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Director-General of Health
Attention: Director: Food Control
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Dear Sirs

COMMENT SUBMISSION: REGULATIONS RELATING TO THE LABELLING AND ADVERTISING OF FOODSTUFFS. No. R. 642 OF 20TH JULY 2007

We thank the Department of Health for the opportunity to comment on the above regulations. The Nutrition Society of South Africa and the Association for Dietetics in South Africa (ADSA) are the two scientific and professional bodies representing the science and practice of nutrition in South Africa. As a result, we believe we are qualified to give input to the nutritional science component of these regulations and will, as such, limit our comments to the aspects of the regulations where we feel we can add value and expertise. The Association for Dietetics in South Africa and the Nutrition Society of South Africa agreed to develop a joint submission and formed a working group of the relevant and interested experts to focus on the regulations, and also requested input from our members. Where necessary, we also drew expertise from a wider range of members and international nutrition scientists.

We congratulate the Department of Health on the publication of these draft regulations, which have been long awaited. We believe these regulations to be vitally important in ensuring that the labels of foodstuffs provide consumers with information that is truthful, not misleading and above all evidence-based, in order to allow and encourage South Africans to make well considered and wise food choices. We welcome the debate that the publication of these regulations has resulted in and the opening of the discussion on the role of the food industry in addressing the nutritional

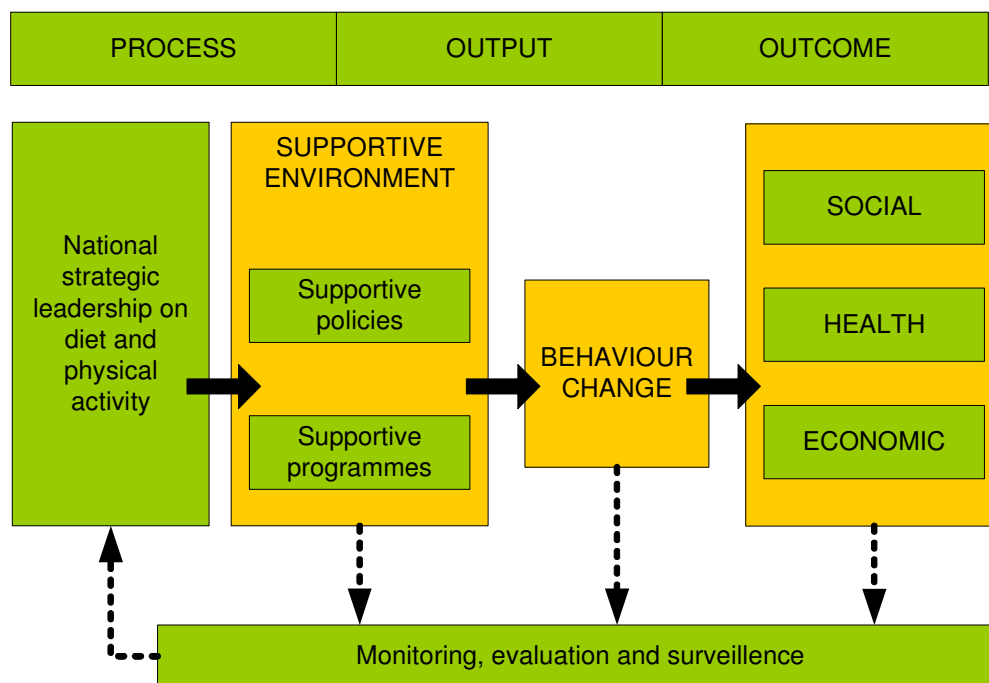
challenges that we face in South Africa as a country in transition. We appreciate nutrition being placed high on the Department's agenda.

National Strategy

We understand that the basis and principles behind many of the elements of the regulation are taken from the World Health Organization's Global Strategy on Diet, Physical Activity and Health. The overall goal and objective of the strategy being to *'promote and protect health by guiding the development of an enabling environment for sustainable actions at individual, community, national and global levels that, when taken together will lead to reduced disease and death rates related to unhealthy diet and physical inactivity.'* We laud this goal and fully support its application within the South African context. We are of the firm opinion, that as clearly stated by the WHO, this strategy is not a national programme but rather a comprehensive tool to guide member states. A commentary by A Waxman and KR Norum, titled 'Why a global strategy on diet, physical activity and health? The growing burden of non-communicable diseases' which was published in Public Health Nutrition, 7(3):381-383 highlights that, *'one of the strategy's most important conclusions is that reducing the burden of non-communicable diseases requires a multi-sector, multi-stakeholder approach. The strategy is not prescriptive but like a toolbox, and provides WHO member states with a comprehensive range of policy options from which to choose. The goals to advance public health world-wide can only be met through decisive and coherent action by countries, sustained political commitment and broader multi-level involvement with all relevant stakeholders'.*

We firmly believe that the application of the Global Strategy within the South African context needs to be undertaken as a consultative process that is inclusive and transparent and ultimately results in a comprehensive national strategy for addressing our unique nutritional challenges ranging from the continued burden of undernutrition to the rapidly growing burden of overnutrition. We do not believe that these proposed regulations should occur in isolation but that they should be part of a well planned, carefully implemented and then monitored and evaluated overall strategy.

We draw your attention to the many other documents that have emanated from the WHO further to the adoption of the Global Strategy, that also need to be considered in the light of the proposed regulations. Key to the finalization of many aspects of these proposed regulations is ensuring that the ultimate desired objectives and public health outcomes are monitored and evaluated. The figure below, taken from the WHO document, 'The Global Strategy on Diet, Physical Activity and Health: A Framework to Monitor and Evaluate Implementation', shows the broad and comprehensive development and implementation process required if the Global Strategy is to be effectively implemented at a national level. We therefore urge the Department of Health to begin the greater process of establishing a National Strategy and would, as the nutrition scientists, be prepared to be actively engaged, in such as strategy development. We believe that this is crucial if we are in reality to have a significant positive impact on public health. Regulating foodstuffs is only one component and unless the other influencing factors are also addressed (such as health promotion campaigns, activity programmers, school curriculums, farming projects), it is our opinion that the Department will not succeed in achieving the desired outcome of improved health and a reduction in the mortality, morbidity and disability attributable to non communicable diseases in South Africa.



The remainder of the submission document will deal with each of the regulations, where we feel we can offer our scientific expertise, in numerical order of appearance within the proposed regulations. All our comments will be firmly based on the latest available scientific evidence, as it is our opinion that all regulations that deal with nutrition issues must be evidence-based.

Although we, for the purposes of brevity of the submission, have not fully referenced our comments, both ADSA and the Nutrition Society are willing to share the vast pool of knowledge, expertise and reference literature available through our members, with the Department at any time as they may request it.

We draw attention to the definition that we have used for evidence-based nutrition, namely '*the application of the best available systematically assembled evidence in setting nutrition policy & practice.*' We note that this is the same definition given in the definition section of the proposed regulations and it is our opinion that the Department should apply this definition both when considering submissions and when themselves drafting regulations.

Regulation 1: Definitions

This is a critical section of any regulation as the interpretation of much of the text relies on the accuracy of the definitions. This is especially true when it comes to scientific terminology included in the regulations.

It is our opinion that each of the definitions included in the proposed regulation needs to be checked by the relevant, recognised scientists working in the specific field as we have noticed that:

- Many of the definitions are factually incorrect or incorrect when applied under the conditions of the regulation text. For example: The definition of omega-3 fatty acid includes ALA, DHA and EPA. Although this might be scientifically sound, it has a significant impact on the health and nutrition claims section of the regulation where only EPA and DHA should be included when health claims are made, as it is for these components of omega-3 that the evidence

exists in terms of delivering a proven health benefit. A further example is the definition of 'reduction of disease risk claim' where there is no reference to risk factors in the definition when this is critical in assessing such a claim and is included in both the EU and CODEX definitions. Such errors could have a significant and negative impact on the application of the regulations and ultimately public health.

- Many definitions that are critical to the understanding and interpretation of the regulations are missing. These include for example, partially hydrogenated, hydrogenated, elemental mineral and even the word foodstuff.

