Centre, Cardiff School of Health Sciences, Llandaff Campus, University of Wales Institute, Cardiff, CF52 YB.

Telephone: 02920 416452 Email: eredmond@uwic.ac.uk

Parent Consent Form

Powdered Infant Formula Research, 2010

Consent Form: Datalogger study



Please tick each box

1. I confirm that I have agreed to attach data loggers (provided by UWIC) to bottles of made up powdered infant formula.

2. I have received and understand the Participant Information Sheet for the Datalogger study.

3. I have received and understand the instructions required to participate in this datalogger study and agree to carry out such methods.

4. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

5. I understand that all information gathered from the study will remain confidential and data reported will be anonymous.

6. I agree to be responsible for safe keeping of the dataloggers and will ensure that dataloggers will be kept away from infants and children at all times. I agree to remove each data logger from feeding bottles BEFORE feeding any infant.

7. I have had the opportunity to ask any questions about taking part in the study.

8. I agree to take part in the above study.

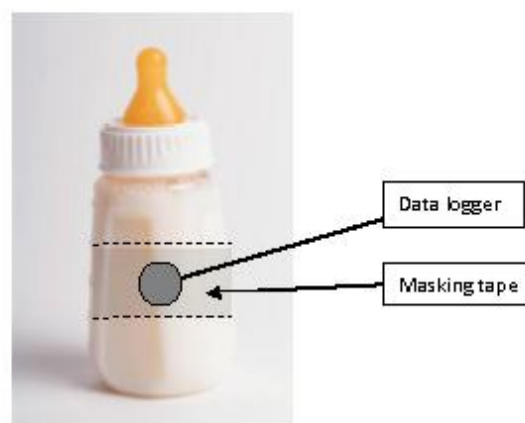
.....
Name of participant Date Signature

.....
Name of researcher Date Signature

Parent Instructions

UWIC / FOOD STANDARDS AGENCY POWDERED INFANT FORMULA DATALOGGER RESEARCH: INSTRUCTIONS

1. Before adding any water to the bottle, use the masking tape to attach one data logger half way down the side of the feeding bottle (see image below).
2. Make sure the number on the data logger faces outwards
3. Add water and powdered infant formula to the feeding bottle.
4. Write down the time when the water is poured into the feeding bottle and added to the powdered formula.
5. Store and handle the bottle of made-up powdered formula with attached data logger (as shown above) exactly as you would do normally.
6. Immediately before feeding, remove the data logger from the bottle and place in plastic storage tube ready for collection. Write down the time of feeding (and removal of data logger from bottle) on the attached sheet.



Please do not let the data loggers get wet!

You will be provided with £3 supermarket voucher of your choice for each bottle of powdered infant formula that you attach a data logger to.

PLEASE ENSURE THAT DATA LOGGERS ARE STORED SAFELY AND KEPT AWAY FROM ALL INFANTS AND CHILDREN AT ALL TIMES.

ATTACH THE DATALOGGER TO THE BOTTLE BEFORE ADDING THE WATER
STORE THE MADE UP POWDERED INFANT FORMULA FOR 3 HOURS OR MORE
USE THE DIGITAL CLOCK PROVIDED FOR RECORDING TIMES ON THIS FORM

Please record the following for each bottle of made-up powdered infant formula that has a data logger attached.

Parent Additional Information Sheet

ID	BOTTLE / DATA LOGGER	DATE
Q1. Age of infant <i>(please insert age)</i>	
Q2. Please indicate where the bottle of powdered infant formula is made-up <i>(please tick one only)</i>		
Home kitchen	<input type="checkbox"/>	
Elsewhere in the home <i>(state where)</i>	<input type="checkbox"/>	
Away from the home <i>(state where)</i>	<input type="checkbox"/>	
Q3. Brand and type of feeding bottle <i>(please insert brand and type of feeding bottle)</i>	
Q4. Size of feeding bottle <i>(please tick one only)</i>		
125ml	<input type="checkbox"/>	
260ml	<input type="checkbox"/>	
Other <i>(please state)</i>	<input type="checkbox"/>	
Q5. Volume of feed <i>(please state)</i>ml or/andoz	
Q6. Time when datalogger is attached to the feeding bottle <i>(please write time)</i>	
Q7. Time when water is added to the feeding bottle <i>(please write time)</i>	
Q8. Is the powdered formula made-up using <i>(please tick as many applicable per bottle)</i>		
...boiled tap water – hot / warm from the kettle	<input type="checkbox"/> <i>go to Q9</i>	
...boiled tap water – cooled to room temperature in the kettle	<input type="checkbox"/> <i>go to Q9</i>	
...boiled tap water – cooled to room temperature in the bottle	<input type="checkbox"/> <i>go to Q9</i>	
...boiled tap water – cooled and refrigerated	<input type="checkbox"/> <i>go to Q9</i>	
...boiled tap water – stored in a flask	<input type="checkbox"/> <i>go to Q9</i>	
... tap water (not boiled)	<input type="checkbox"/>	
...bottled water	<input type="checkbox"/>	
...Other <i>(please state)</i>	<input type="checkbox"/>	
Q9. State length of time between end of kettle boiling and addition of the water to the feeding bottlehour(s)minutes	
Q10. Time when formula is made-up (i.e. powdered formula is added to water) <i>(please write time)</i>	
Q11. Is the powdered formula made-up with boiled water..... <i>(please tick as many applicable per bottle)</i>		
...cooled for more than 30mins in the kettle	<input type="checkbox"/>	
... cooled for less than 30mins in the kettle	<input type="checkbox"/>	
... cooled for more than 30mins in the bottle	<input type="checkbox"/>	
... cooled for less than 30mins in the bottle	<input type="checkbox"/>	
... Other <i>(please state)</i>	<input type="checkbox"/>	

Q12. Once water and powder infant formula are mixed please indicate where the bottle of formula milk is stored until feeding time (please tick as many applicable per bottle)

- On a surface at room temperature only go to Q16
On a surface at room temperature, then in the fridge go to Q13
In the fridge as soon as it is made up go to Q13
...Other e.g. cool bag / thermal bag etc (please state)

Q13. Time when made-up powdered formula feed is placed in the fridge (please write time)

.....

Q14. Please indicate where in the fridge the bottle of made up powdered infant formula is stored (please tick as many as applicable) (Go to Q16)

- Door of fridge
Top shelf of fridge
Middle shelf of fridge
Bottom of fridge
Front of fridge
Back of fridge

Q15. Time when made-up powdered formula feed is placed in the cool bag / thermal bag (please write time)

.....

Q16A. Is the made up powdered infant formula feed reheated before feeding? (please tick one only)

- Yes PLEASE REMOVE DAT ALDGER FROM FEEDING BOTTLE Go to Q16B
No Go to Q17

Q16B. Time when datalogger is removed from the feeding bottle (please write time)

.....

Please describe how the feed is reheated and for how long:

Eg. 'Placed feed in the microwave on high (800W) for 50 seconds' or 'placed feed in jug of boiled water for 4 minutes'

IF POSSIBLE PLEASE REATTACH THE DATA LOGGER TO THE REHEATED FEED AFTER REHEATING GO TO Q16C

Q16C. Time when datalogger is reattached to the feeding bottle after reheating (please write time)

.....

Q17. Time of start of feeding (please write time)

.....

Q18. Time of end of feeding (please write time)

.....

Q19. Time when datalogger is removed from the feeding bottle (please write time)

.....