From: richard.w.ross@sb.com [mailto:richard.w.ross@sb.com]
Sent: vendredi 20 juillet 2001 0:00
To: SANCO FOODCLAIMS
Subject: Nutrition and Function claims

Dear Sir

Please find attached the GlaxoSmithKline comments on this discussion paper.

GlaxoSmithKline is a science driven nutritional healthcare company and therefore welcomes this consultation and looks forward to harmonisation of the EU legislation to copver health claims. We therefore urge the wider remit mentioned in the introduction to be included as soon as possible.

(See attached file: Comments on The Discussion Paper on Nutrition.doc)

Regards

Richard W. Ross

GLAXOSMITHKLINE

Comments on The Discussion Paper on Nutrition Claims and Function Claims prepared by Directorate General Health and Consumer Protection (SANCO D4) European Commission (SANCO/1341/2001)

We welcome this review and opportunity to comment on the situation and discussion paper. We note that at this stage "Health Claims as such, and in particular "Disease Risk Reduction Claims" are not being dealt with and will be subject to a consultation later. This is a crucial area for the food industry and as it is now being considered by Codex Alimentarius we believe it is important that these are considered in a positive way in the near future. Enabling this type of claim will encourage innovation from industry that will benefit society as a whole and reduce consumers dependence on medicines to maintain certain diseases in abeyance.

We find it difficult to accurately define the types of claim unless all the definitions are developed together. Dealing with some in isolation increases the possibility of dead zones between the different definitions and therefore lack of harmonisation and legal clarity.

Para 3. As nutrition information in conformance with the Directive (90/496/EEC) is widely given on pre-packaged foods particularly in the UK it is now time to reconsider the format and content in light of consumer understanding. Consumer research carried out by The Institute of Grocery Distributors in the UK shows poor understanding of the information and developed improved ways of presenting the information. The American

format also is worthy of further consideration. This work is by no means concluded and should therefore be used as a basis for further consumer research to develop a presentation that would be better understood by consumers and therefore enable consumers to improve their diets. Calls to industry care lines clearly demonstrate the current format is failing in its objective of giving consumers nutrition information in an understandable way.

Para 9. As there is no such thing as a good or bad food (as stated in para 41) only good or bad diets this premis is flawed. It is important that all(products which can form part of a normal diet) can be developed to make claims and provide consumer benefit.

Para 11. The important issue for the consumer is the food as consumed therefore any claims criteria must be valid at the time of consumption. It is vital that any instructions for use are clear and if any other ingredients are required in the product preparation this is clear at the time of purchase. The claims and nutrition information must be valid at the end of the declared shelf-life and relate to the product as consumed. In addition the claim must be valid for a normal level of consumption of the product as part of normal diet.

Para 13. The Codex Alimentarius definition of a claim is a good starting point. Our only concern is the word attribute needs inserting to ensure that the benefits of microbial

cultures and other non nutrients are included. In addition there must be consistency with other definitions as to whether it includes advertising or not for example (see para 16).

Para 16. We consider substances having a physiological effect are functional claims rather than nutrition claims and therefore the current definition of a nutrition claims is probably still appropriate.

Para 18. Harmonisation of the criteria for making claims such as “low”, “rich” etc is vital to ensure free trade within Europe and we recommend the agreed Codex Alimentarius guidelines should be used.

Para 20. We recommend a review of the reasoning for prohibition of non addition claims if all foods in the same category are free from. We feel these claims can be useful to the consumer providing the claim makes it clear that all foods in the category are free from.

Para 21. The term “light” is used for attributes such as texture and density as well as for nutrients as proposed in the Codex guidelines. This wider use must continue to be permitted.

Para 24. Claims on pack concerning “dietary cholesterol” are misleading to consumers and we agree as proposed in the UK by the Food Standards Agency these should not be

permitted. The important issue for consumers is their blood cholesterol level and its LDL/HDL split.

Para 26. Low sodium and very low sodium should not be restricted to PARNUTS foods. We therefore support a move to the Codex approach. As sodium is an important issue in certain consumers diets not only should information be available to consumers but also industry should be encouraged to develop normal foods to meet these consumers needs. It is also essential to keep the sodium and salt declarations separate to avoid confusing consumers. Some products eg Fat Spreads legally have to declare the salt level in the ingredient list and if a declaration based on sodium level was required it would result in a second different figure being declared owing to the sodium contribution from additives.

Para 27. We support all foods that meet the specified criteria should be able to make claims.

Para 29. It is important to retain these claims “without added” or “no added” as they are often used where the ingredient is not added but may be detectable. In the case of fermented milks sometimes traces of substances such as preservatives well below their effective level are natural by-products and using the modern sensitive analytical methods traces can be detected.

Para 30. The current list of vitamins and minerals in Directive 90/496/EEC needs to be extended to include all which have an RDA set by the SCF. Also in light of the latest nutrition science there are others without an agreed RDA that consumers may find useful if they were also declared. We also believe the 15% figure for a significant quantity should be reviewed as this figure is not appropriate for all foods.

Para 32. Intellectual property eg trademarks often makes comparative claims difficult. It should be sufficient to use terms such as “leading brands of breakfast cereals”.

Para 38. The definition “nutrient function claim” needs to be wider in this context to include what codex term “enhanced function claims”. This would ensure claims on microbial cultures or products that reduce the risk of tooth erosion or decay are included. These are an important category of claims already accepted by consumers that need to be regulated to ensure proper validation.

Para 40. The conditions that have to be fulfilled when making these claims must be stringent and ensure a proper standard of scientific validation otherwise consumers will lose confidence in the claims made. A good starting point for this could be the Council of Europe paper "Draft Proposal for Guidelines on Health Claims for Functional Foods” or The UK Joint Health Claims Initiative Code.

Para 44. For some claims there may be several criteria required to validate the claim and in some cases it can be the absence of substances. In all cases there need to be validated analytical methods to control the criteria or substance level. The term validated is not taken in the Codex sense rather it is scientifically proven/accepted.

Para 46. The claim needs to be reviewed at regular intervals and as and when new scientific evidence becomes available. An example is under the British Dental association accreditation scheme it has to be reassessed every 3 years.

Para 47. Human studies must be the preferred validation as appropriate. The trials must be done to GLP standards and GCP standards when appropriate.

Para 48. Pre-market approval is very cumbersome and as such we would not support. Anyone making claims should have a dossier which has been reviewed by an independent expert that validates the claim being made. This dossier should be available on demand by the enforcement authorities.

Para 49. Rather than have a notification in each Member State we would propose notification in the first Member State of sale.

Para 50. A two step claim is not appropriate for many claims. In addition they do not fall within PARNUTS or the natural remedy regulations. This is therefore not a practical approach.