We appreciate the expansion of the definitions section from the initial draft, however we feel that this section still requires a great deal of work before it can be considered complete and correct. We would be willing to ask our members, who have specific expertise in the areas covered by the regulation, to give input and suggestions for exact text wording, however this was not possible in the limited comment period.

Regulation 4 / Regulation 64 / Regulation 65: Nutritional Information

We believe from the presentations given by the Directorate of Food Control subsequent to the publication of the proposed regulations, that one of the overriding principles of these regulations is to ensure that consumers are given adequate, honest information that is also not misleading in order to be able to make informed food choices that meet their needs and improve their health and ultimately the overall health of the nation. If this is indeed the intention of the Department, then the Nutrition Society and ADSA feel strongly that the provision of some basic nutrition information should be made mandatory on all packaged foodstuffs. It has to be accepted that processed and packaged foods are an integral part of the food chain and so all packaged foods should provide the consumer with basic information that can be used to assess its contribution to the overall dietary intake of the individual.

We would like to remind the Department that ADSA first made this proposal some 12 years ago at FLAG and included it in our comments on the first draft of the proposed regulations. We again re-iterate our belief that the provision of certain nutrition information should be mandatory for all packaged foodstuffs.

We believe that the mandatory information that should be:

- Energy
- Protein
- Carbohydrate
- Carbohydrate of which sugars
- Total fat
- Saturated fat
- Total fibre
- Sodium

We are of the opinion that unless a health claim is made, this information can be based on a calculation of the nutrition information of each ingredient as supplied by the ingredient supplier based on laboratory analysis, unless the product is a common agricultural product where information from a recognised database, may be used.

We acknowledge that in order for this information to be used and be accurately understood by the consumer, a great deal of nutrition education will be required. This education would need to form part of the broader national strategy. We urge the Department to ensure that any

suggestions for such on pack information, both content or format (e.g. GDAs, Smart Choices, Traffic light), should be assessed by a working group of relevant scientific and communication experts. We would be willing to participate in such a working group.

Further, with regards to laboratory analysis as referred to in these regulations, we recognise that there are numerous problems in terms of capacity, methodology and costs. We believe that an organisation such as SAAFoST should be asked to facilitate a working group to address the real concerns.

Regulation 14: Prohibited Statements

The Nutrition Society and ADSA support the Departments tightening of the regulations pertaining to endorsement, as we feel that this has in the past often been abused and unless regulated will always result in misuse. We support Regulation 14 (a)(i) that would prevent our members from endorsing foods, but have some concerns regarding the restrictions in Regulation 14(a)(ii). It is our opinion that the Department should actively engage and consult with the not for profit organisations, associations and foundations that are currently involved with endorsement of foods as we believe that they in many instances play a critical role in health promotion and consumer education, often assisting in the work of the Department that is limited by its resources.

In addition many of these bodies base their criteria on an evidence-based approach and best global practice. We fully support that any for profit organisations, associations, foundations or other entities should be prevented from endorsement.

We are, based on the above comments, concerned with two sections of the text in Regulation 14(a)(ii) that read, '*involved in generic health promotion*' and '*do not contradict the requirements of these regulations*' as we believe these may be problematic in interpretation and thus require clear definitions. It would, in our expert opinion, be both tragic and unsubstantiated to see this regulation stop the activities of many of the excellent health promotion organisations currently operating in South Africa. We therefore suggest that Regulation 14(a)(ii) should read: 'organisations, associations, foundations and other entities, unless approved by the Director-General.'

Regulation 33: Fats and Oils

The role of fats and oils in health is a scientific issue of substantial public health importance and therefore any regulations must be evidence-based. ADSA and the Nutrition Society fully support strict regulations pertaining to fats and oils, especially trans fatty acids but are concerned that the current text and associated definitions cannot be substantiated. We therefore believe that a working group comprised of both food science experts and nutrition science experts in the field of fats and oils should be formed to discuss and debate these proposed regulations and to suggest text.

Regulations 46 – 50: Allergens

It is well recognised that allergy is a topic of concern to both the nutrition and medical scientists and consumers and we therefore welcome the tightening of regulations in this regard and congratulate the Department on the work that has been done on this section of the regulations.

We do believe that the Department should however have an open consultation on the text in the form of a one day workshop that includes a broad range of the recognised experts and practitioners in the field, as we have been made aware by our members of concerns pertaining to the substantiation around Regulation 46(b) and the recent EU directive (Commission Directive 2007/68/EC of 27/11/2007) that grants certain exemptions to the requirement for compulsory allergen declarations.

As it is commonly dietitians that are consulted to give dietary advice to allergy sufferers and to translate the information provided in regulations to consumers, ADSA is especially aware of the need to ensure that wording used to communicate health messages to the consumer, is not only scientifically correct but is also accurately understood and interpreted by the consumer. For this reason, we are concerned about the nature of the wording of the warning in Regulation 49(b) namely, '*unavoidably contaminated with...(name of allergen)*'. We understand and support the intention to encourage manufacturers to follow best practice when it comes to controlling allergens and to avoid all foods carrying allergy warnings to cover up for lesser HACCP practices. However, we believe that the Department needs to carry out local consumer research to understand what such a warning means to allergy sufferers reading the label of these foods. As due to limited financial resources, this might not be possible, we suggest that the wording should be reconsidered so as not to imply that these foods are fundamentally unsafe as we believe the word 'contaminated' would be interpreted. A suggestion is, 'May unavoidably contain...(name of allergen)'

Regulations 52 – 63: Health and Nutrition Claims

The Nutrition Society and ADSA would like to put on record our support for the strict regulation of health and nutrition claims as we believe that many food manufacturers have been and continue to be irresponsible and misleading and that unless regulated, this practice will continue. Unfortunately we believe that health claims are generally seen by the food industry as being a way to grow market share rather than a way to improve the health and nutritional status of South Africans. The price premium charged for most of these products is also an indication of how generally health and wellness is viewed, as being an opportunity for greater profit and as a result often those who should benefit from such products, cannot afford them.

We also look forward to seeing similar regulations being applied to the dietary supplements industry, as it is our opinion that it is in this market that untruthful, unsubstantiated and misleading information and claims are the most common.

It is critical that this section of the regulation focuses strictly on an evidence-based approach, as a number of issues critical to public health come to the fore and must be addressed. Evidence is the only basis for making public health and policy decisions. We reiterate our proposal that all packaged products should have to give certain mandatory nutrition information and not only products making a health claim. We have addressed each of these individually.

Concept of Minimum Daily Requirement (MDR) versus Recommended Dietary Allowance (RDA):

We draw the Departments attention to the recent international harmonisation project initiated by the WHO/FAO/UNICEF/IUNS to discuss the issue of nutrient-based dietary standards and its subsequent publication as a supplement in the Food and Nutrition Bulletin (King, J.C., Garza, C. 2007. International harmonization of approaches for developing nutrient-based dietary standards. *Food and Nutrition Bulletin* 28(1):S3-S153). This consultation included a wide range

of eminent scientists including our own Professor Esté Vorster. The consultation looked at terminology currently used and made suggestions for harmonization. Although the proposal is still being debated and it is unlikely that all countries will accept it, we are strongly opposed to South Africa now developing their own term (MDR) especially without the necessary rigorous evidence-based process needed to substantiate such a change.

If the Department is not satisfied with the terms that are currently being used in South Africa, they should refer to this consultation or should begin the necessary evidence-based approach to make changes based on substantiation.

It is our suggestion that the current term, RDA be retained as it is not only a globally recognised and defined term but also forms the basis of nutrition education by dietitians and of dietary assessment in consumption studies. In addition the consumer is, we believe, familiar with the term (it has been used on labels for many years). The changing of recognised and defined terminology has consequences and the Department cannot simply change such terms unless there is sufficient evidence for such a change. The ramifications of changing from RDA to MDR could be wider than we believe has been considered by the Department.

Although we understand the principle of having a single RDA for use on all food labels, how the values attributed to the nutrients listed in Annexure 3 have been derived needs to be substantiated by the Department, as the public health consequences of using these figures needs to be fully assessed.

Any values used should be determined by the recognised scientists following an evidence-based approach in order to ensure that they are both practical and compatible with optimal health in the context of the South African population.

