ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD

AD HOC GROUP ON INFANT BOTULISM: INTERIM REPORT

Introduction

1. This interim report outlines work undertaken to date by the *ad hoc* group to consider the potential human health risk associated with the consumption of chilled or frozen, pureed baby foods, particularly in relation to *Clostridium botulinum* and infant botulism. The scope of the group's activity and its constitution is shown in Appendix 1. The Group met on five occasions and considered documentary and verbal evidence relating to the clinical epidemiology of infant botulism, and Sudden Infant Death Syndrome and *C. botulinum*. The Group also considered documentary and verbal evidence relating to minimally processed baby foods manufacturing and process safety controls, enforcement of process safety controls, infant food production in the home and guidance available to manufacturers, enforcement and consumers. A Sub-Group was convened to carry out a semi-quantitative risk profile for *C. botulinum* in infant foods.

2. Having considered documentary and oral evidence from a wide range of sources, the Group is currently in the process of drawing together its conclusions and recommendations. Prior to the Group formally reporting the outcome of its deliberations to the ACMSF, an independent peer-review of the risk profiling work carried out by the *ad hoc* Sub-Group will be undertaken.

Overview

3. The Group considered information received and/or heard evidence from 6 highly diverse manufacturers of baby food, relating to product development, processing and food safety systems in place to produce safe chilled or frozen baby food. The Group also heard evidence from three Local Authorities giving guidance to some of those minimally processed weaning food companies. Data from a trade association on the possible risks from minimally processed foods, and steps taken by the retailer to assure the safety of the infant food it sells was considered. Information on industry post production control processes and opportunities for post control contamination was reviewed. The Group also considered infant food preparation on the home. In addition, current available guidance to manufacturers, enforcement officers and consumers was reviewed.

4. An expert on infant botulism provided information on the clinical and diagnostic epidemiology of *C.botulinum*. The Group also examined the advice to new manufacturers, including the advice provided by Local Authorities. A literature review was carried out to revisit the published

evidence examining the relationship between infant botulism and Sudden Infant Death Syndrome.

5. Information from an R&D Department of a Company on hazard characterisation and modelling of the distribution and numbers of spores in raw materials, designed to help assess the risk of infant botulism from non-sterilised baby foods, was reviewed. In addition, presentations were received from independent experts on the risks associated with baby food manufacturing processes. The Health Protection Agency also provided information on the probability of a possible infectious dose of *C.botulinum* being present in infant formula. The Group concluded that a semi-quantitative risk profile was required in order to provide a scientific basis for any recommendations resulting from its work. A small sub-Group of experts was set up to carry out a risk profile.

6. The Sub-Group met once to consider: (i) the minimum infectious dose for spores of proteolytic *C. botulinum*; and (ii) the most likely number of spores of proteolytic *C. botulinum* per 100g pack of food consumed by an infant. Information from these areas was combined to provide an estimate of the rate of illness. A software tool was used to examine dose response. Key limitations of the risk profile work were identified. Work is in progress to refine an estimate of dose response (number of spores/kilogram food) and to finalise conclusions from the outputs of the Group. The Sub-Group also reviewed recent infant foods market data and derived annual figures relating to the total number of sterilised and unsterilised meals consumed. Further refinements to the data are in progress in order to estimate the number of likely cases of botulism attributable to consumption of infant meals.

Outcome

7. Having reviewed the current position regarding risks to human health from *C. botulinum* or infant botulism associated with the consumption of chilled or frozen, pureed baby foods, the Group is satisfied that it has met with sufficient individuals or reviewed documentary evidence to allow it to inform the development of ACMSF advice to the Food Standards Agency.

8. The Group is currently drafting a full report of the outcome of its deliberations. This Report will be submitted to the ACMSF for consideration at its March 2005 meeting, pending the outcome of the peer-review of the risk profile element of the work.

***Ad Hoc* Group on infant botulism**
November 2004

APPENDIX 1

Membership and scope of the ad hoc Group of the ACMSF on infant botulism

Membership

Chair
Professor S J O'Brien

Members
Mr J Bassett
Dr K M Hadley
Mr A Kyriakides
Ms E Lewis
Mr P Mepham
Professor M Peck
Dr M Stringer

Assessors
Dr J Hilton (FSA)

Secretariat
Dr L H Foster
Mrs O Coffey
Mrs L Stretton

Terms of Reference

To consider the potential human health risk associated with the consumption of chilled or frozen, pureed baby foods, in particular in relation to *Clostridium botulinum* and infant botulism, to inform the development of ACMSF advice to the Food Standards Agency.