

Comments from the Department of Health, Victoria 14 May 2012

The Department of Health, Victoria (DH) welcomes the opportunity to make comment on Proposal P1020 which is intended to correct an oversight that resulted in sausages and sausage meat containing raw, unprocessed meat not being included in the final drafting following the approval of A1015.

DH notes that the Executive Summary for P1020 states

The original risk assessment performed as part of Application A1015 included [sausage and sausage meat containing raw, unprocessed meat] so a new risk assessment has not been undertaken.

DH also notes the following extract from FSANZ's first review report, section 6.1.1.2 Research on the reproductive and developmental toxicity studies, page 4:

Ministerial Council statement: 'It is also noted *In reproductive and developmental toxicity studies the only notable and consistent finding was delayed onset of puberty in female rats There was no information to indicate that this effect may not be relevant to humans* (page 5 of the Approval Report). Accordingly it would appear further research needs to be initiated on this issue.

Response: As FSANZ was unable to conclude that the delayed onset of puberty observed in female rat pups was not relevant for a human risk assessment this endpoint was used as a conservative basis to derive a human health standard. The ADI, which in turn was used to derive the limits on levels of ELA permitted in food. If the resulting health standard was too low to permit ELA to be used in a range of human foods then it would be the responsibility of the sponsor to provide additional data to demonstrate that this endpoint observed in rats was not relevant for a human risk assessment. Dietary exposure estimates for ELA in a wide range of foods indicates that this health standard (ADI) will not be exceeded when ELA is used at levels specified in the code.

It has been three years since FSANZ undertook its risk assessment on Ethyl Lauroyl Arginate (ELA), and since the Ministerial Council requested a review of the FSANZ approval report. Given the time that has since elapsed, and Ministerial Council concern about research on the reproductive and developmental toxicity studies, DH requests that FSANZ undertake a comprehensive literature review of pertinent research conducted since the original FSANZ risk assessment.

This request stems from DH's view that there is likely to be wide uptake of the permission to use ELA in sausages and sausage meat containing raw, unprocessed meat; a view that is based upon anecdotal information that suggests that pressure is being placed on manufactures to increase the shelf life of their products.