As the proposed MDR's/RDA's serve as a basis for most forms of health and nutrition claims, it is imperative that consensus is reached within both the nutrition science and dietetics sector. In South Africa (as is the case globally) there is no consensus on which level of nutrient should be used as a reference intake or the name that should be ascribed to this reference value. Even in discussions within the two societies there are varying opinions and so it concerns us that, as the associations representing the nutrition scientists and dietetics practitioners in South Africa, we have at no time been approached by the Department for consultation on this matter and neither has the Medical Research Council. We would therefore suggest that any possible change be referred to a knowledgeable, transparent and objective working group made up of the Medical Research Council, the Committee that developed the South African Food Based Dietary Guidelines, other science based organisations such as ourselves and the relevant Directorates within the Department of Health. Professor Esté Vorster of the Nutrition Society of South Africa would be willing to lead this group.

Regulations 52(2)&(3)&(4) and Annexure 6: Non-essential foods

These regulations and associated Annexure are of great concern to ADSA and the Nutrition Society as we do not believe, as the associations representing nutrition science in South Africa, that there is any substantiation for dividing foods into 'essential' and 'non essential' especially in light of the official South African Food Based Dietary Guidelines and the global move towards more positive health messaging.

We note a recent publication by the American Dietetics Association, 'Total Diet Approach to Communicating Food and Nutrition Information' that was in the July 2007 edition of the Journal of the American Dietetics Association, Volume 107, Issue 7;1224-1232. We quote, '*It is the*

position of the American Dietetic Association that the total diet or overall pattern of food eaten is the most important focus of a healthful eating style. All foods can fit within this pattern, if consumed in moderation with appropriate portion size and combined with regular physical activity. The American Dietetic Association strives to communicate healthful eating messages to the public that emphasize a balance of foods, rather than any one food or meal...The value of a food should be determined within the context of the total diet because classifying foods as "good" or "bad" may foster unhealthful eating behaviors.' We support this view and would warn the Department of such classification of foods.

While we strongly believe that health claims and advertising of certain foods to children need to be controlled, any regulations must be grounded in evidence and we do not believe that this type of 'good' and 'bad' categorisation is evidence-based. We also believe that the food industry has taken advantage of the lack of regulations to make excessive and often unsubstantiated claims and we do not condone this disregard of the consumer's rights to information that is truthful and not misleading but do not believe that the response of the Department should be unsubstantiated regulations.

The issue of restricting health claims and advertising to children is a global issue and one, which many countries are grappling with, as a balance needs to be established between restrictions on the one hand and recognising the potential positive role that foods, as a result of latest innovation technology, could play in addressing public health issues on the other hand.

The greatest example of how nutrition science and modern food technology can combine to result in improved global health is demonstrated by how the fortification of staple foods can have a significant and positive impact in addressing and eradicating micronutrient malnutrition. This is just one of many examples of how judicious and evidence-based use of technology can benefit nations.

We therefore believe that this issue needs to be progressed with care and that it should be a priority of the Department to establish a broad based working group of relevant experts that can discuss and debate the issues and options available and present proposals that are both evidence-based and practical. We note that the countries that have either been through, or are going through this process, have all taken time to do so and have ensured wide consultation of all the stakeholders.

It was fortuitous that in October, the European Food Safety Authority held a colloquium on nutrient profiling and as a result of a sponsorship from the CGCSA, the Nutrition Society and ADSA were able to send Dr Edelweiss Wenzel-Viljoen as an observer to the meeting. A full copy of Dr Wenzel-Viljoen's report will be given to Mrs Antoinette Booyzen of the Directorate of Food Control but a document outlining the scientific basis of nutrient profiling has already been given to Mrs Booyzen.

The EU recognises that claims are used to present products as having an additional nutritional or health benefit and that in most cases, consumers perceive products carrying certain claims to be better for their health and wellbeing. The overall aim of nutrient profiling is to avoid a situation where nutrient and health claims mask the total nutrient profile of a food and thus mislead the consumer.

It would therefore seem that a form of evidence-based nutrient profiling might well meet the Department's need for some restriction on health claims. We however acknowledge that developing a nutrient profile system is not a simple task and that many factors need to be

considered. Drawing from Dr Wentzel-Viljoen's report, nutrient profiling should be based on generally accepted scientific evidence relative to the relationship between diet and health (based on the dietary recommendations and public health considerations). Yet profiles should also allow for product innovation and should take into account the variability of dietary habits and traditions and the fact that individual products may have an important role in the context of an overall diet.

The meeting, through discussion groups, debated key issues that also need to be given due consideration in South Africa:

- Nutrient profiles across the board or by category of food?
- Identification of critical nutrients
- Reference quantity, scoring versus threshold systems
- Testing methods.

We quote from Dr Wentzel-Viljoen's report, the suggested way forward for South Africa:

'Nutrient profiling could be used as a method to determine whether nutrient and/or health claims can be made on food products and should be fully investigated. Nutrient profiling could be an alternative method to disqualify certain products to be eligible for nutrient/health claims instead of Annexure 6 in the present draft regulations.'

Some of the decisions that should be made, before and during the process of developing a nutrient profiling system for South Africa, include the following:

- *The aim of nutrient profiling – needs to be clearly defined*
- *Should the nutrients used in a profiling system be linked to proven public health/disease concerns in South Africa (under- and over nutrition)?*
- *It should surely be linked to the Food Based Dietary Guidelines, as these are the official nutrition recommendations for South Africans (older than 7 years)*
- *Will enrichment of products be allowed, macronutrients and micronutrients? For example will a refined product enriched with dietary fibre be eligible for a nutrient/health claim?*
- *All the questions raised and discussed within the EU discussion groups should be considered in the South African context, as they are equally relevant.*

There is no doubt that nutrient profiling cannot be undertaken lightly and such profiles cannot be developed overnight and without extensive consultation. Fortunately South Africa can and should learn from other countries experiences, for example the UK and Australian models. The scientists involved with the UK, Australian and Belgium models are all willing to assist us and were very interested in the fact that we are investigating the possibility of using nutrient profiles as a basis for nutrient and health claims.

I suggest the following process:

- *Initial meeting with the Department of Health: Directorate Food Control to explain the concept of nutrient profiling as a possible way of establishing if a food/food product is eligible for a nutrient/health claim or not*
- *Establishment of a multidisciplinary working group, that includes industry and government, but led by the scientists, to ensure an evidence-based approach and avoid specific agendas being pushed to investigate the feasibility of using nutrient profiling in South Africa for nutrient and health claims*
- *In-depth investigation of the current available models by scientists and report back to the working group*

- *Wide consultation with relevant stakeholders*
- *Final proposal to the Department of Health: Directorate Food Control for consideration.*

It must be noted and accepted by all that it will take time and money to investigate and develop or adapt a system for South Africa. We would be wise not to rush ahead with a system that is not clearly thought out and given due consideration as there are possible negative public health implications. The financial implications should be considered and decided upon."

The Nutrition Society and ADSA support Dr Wentzel-Viljoen's view and her proposal for the way forward and firmly believe that Regulation 52(2), (3) and (4) and Annexure 6 cannot be maintained in their present form, as they are unduly simplistic and scientifically unsubstantiated. We therefore urge the Department, as a matter of urgency, to form a multidisciplinary working group to progress this matter. The Nutrition Society and ADSA offer to facilitate this process but acknowledge that a major issue will be the funding of such a working group, as the task is large and cannot be funded by our societies. In other countries, this task is undertaken and funded by the government. This is a matter for the Department to resolve.

Annexure 7: Reference amounts for single serving sizes

ADSA and the Nutrition Society recognise that serving sizes are of critical importance as they together with MDR/RDA form the basis of many of the nutrition and health claim regulations.

We therefore support the principle of ensuring that the serving sizes listed on the labels of foodstuffs, as part of the provision of nutritional information relating to the product, should not be used to mislead consumers. We believe that in the past there has been abuse of serving size in order to make inflated nutrition claims and we deplore this practice.

We however believe that the setting of serving sizes must be evidence-based; must take into consideration public health issues; must be fully inclusive of all products consumed by South Africans; must take into consideration portion sizes typically consumed by South Africans; must be maintained as new categories of food are developed and must allow for variations within categories where relevant. This becomes a complex task and one, which we believe the Department does not have either the human or financial resources to undertake.

