Question for written answer E-004428/2012
to the Commission
Rule 117
Liam Aylward (ALDE), Pat the Cope Gallagher (ALDE) and Brian Crowley (ALDE)

Subject: EFSA and the nutrition and health claims regulation and its impact on SMEs

In response to written question E-002088/2012, the Commission indicated that only a 'very small part' of the European food industry was unhappy with the implementation of Article 13(1) of Regulation (EC) No 1924/2006. The European food supplement industry constitutes the majority of this 'very small part' of the European food industry referred to by the Commission. The majority of the companies operating in the European food supplement sector are SMEs. The pharmaceutical level of supporting evidence required for the approval of Article 13(1) health claims is difficult and sometimes impossible for SMEs to comply with. For example, the rigidity of the approach taken to claims assessment resulted in the evidence supporting many claims not even being considered by the European Food Safety Authority (EFSA) due to substance characterisation requirements that were never made clear to applicants in advance.

The ALDE group has recently launched a campaign in support of SMEs. SMEs are regularly cited by the Commission as the drivers of Europe's economic recovery. While it is clear that a successful SME sector is crucial to Europe's economic recovery, it is equally clear that the health claims regulation is going to have a seriously negative impact on SMEs.

– Does the Commission think that it is feasible to expect SMEs to comply with the requirements for the approval of health claims set by EFSA?

– If SMEs cannot provide the level of evidence (randomised controlled trials) required by EFSA, does the Commission accept that this will threaten the livelihood of these SMEs as products will have to be removed from the market?

– Can the Commission clarify whether the 'think small first' approach was followed in the implementation of Article 13(1)?