

HEALTH FOOD MANUFACTURERS' ASSOCIATION

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Jeff Alder
SACN Secretariat
Room 808c Aviation House
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Dear Jeff

Re SACN Vitamin A Draft Report

Thank you for the opportunity to comment on this draft Report that was issued on 11.01.05.

1. HFMA: Background

The HFMA (Health Food Manufacturers' Association) is a non-profit organisation that was founded in 1965 to represent the interests of manufacturers and suppliers of specialist health products in the UK. Our c.140 member companies include many suppliers of specialist food supplements and health foods.

The HFMA operates three long-standing codes of practice - for GMP, Labelling & Advertising and Upper Safe Levels for Supplements - to ensure that member companies adhere to high standards and offer good quality, safe products to UK consumers.

2. Topline Comments

We broadly agree with the content of this thorough Review and are pleased that SACN has incorporated the key points from the Commentary on the SACN Opinion submitted by Professor David Richardson and Dr Ann Walker in early 2004.

We note, in particular, the following conclusions from the SACN Report:

- There is insufficient evidence for association between bone health and retinol intakes of >1500 mcg/day to justify change in dietary advice to all consumers
- The majority of data are from epidemiological studies, and thus suffer from the inherent limitations of observational data. There are few studies available and most were not designed to examine the relationship between retinol and bone health
- Data published since the EVM Report do not strengthen the evidence for an association between retinol intake and bone health
- The studies vary in the extent to which they have taken account of other nutrients that affect bone health, and the clustering of nutrients and strong correlation between many nutrients makes it difficult to separate their individual effects. Thus while the data provided a basis for concern it is difficult to establish causality from the available data
- The evidence on the relationship between retinol intake and risk to bone health originates mainly from the USA and Sweden

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- It may be advisable for regular liver consumers not to take retinol supplements and not to increase liver intakes
- It may be advisable for subgroups at risk of osteoporosis not to consume retinol intakes of >1500 mcg/day
- Reduction in retinol intake in poultry and livestock should be explored further

3. Specific Comments

We have two specific comments re points 116-118:

- It would be interesting to also cover trends at the lower end of retinol/Vitamin A intakes in this section.
- Lower retinol intakes in 2001 NDNS vs. 1986 NDNS are explained by a lower percentage of liver consumers of liver in 2001 vs. 1986 NDNS, but has the content of Vitamin A in liver also decreased over this time period?

4. Action Proposal

Given the HFMA emphasis on product safety and in recognition of the advice suggested in the SACN Report, we would propose the use of two advisory statements on the labels of retinol-containing supplements (in addition to the existing DoH warning) as follows:

	<u>Trigger Levels</u>	<u>Statements/Reformulation</u>
Vitamin A (preformed retinol)	All retinol- containing products	Label statement: <i>"Supplements containing vitamin A as retinol are best avoided by those who regularly eat liver."</i>
	>800 µg (existing DoH warning)	Label statement: <i>"[This product] contains Vitamin A. Do not take if you are pregnant or likely to become pregnant except on the advice of a doctor or ante-natal clinic."</i>
	> 1150 µg*	Label statement: <i>"Long term intakes of [this amount] of vitamin A (as retinol) are best avoided by postmenopausal women and older people who are at increased risk of osteoporosis."</i>

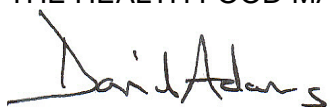
Details of the methodology used to determine the trigger level for the osteoporosis statement are attached.

We hope this is recognised as a responsible and appropriate contribution to consideration of the practical implications of SACN's findings.

If you have any queries about this submission, please don't hesitate to contact me.

Yours sincerely

THE HEALTH FOOD MANUFACTURERS' ASSOCIATION



Director

HFMA: Proposed Action/Advisory Statements for Vitamin A
April 2005

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* The EVM guidance level for retinol in respect of bone health (1500µg) is for the total diet, and does not give a component from supplementation. The draft SACN report recommends that those at risk of osteoporosis do not exceed total intakes of 1500µg retinol per day, and while it advises that, to achieve this aim, intakes of retinol supplements should be limited, no maximum intake from supplements is suggested. Those at risk of osteoporosis include postmenopausal women and older people (including men and women).

Approaches to determine the most appropriate level of retinol to trigger the statement are:

A 1500µg – [average RNI for men and women (50+ yrs) – contribution from carotenes]

Or

B 1500µg – intake of retinol in women 50+ yrs and men 65+ yrs from NDNS survey.

Factors to consider in arriving at the intake value are:

- Use data for food sources only
- Use data for free living elderly only
- Take out contribution from liver (as liver consumers are already advised not to take retinol supplements) and retinol from liver skews the intake data
- Whether the mean intake is the most appropriate factor to subtract (or a lower or higher centile of intake)

WORKINGS

A: NDNS data for carotene intakes (food sources) by women aged 50+ and men aged 65+ are detailed below, showing the contribution from beta-carotene.

Age group	Total carotene intake (food sources) as Beta-carotene equivalents (µg/day)	Equivalent to µg RE /day
50-64 (women)	2205	
65-74 (women)	1699	
75-84 (women)	1525	
85+ (women)	1486	
65-74 (men)	1966	
75-84 (men)	1921	
85+ (men)	1933	
Average for all age groups	1819	303

Average requirement less element for carotenoids: $650\mu\text{g/day} - 303\mu\text{gRE/day} = 347\mu\text{g/day}$
 $1500\mu\text{g/day} - 347\mu\text{g/day} = 1153\mu\text{g/day}$,
suggesting that approx $1150\mu\text{g/day}$ may be an appropriate figure to trigger the advisory statement.

B: NDNS data for retinol intakes (food sources) by women aged 50+ less the contribution from liver are detailed below.

Age group	Total RE from food (µg/day)	Retinol from liver (µg /day) (% of RE)	Retinol from food (µg/day)	Retinol from food minus liver (µg/day)
50-64 (women)	816	171 (21%)	449	278
65-74 (free living women)	966	348 (36%)	683	335
75-84 (free living women)	991	387 (39%)	737	350
85+ (free living women)	911	292 (32%)	663	371
65-74 (free living men)	1208	471 (39%)	880	409
75-84 (free living men)	1117	380 (34%)	797	417
85+ (free living men)	1042	281 (27%)	720	439
Average for all age groups				371

The overall average retinol intake for these groups from food sources except liver is $371\mu\text{g}$ per day.

Thus $1500\mu\text{g} - 371\mu\text{g} = 1129\mu\text{g}$ per day

Taking this approach (using average intakes) and rounding to the nearest 50 also supports $1150\mu\text{g}$ per day as an appropriate level to trigger the advisory statement.