As a result the Nutrition Society and ADSA propose that the choice of serving size be left to the manufacturers with the following provisions:

1. In the case of a product where there are single serving size packages, the serving size given in the nutrition information table must be the same as that of the single serving size package.
2. In the case of a product where there are larger packaging sizes as well as single serving size packages available, the serving size given in the nutrition information table must be that of the single serving.
3. In the case of a product where there are no single serving size packages available but only multiple serving packages, the manufacturer can determine the size of a single serving to be given in the nutrition information table but must be able to produce documented substantiation as to the rationale behind how the serving size was derived.

Regulations 52(2)(f) and 52(3): Health warnings/notices on foodstuffs

ADSA and the Nutrition Society firmly believe that science supports the concept that 'all foods can fit' and that all foods can and should be consumed as part of a balanced, varied and

moderate diet and a lifestyle that includes physical activity. For this reason we do not believe that warnings or notices should be placed on selected foods as proposed by these regulations and that nutrition education and health promotion campaigns should communicate this message in a relevant way to key target audiences. If nutrition messages, apart from health claims themselves, are to be included on food labels, we believe that they should be based on the Food Based Dietary Guidelines and should be health promotion messages that educate regarding the elements that make up healthy eating and healthy living rather than the warning format currently proposed in the regulations.

We strongly believe that health promotion and nutrition education should form part of the National Strategy that we elaborate on at the beginning of and refer to throughout this submission document and urge the Department to establish.

Concept of health claims: Regulations 57, 58, 59, 60, 61, 62, 63

Although health claims on foods could easily be interpreted as being no more than marketing hype, the Nutrition Society and ADSA acknowledge that they are also an important nutrition education tool. For this reason we are supportive of health messages on foods. We agree with the basic principle that all health messages/claims should be truthful and not misleading. We would like to suggest that ALL health claims referred to in the regulations are built on sound scientific evidence and best evidence-based nutrition practice.

Regulation 57: Nutrient content claims

It is our opinion that the principle of nutrient content claims is fully acceptable and based in sound science, we however believe that the conditions set in Regulation 57, Table 1 need to be based in sound science. As a result, in the case where such conditions are given in CODEX Guidelines, we believe that these levels can be transferred directly to our regulations, noting that they were taken from CODEX. In the case where required content conditions are not available in CODEX Guidelines, it is our opinion that the Department should be required to reference the source of the listed conditions or how they were established. As we have some concerns pertaining to the values given in the conditions for content claims of some nutrients listed in Regulation 57, Table 1 we would like to recommend that all the conditions referred to in Table 1, column 3, for which there are no CODEX Guidelines, be reassessed by the recognised scientific experts in the specific field and be referenced. ADSA and the Nutrition Society would be happy to propose members of our associations that could be approached to assist the Department.

Regulation 58: Glycaemic index

1. Definitions

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It is recommended that the definitions "Glycaemic Index (GI)" and "Glycaemic load (GL)" be written out in full and not be referred to the Guidelines. The definition (apart from the formula) of GL does not quite explain its difference to GI and does not state that it takes the portion size into consideration. Another definition is suggested:

"The glycaemic load (GL) is a ranking system for carbohydrate content in food portions based on their glycemic index (GI) and the serving size"

OR serving size/portion could be added to the existing definition as follows:

"Glycaemic load (GL)" means a numerical expression of how much impact a specific serving size/portion of carbohydrate food will have in affecting blood glucose levels and which is calculated according to the formula in the Guidelines"

Recently there have been a number of attempts to create reliable in vitro methods of GI testing and although they are not adequate yet a scientific breakthrough seems likely in the coming 2-5 years. For this reason we would like to suggest that the text be deleted from the opening sentence of Regulation 58 as follows 'The glycaemic index category claim shall, if used, be the category as determined in accordance with the method described in Part A of the Guidelines' ~~and shall not include any method whereby a glycaemic index value is calculated to determine its category"~~

Regulation 58(c) describes the GI categories. The Nutrition Society and ADSA would like to suggest that a more robust type of system (other than categories) be used to acknowledge the interperson variation in GI of the same product. There are a number of ways to do this but scientific consensus has to be reached first. What makes the GI particularly difficult as a topic is the fact that it is so difficult to distinguish business interests from genuine unbiased scientific interest as many of the top international researchers in the field have clear vested interests in the field. At this point in time we would like to suggest that 25th to 75th percentile range be used as an indication of the probable range one could expect the GI of a product to be within. This would be a less misleading way of labeling GI.

Regulation 58(d) states *"(d) shall in addition indicate the glycaemic load (GL), calculated according to the formula mentioned in the Guidelines, of a single serving, in numerical form, directly underneath the GI category; Provided the serving size is in accordance with the serving sizes listed in Annexure 7 and an indication of the GL is subjected to the indication of the GI"*

We believe that the GL is a more useful tool than GI to estimate the impact of a carbohydrate rich food's effect on blood glucose levels. It is however true that the concept of GL has not been established amongst consumers and we seriously question the ability of consumers to interpret GL values. We therefore recommend that they not be expressed as a number but also as a range of possible values to accurately reflect the natural variation one could expect.

It has to be recognized that the Glycaemic index claims in Regulation 58(e)(i), (ii) and (iii) amount to a proper enhanced function claim. As a good governance measure we would expect that the Department has considered these GI claim to the same extent it would any other enhanced function claim and that a dossier of evidence has been compiled to substantiate all GI claims. Although Nutrition Society and ADSA have not compiled a dossier on the subject it seems quite unlikely that the level of evidence would suffice for any satiety claim on low GI products. We would recommend that this claim be removed from the regulations until such time that a proper dossier is compiled on the claim. Failing to do so would amount to an unfair and inconsistent process.

Guideline 6 comments on procedure

5. *Decide on type of subjects [healthy and/or IDDM and/or NIDDM, age (subjects shall be older than 18 years), BMI]. Subjects may be made up of singular groups, e.g., non diabetics or diabetics or mixed groups, e.g., non diabetics and diabetics together.*

Although correlations exist between the GI of normal individuals, type 1 and type 2 diabetics, the absolute values may differ significantly and its is not recommended that the three types of subjects should be combined into one test group for GI determination (Pieters & Jerling, 2005. SAJCN 18(3):232-236).

Another reason for not combining diabetics and healthy individuals is the fact that the calculation of the AUC for diabetics is done over a period of 3 hours while for normal individuals it is done over only 2 hours. No published studies could be found in which diabetics and normal individuals were combined in one group. Therefore, because of a lack of scientifically sound, evidence-based research it is suggested that diabetics and normal individuals be divided into two separate groups for GI determination (Pieters & Jerling, 2005. SAJCN 18(3):232-236). It has to be pointed out however that the results of a large multi-centre trial is to be published early in 2008 (the proofs have been printed) in the American Journal of Clinical Nutrition that will give some further guidance in this regard.

6. *Recruit a minimum of 10 subjects based on willingness to comply with protocol and inclusion and exclusion criteria, since Truswell, AS, recommended this requirement in his article: Glycaemic Index of foods (European J of Clin Nutr 1992, 46: Suppl. 2, S91 – 101).*

A more recent reference is: Brouns et al. 2005. Glycaemic index methodology. Nutr Res Rev, 18:145-171

12. *The total carbohydrate intake for the three days prior to the testing should be in line with the prudent diet and therefore contain at least 50% of total energy as CHO, 30% fat and 20% protein, as recommended for the pre-evening meal by Gresse A. & Vorster H.H.: The Glycaemic index and second meal effect of a typical African meal in black non-insulin dependent diabetic subjects. (SA J Fd Sc Nutr 1992; 4: 64 – 69).*

The only way to control dietary intake for three days prior to the testing is to prescribe a menu plan for the subjects which is difficult to control and is unlikely to have a significant impact. Because there is already a standardized pre-evening meal in place, there is no need to control the diet for three days prior to testing.

23. *Number of measurements:*

- (a) *The reference food requires 3 measurements.*
- (b) *The test food requires 1 measurement.*
- (c) *Testing of the reference food must be redone every 6 months if the same subjects are used on a regular basis.*

Since the GI is expressed as the individual's glycaemic response to a test food compared with a standard food it is essential that there be no change in glucose homeostasis from the time the standard food is consumed until the test food is consumed. This is, after all, the principle on which the GI is based. However, over a 6-month period several factors might influence glucose homeostasis and these should be strictly controlled for if the standard food is to be consumed only every 6 months. Some of these factors include change in exercise pattern, weight change, presence of infections, change in alcohol consumption patterns, change in stress levels, seasonal variation in glucose and insulin levels, use of certain medications, e.g. corticosteroids (Meticorten), oestrogens (Premarin), diuretics (Dyazide), nicotinic acid, beta-blockers (Inderal or Tenormin) and even aspirin. Another basic scientific prerequisite is that all subjects should receive all treatments but in random order. The current proposal is that the standard food is only tested once every 6 months, which means that there will be no randomisation of subjects to

intervention since subjects will consume only the test food at a given time. This might further lead to introduction of analytical bias since the standard and test food GI analysis will not take place on the same day. It is therefore proposed that facilities that measure GI should test foods in batches with the appropriate measurement of standards to ensure randomisation to treatment. More than one group of volunteers could be used to increase analytical throughput as long as the appropriate randomisation is done (Pieters & Jerling, 2005. SAJCN 18(3):232-236).

Regulation 59: Comparative claims

We believe that the principle behind comparative claims is to allow the consumer to be informed as to the significant (minimum 25%) nutritional differences between foodstuffs that they would generally consider as alternatives at any single eating occasion. We support such a principle and believe it can, if correctly applied, be of value to consumers and play an important educational function. Considering the above, we believe that Regulation 59(1)(a) and Regulation 59(1)(e) prevent this type of valuable comparison as they require the foodstuffs being compared to have 'common base formulations' and 'the same organoleptic properties'. This will limit the range of foods that can be compared to each other as often the alternatives do not have the same base formulations nor do they have the same organoleptic properties. ADSA and the Nutrition Society believe that this can easily be resolved by deleting Regulation 59(1)(e) and altering Regulation 59(1)(a) to read as follows: 'The foodstuffs being compared are foodstuffs that are typically used as alternatives at any particular consumption occasion.' Regulation 15 pertaining to negative claims would prevent any abuse of the above-suggested wording.

We also believe that Regulation 59(1)(b)(ii) requires clarity as to whether the actual brand name of the general category should be identified.

Regulation 60: Function claims

We have assumed that the purposes of nutrient function claims are to impact public health and educate consumers on the one hand and to provide manufacturers whose products contain certain levels of these nutrients with an opportunity to position their products as a better choice or alternative than products not containing these nutrients.

The Nutrition Society and ADSA believe that nutrient function claims should play a role in encouraging the consumption of foods that will aid in the alleviation of scientifically proven nutritional deficiencies or public health problems in South Africa. It is essential that we guard against the principle that "more is better", which often is not the case and could actually mislead when the intention is to educate consumers.

These claims are often referred to as "textbook claims". The content nevertheless should be scientifically sound and in accordance with the guiding principles for the establishment of such a category of claims.

It is our opinion that the guiding principles should be that:

- a food containing such a nutrient would actually be expected to deliver on the function claim
- the claim should aid in promoting health and address a proven health issue
- the function should be important under general physiological conditions and not under conditions of severe deficiency
- there is a risk for deficiency and loss of function if diet is severely restricted in terms of food items consumed

Considering the above, the issue of nutrient function claims is more complex than it would initially seem and we would therefore suggest that a working group be formed that is tasked with:

- defining the guiding principles for accepting nutrient function claims
- investigating the physiological functions of each nutrient and how it applies to the guiding principles and to then establish if it is factually correct and physiologically relevant
- formulating accurate alternative wording in line with the guiding principles based on state of the art scientific knowledge. We are of the opinion that allowing text to be selectively used within a nutrient function claim or allowing for alteration of the wording should not be allowed as small changes in these could significantly alter the meaning and context of the nutrient function claim.

We believe that such a working group should include 5-10 scientists who teach nutrition at university level or who do research in the area of the particular nutrient under discussion. The group should also include public health specialists and individuals who understand the need of industry and society to innovate within the food sector. The group could be a virtual group who work on each of the nutrients one by one. The group must have the ability to evaluate the public health impact of the nutrient, the physiological role and the impact of the approved function claim.

We draw the Departments attention to the fact that the specified regulation in Regulation 60(1)(a) requires that nutrient function claims may only be made for nutrients that have an MDR/RDA and yet a number of the approved function claims in Guideline 8 are for nutrients that do not have an MDR/RDA and so should be deleted from being included in Guideline 8.

Regulation 61: Enhanced function claims

We are supportive of this category of claim since it is firmly based on scientific evidence and there is less uncertainty than with the general nutrient function claims. We believe that all the relevant substantiation (in the form of evidence from human trials using the final product format containing the efficacious levels of ingredient/s consumed at intended level of consumption as it is intended to be brought onto the market) should be contained in a dossier submitted for pre-market approval. We believe that the Guidelines for dossiers should contain all the information required to evaluate any health or nutrition claim and so referring in Regulation 61 to the elements required should not be necessary and therefore the text of Regulation 61 can be changed so that Regulation 61(a) and Regulation 61(b) are deleted.

Regulation 61 will then read:

- '61. Subject to the requirements of relevant Regulations for Foodstuffs for Infants and Young Children made under the Act, enhanced function claims require pre-market approval from the Director-General following submission of a dossier of which the order and format is stipulated in the Guidelines and
- (a)(i) Only the claim as approved by the Director-General may be used in the advertising and/or labelling with no alteration whatsoever to the wording and
 - (a)(ii) The claim will only be permitted for the specific foodstuff that was included in the dossier and is not transferable to another foodstuff or a similar foodstuff under a different brand name and
 - (a)(iii) The foodstuff shall be labelled with the prescribed nutritional information declaration as described in point 1 of Annexure 2 per single serving and per 100g/ml and
 - (a)(iii) The nutritional information relevant to the enhanced function claim present in a single serving and per 100g/ml is indicated in the nutritional information table.'

Regulation 62: Disease risk reduction claims

The Nutrition Society and ADSA would like to suggest that only the full health claims that have been approved by the FDA be included in our regulations. The disease risk reduction claims that have been approved by the FDA are:

1. Potassium and the Risk of High Blood Pressure and Stroke
2. Whole Grain Foods and Risk of Heart Disease and Certain Cancers
3. Plant Sterol/stanol esters and Risk of Coronary Heart Disease
4. Soy Protein and Risk of Coronary Heart Disease
5. Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease
6. Dietary Sugar Alcohol and Dental Caries
7. Folate and Neural Tube Defects
8. Fruits and Vegetables and Cancer
9. Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble Fiber, and Risk of Coronary Heart Disease
10. Fiber-Containing Grain Products, Fruits, and Vegetables and Cancer
11. Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease
12. Dietary Fat and Cancer
13. Sodium and Hypertension
14. Calcium and Osteoporosis

The FDA has also developed a system whereby they approve health claims with varying degrees of certainty (qualified health claims). It seems as if the current proposed Regulation 62(a), Table 2 has included some of these qualified health claims. We would strongly suggest that no qualified health claims be included as disease risk reduction claims in our regulations. In support of this we would like to point to the fact that research from the FDA (Derby, B.A. and Levy, A.S. Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims. 1, 1-41. 2005. Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration) showed that consumers' perceptions of product health benefits are not diminished by conveying greater scientific uncertainty for a claim, which means that consumers interpret all health claims as being equal. This is in essence misleading and the standards for health claims should remain high and should be supported by the most current science and be beyond all reasonable doubt.

The following disease risk reduction claims in the proposed regulations under Regulation 62(a) are in fact considered qualified health claims and are not fully supported by the best form of evidence available and ADSA and the Nutrition Society believe that they should be removed from the proposed regulations:

- 62(a)(ix): Folate, Vitamins B12 and B6 and coronary heart disease
- 62(a) (x): Oats and coronary heart disease
- 62(a) (xii): Psyllium fiber and coronary heart disease
- 62(a)(xvi): Walnuts and heart disease
- 62(a)(xvii): Omega-3 fatty acids and coronary heart disease
- 62(a)(xviii): Olive oil and coronary heart disease

Regulation 63: Probiotic and prebiotic claims

The Nutrition Society and ADSA firmly believe that all health and nutrition claims should be evidence-based and that in the case of probiotic and prebiotic claims relevant scientific substantiation should be provided in order to avoid consumers being misled.

Members of both ADSA and the Nutrition Society were asked to be part of a Working Group facilitated by Danone Clover, the objective of which was to discuss and debate the text pertaining to probiotic claims (Regulation 63) from an evidence-based approach. We therefore fully endorse the recommendations of this working group.

We include below the text from the working group:

DEFINITIONS:

The overriding principle of a definition is to give clarity on what is meant by the word when used in a regulation. As such, the definitions become critically important to the regulations. It is therefore essential that the definitions be evidence-based and be supported by the most current scientific literature, in order to ensure that they are truthful and in no way misleading.

PREBIOTIC definition:

The working group suggests that the current definition be deleted and replaced. This is based on the latest prebiotic definition from Gibson et al 2004 [Gibson GR, Probert HM, van Loo JAE, Rastall RA, Roberfroid MB. Dietary modulation of the human colonic microbiota: Updating the concept of prebiotics. *Nutr Res Rev.* 2004;17:259–75.]: *‘A prebiotic is a selectively fermented ingredient that allows specific changes, both in the composition and/or activity in the gastrointestinal microflora that confers benefits upon host wellbeing and health.’*

The working group then altered the Gibson et al definition, in the interest of the two definitions (prebiotic and probiotic) being aligned whilst still maintaining all the elements of the Gibson et al definition, to:

‘An ingredient which is selectively fermented by the gut flora, and which when administered in an adequate amount, provides a demonstrated health benefit.’

PROBIOTIC definition:

The Working Group suggests that the current definition be deleted and replaced. The suggested replacement wording, given below, is based on a combination of the latest ILSI definition and the internationally accepted FAO/WHO definition (A report of a joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food including Powdered Milk with Live Lactic Acid Bacteria: Cordoba 2001) in order to ensure that the key elements (live, microorganism, amount, demonstrated, benefit) are captured.

Replace current text with: *‘Live microorganisms which, when administered to the host in an adequate amount, provide a demonstrated health benefit.’*

The Working Group stresses that the word ‘bacteria’ needs to be removed throughout the text, as the term probiotic (per the definition suggested above) should not be limited to bacteria as there is scientific evidence for other microorganisms (e.g. yeast) to be probiotics. The Working Group recommends that if the Directorate of Food Control disagrees with this concept, that it should be discussed and debated in an expert forum including a wide range of scientists/microbiologists with probiotic expertise.

PROBIOTIC BACTERIA definition:

The Working Group suggests that this text be deleted as all the critical elements are covered by the probiotic definition suggested by the Working Group, and all other elements are adequately covered in the guidelines for dossiers (Guideline 7&13).

PROBIOTIC PROPERTIES definition:

The Working Group suggests that this text be deleted as all the critical elements are covered by the probiotic definition suggested by the Working Group, and all other elements are adequately covered in the guidelines for dossiers (Guideline 7 &13).

SYNBIOTIC definition:

The Working Group suggests that the text be altered to read:

'Synbiotic means a combination of a prebiotic and a probiotic in a foodstuff'

REGULATION 63: PROBIOTIC AND PREBIOTIC CLAIMS

The Working Group stressed the importance of understanding that the addition of a probiotic or prebiotic cannot and should not be seen in itself as being a claim. The addition of probiotics or prebiotics or synbiotics to a foodstuff, is simply the start of the process of making a claim. What ultimately results in a claim is the specificity of the strain, the administered dose and the scientifically proven benefit when consumed in the specified matrix. The regulation needs to ensure that this clarity is maintained in the text in order to avoid consumers being misled and the truth being misconstrued.

Regulation 63(1):

The Working Group suggests that the current text be replaced with:

'A claim or implication that a foodstuff contains a 'probiotic' or a 'prebiotic' or a 'synbiotic' or words with a similar meaning shall not be made on the label of a foodstuff unless the foodstuff complies with the relevant conditions specified in Reg 63(1)(a) – (j) as well as 63(2) – 63(7)

Regulation 63(1)(a):

The Working Group suggests that the current text be replaced with:

'Any 'probiotic' claim shall only be permitted for one or more live strains which comply with the definition for probiotic, and for which premarket approval for both the strain and the claim has been granted through submission of a dossier (Guidelines 7 & 13).'

The reason for this suggested text change links to the suggested probiotic definition. There is extensive scientific literature available to show that more than the 4 strains listed in the draft text fulfil the definition of a probiotic. The FAO/WHO Report makes this clear.

In addition it is the opinion of the Working Group that the requirement for premarket approval by means of a dossier submission for any probiotic and associated claim, will ensure that all approved probiotics and claims can be substantiated.

In addition the Working Group highlights that limiting probiotic claims to only the 4 strains listed in the draft text, would in fact stifle scientific research into the health benefits of any other strains and would potentially restrict the possible development of other strains delivering probiotic benefits that could positively and significantly impact on public health.

Should the Directorate of Food Control disagree, it is suggested that they convene a working group of expert scientists to discuss and debate this as the significance of this limitation potentially has a great public health impact.

Regulation 63(1)(b):

The Working Group suggests that the current text be replaced with:

'All claims for 'probiotics', 'prebiotics' or 'synbiotics' shall be based on premarket approval through the submission of a dossier (Guideline 7 & 13).'

The reason for this change is that both Guideline 7 and 13 should adequately address all the components required to forge a dossier that provides sufficient information for an expert panel to determine if the requested claim has the necessary scientific substantiation. The Working Group believes that it is not for regulations to define the scientific process.

Regulation 63(1)(c):

The Working Group suggests that the current text be replaced with:

'Probiotic containing foodstuffs for which a specific claim is made shall indicate, in the table with nutritional information, the number of viable, colony-forming-units of probiotic at the end of the shelf-life period subject to the provisions of paragraph (f) hereunder, and shall identify the probiotic strain by its full scientific name (genus, species, subspecies) according to the International Code of Nomenclature as indicated in point 1 of the Guideline 7, and the strain number. In cases where the manufacturer has allocated a commercial name for the said strain, this can be given in parenthesis after the full scientific name and strain number'

The Working Group has deleted the text on the number of viable colony-forming units as well as the serving size requirement. The reason for this is that this information will have to form part of the dossier (Guideline 7 & 13) and both the probiotic dose (amount of viable colony-forming units at time of consumption) and the product dose (serving size) will have to be substantiated in the dossier in order for the dose and claim to be approved.

The Working Group suggests that this regulation [63(1)(c)] should also contain text pertaining to the inclusion in the table with nutritional information, details on the amount, type and source of prebiotic. The Working Group did not feel it was in their area of expertise to address prebiotics and suggest that the Directorate of Food Control convenes a prebiotic expert working group to suggest relevant, science based text.

The Working Group suggests that an additional regulation should be added at this point that reads: *'The suggested serving size to deliver the effective probiotic and/or prebiotic and/or synbiotic dose related to the approved claim and the regularity of use and required duration of use shall be included on the label of the product.'*

Regulation 63(1)(d):

The Working Group supports the principle that disease risk reduction claims are the highest form of claim and therefore need strict evaluation criteria and sound scientific substantiation.

The Working Group suggests that the current text be deleted as the required dossier (Guidelines 7 & 13) provides for including any claims substantiation.

The ad hoc expert group assessing the dossier and giving claim wording approval, should therefore be able to make the decision on the allowance for a disease risk reduction claim based on the level of scientific substantiation.

Regulation 63(1)(e):

The Working Group suggests that the current text be replaced with:

'The prescribed nutritional information as per Annexure 2 of a serving and per 100g or 100ml shall be provided on the label.'

Regulation 63(1)(f):

The Working Group supports the current draft text as included in the draft regulation, namely 'In those cases where the strains are not stable at room temperature foodstuffs for which a probiotic claim is made shall bear on the main panel of the label the instruction 'KEEP REFRIGERATED' or 'KEEP FROZEN', as the case may be, in capital (upper-case) letters not less than 3.0mm in height.

Regulation 63(1)(g):

The Working Group suggests that the current text be replaced with:

'Details of where the strain was isolated from must form part of the characterisation of the probiotic in the dossier (Guideline 13).'

Regulation 63(1)(h) and Regulation 63(1)(i):

The Working Group notes that there is an error in the numbering as these regulations are missing.

Regulation 63(1)(j):

Delete this as the Working Group feel that this is covered in the suggested text for Regulation 63(1)(c)

Regulation 63(2):

The Working Group suggests that the current text be replaced with:

'Claims on a foodstuff containing a probiotic and/or synbiotic shall not be permitted for a foodstuff that requires any further cooking or heating.'

The reason for this change links to the preamble indicating that the term probiotic itself is not a claim and also accommodates synbiotics.

Regulation 63(3):

The Working Group suggests that the current text can be deleted as synbiotics have been included and covered in the suggested text of Regulation 63(1).

Regulation 63 expanded:

It is the opinion of the Working Group that the text in Guideline 7 as 1(d) and 1(e) should in fact be moved to be included as part of Regulation 63.

This is the text in Guideline 7 that reads:

- (d) Any person or company who uses incorrect names that could lead consumers and regulatory authorities to make incorrect assumptions about the identity of the real bacterium used shall be guilty of an offence.
- (a) All strains shall be deposited in an internationally recognised culture collection and proof thereof must be on record for law enforcement purposes.

In addition the Working Group suggests that 3 additional points should be added that 1. makes provision for the nomenclature used on the label of the product to be updated as it changes on the International List and provision for a phase-in-time for change over and 2. makes provision for survival data to be made available and 3. covers the manufacturers responsibility to ensure that the deposited and commercially used strain is the same.

The suggestion of the Working Group would then be as follows:

'Regulation 63(4)(i): Any person or company who uses incorrect names that could lead consumers and regulatory authorities to make incorrect assumptions about the identity of the real probiotic used shall be guilty of an offence.

Regulation 63(4)(ii): Taking into consideration that the International Nomenclature Lists change from time to time, it is the responsibility of the manufacturer, to within 12 months of the change, update the information on the label of the packaging as well as information in the dossier.

Regulation 63(5): All strains shall be deposited in an internationally recognised culture collection and proof thereof must be on record for law enforcement purposes.

Regulation 63(6): The manufacturer shall within 48 hours of request, provide survival data of the probiotic in the product at the end of shelf-life, in the demonstrated dose, together with the methodology used to determine this.

Regulation 63(7): It is the responsibility of the manufacturer to regularly validate that the commercially used strain is the same as the originally deposited strain.

TABLE 3:

PROBIOTIC/PREBIOTIC CLAIM:

The Working Group suggests that Table 3 should be deleted in its entirety as all probiotic, prebiotic and synbiotic claims should require premarket approval on submission of a substantiation dossier (Guidelines 7 & 13).

The Working Group did not feel it was in their area of expertise to address prebiotics and suggests that the Directorate of Food Control convenes a prebiotic expert working group to suggest relevant, science based text pertaining to prebiotics. It is however the Working Group's opinion that as with probiotic claims, prebiotic claim approval should be on a case-by-case basis with submission of a dossier (Guideline 13).

PROBIOTIC/PREBIOTIC CLAIMS for infants from birth to 3 years

It is the Working Group's opinion that this should be deleted from this text and be excluded from this regulation. The reason being, there are specific regulations pertaining to infants and young children and any probiotic / prebiotic / synbiotic claims pertaining to this group should be dealt with under the regulations for Foodstuffs for Infants and Young Children. It is however the Working Groups opinion that the same principles for any claim approval should follow those in these regulations, namely premarket approval on submission of a dossier (Guideline 7 & 13).

GUIDELINE 7

The Working Group did not feel it was in their area of expertise to address prebiotics and suggests that the Directorate of Food Control convenes a prebiotic expert working group to suggest relevant, science based text for prebiotics and if required the development of a similar guideline pertaining to prebiotics.

Heading:

The Working Group suggests that the current heading be replaced with:

'Criteria for a probiotic to be accepted for making a claim.'

The Working Group suggests that the current text beneath the heading be replaced with:

'The following information should be submitted to the Director-General together with a claim substantiation dossier (Guideline 13):'

1. Identification of the genus, species and strain

The Working Group suggests that some of this text be moved from the Guideline to the actual regulation 63. As a result the text in the guideline would read:

- (a) The genus of the probiotic shall be identified.
- (b) The species and specific stain of the probiotic shall be identified using both the genotypic and the phenotypic characteristics.

It is the Working Groups recommendation that a specialist working group of technical experts in the field of strain identification (e.g. microbiologists, control labs) be convened by the Directorate of Food control to discuss this element and to take into consideration what can be done by local laboratories.

- (c) The nomenclature of the probiotic must conform to the current, scientifically recognised names as specified in the following sources
 - (i) Approved lists of Bacterial Names (Int. J. Syst. Bacteriol, 1980, 30:225-420)
 - (ii) Validation lists, published in the International Journal of Systematic and Evolutionary Microbiology (or International Journal of Systematic Bacteriology, prior to 2000)

NOTE: It will be necessary to ensure that texts that cover the nomenclature of non-bacterial probiotics are included.
- (e) Provision of the complete methodology used to determine the viable colony-forming units and the accreditation details of the laboratory that was used.

2. Screening for safety of potential probiotic microorganisms (Phase I)

The Working Group suggests that the wording (Phase I) should be deleted from the title above.

The Working Group noted the following items, as in their opinion, being critical for safety screening but urges the Directorate of Food Control to convene a technical expert group of scientists to discuss this aspect in detail.

The main objective of safety screening was noted by the Working Group to be to assess, control and reduce the risk of infection from any probiotic used in a foodstuff. In this light it was noted that the relevance of each of the safety points, in terms of ultimately assisting the ad hoc expert group in making a decision regarding a dossiers approval, must be discussed.

- Food Grade Status / GRAS recognition
- Must not be a pathogenic strain / Must be a strain not normally associated with human disease (haemolytic activity is included here)
- Need to know the specific antibiotic/s sensitivity
- Assessment of side effects in human studies
- If the strain is producing a potentially toxic metabolite, the risk must be assessed in the dossier
- Gene transfer must be covered
- New products need to build a long history (5-10 years) of safe use.

In addition, the Working Group noted that it should not be possible to give a blanket approval for all strains within a given genus and species, as is currently the case in the draft text, without the Directorate of Food Control having all the above information and a dossier for the specific strain used, as this could potentially result in risks associated with the pre-approved strains. This further supports the need for a case-by-case assessment by an ad hoc working group for any probiotic and associated claim.

3. Assessment of efficacy (Phase II)

The Working Group suggests that the wording (Phase II) should be deleted from the title above.

The Working Group felt that the key objective of this section of the guideline is to ensure that there is scientific substantiation of efficacy for any probiotic claim. The Working Group felt that it was not necessary to give details in this guideline but rather to refer to Guideline 13, which would give extensive information on the type of information and evidence required for the assessment of any claim for both its substantiation and wording approval.

Therefore the Working Group suggests that the wording should read: *'A full dossier as described in Guideline 13 must be provided'*

The Working Group believes that the content of Guideline 13 must be drafted and assessed by expert scientists and would then defer to the recommendations of these scientists.

Regulation 68: Slimming Claims

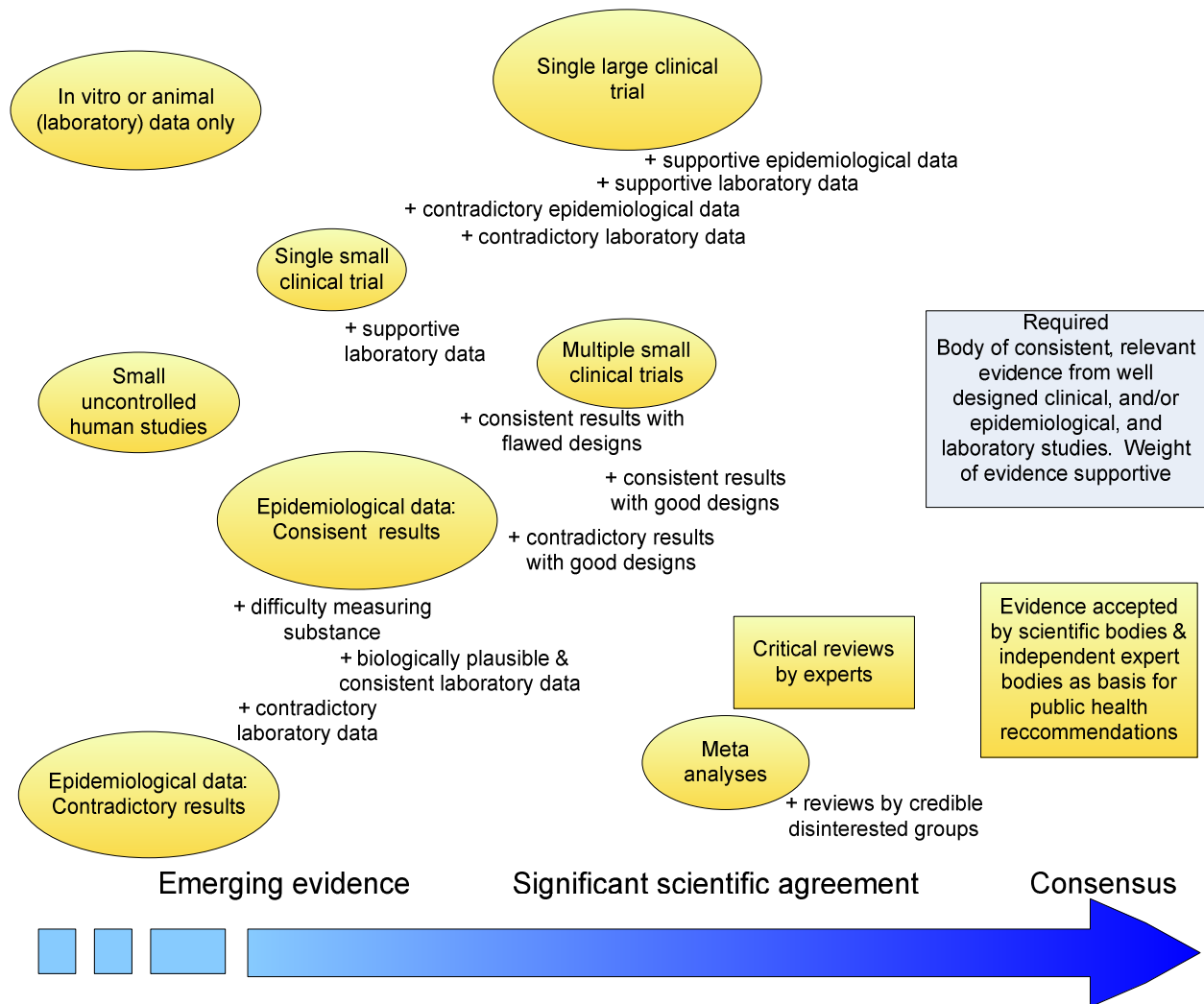
ADSA and the Nutrition Society have grave concerns regarding this text and the principle behind it. We do not believe that the contents of the regulations are based in sound science and that only fat restriction and GI/GL are relevant to slimming. We would suggest that a working group of scientists that specialise in weight reduction is formed and that fully substantiated text is drawn up to replace the existing text.

Guideline 13: Guidelines for preparing dossiers / Ad hoc Scientific Expert Committee

The Nutrition Society and ADSA strongly believes that the only route for approval of health claims must be through a peer-reviewed process that closely scrutinises the submitted evidence supporting any such claim and that submission of a suitable dossier must be the basis for such substantiation. We support the idea of including Guideline 13 and that this should cover all the requirements of the dossier in order to ensure that companies are aware of the contents required when compiling such a dossier and ahead of submission.

Although there are a number of smaller changes we could suggest, we find the principles contained in Guideline 13 scientifically acceptable. Guideline 13 gives good guidance to both industry and scientists when compiling dossiers. In some cases however even more detail will be required to ensure an effective evaluation of dossiers. An example of this is how one would rate the quality of randomised controlled trials and the impact it would have when one interprets its findings (Annexure 2 Point 3).

The following schematic representation could be used as starting point to develop a comprehensive guidance tool to illustrate the hierarchy of evidence.



It is essential that it is made clear that evidence should be provided from randomised controlled human trials using the final product format containing the efficacious levels of ingredient/s consumed at intended level of consumption as it is intended to be brought onto the market. The quality of meta analyses should also play an important role because it is possible to do a meta analysis poorly. We support the spirit of Guideline 13 and recognise that one can only evaluate evidence on a case-by-case basis taking the totality into account. The totality will vary from topic to topic depending on the availability of scientific evidence.

The Nutrition Society and ADSA would like to recommend that small working group of approximately 5 scientists, who have some experience in the field of dossier evaluation or at least the writing of systematic reviews, be established to test the practicality of Guideline 13 and make suggestions for improvement of the scientific review process. In addition this would ensure that the guideline could be a useful tool for industry in the process of compiling a dossier in order to ensure that the submission process runs as smoothly as possible.

Following on from the contents of the dossier, the process for assessing dossier submissions and the composition of the committee assessing any such dossier is vitally important and it is critical that the issues and procedures and logistics pertaining to the *ad hoc* Scientific Expert Committee referred to in Guideline 13 are addressed ahead of the regulations being finalised as

this is a crucial element of the regulations. ADSA and the Nutrition Society urges the Department to urgently consider the points raised below in this regard.

The detailed process to be followed (externally by any applicant and internally by the Department) together with the provision for an appeal and associated timelines need to be defined by the Department. Apart from assessing the scientific adequacy and substantiation of any claim, it is our firm belief that the exact wording of the approved claim should be defined by the ad hoc Scientific Expert Committee and that only those approved words should be permitted for use in the advertising and labelling of such claim.

With regards to the composition of the ad hoc Scientific Expert Committee, the Nutrition society and ADSA suggests that:

- Its composition needs to ensure that a wide range of expert skills are included as nutritional as well as technical substantiation will be required to be assessed. The committee should therefore always be multidisciplinary and might need to include an international expert.
- The members of the committee need to be experienced in the field under review.
- The term 'expert' needs to be carefully considered, as the definition is crucial if the Committee is to follow the definition of evidence-based practice. Some form of peer review of the experts selected by the Department is required and the experts need to be selected based on their proven, published record and relevant university training should be a minimum requirement.
- Contrary to what is currently included in Guideline 13, we believe that it is essential that the names of the experts used to assess any submission should be made known once the submission process has been concluded.
- We also believe that the content of successful submission should be publicly accessible (with the exception of truly proprietary information).
- We believe that it is important to a much as possible rotate members of the Committee so as to ensure that different people are used.
- We believe that as the Department has limited resources, the dossiers and Committee administration could possibly be handled by:
 - National Research Foundation (NRF)
 - Council for Scientific and Industrial Research (CSIR)
 - South African Association of Food Science and Technology (SAAFoST)
 - Academy of Science South Africa (ASSAF)It is our opinion that ASSAF is probably the most appropriate body.
- The Nutrition Society and ADSA know that many of their members will be willing to serve on such a Committee, however a key issue will be the remuneration of the Committee as this is intensive work and will require commitment to deadlines. It cannot be expected for these experts to undertake such work free. It is also our opinion that many of the experts that will be required will be academics or individuals in senior positions and this raises the issue of availability.

ADSA and the Nutrition Society believe that the Department has much work still to do regarding these administrative, remuneration and logistics issues. We would suggest that discussion with Professor Johann Jerling and Professor Esté Vorster who have experience in assessing such dossiers would be of value to the Department.

Conclusion

The Nutrition Society and ADSA once again place on record their support for most of the principles behind these regulations and acknowledges the vast amount of work that has been undertaken to compile these regulations. We believe it is an excellent starting point for going forward but also believe that there are areas, where much work and broad and transparent consultation is required before these regulations, in their totality, can be finalised and published. Most of this pertains to ensuring that the regulations are evidence-based. In this regard ADSA and the Nutrition Society ensure the Department of our willingness and the willingness of our members to assist wherever we can and to be actively engaged in working groups.

In this submission document we have suggested a number of working groups and so include the table below which lists the working group and suggests a relevant person/people/organisations that the Department could consider approaching in this regard.

WORKING GROUP TOPIC	POSSIBLE MEMBERS/CO-ORDINATOR
South African National Strategy for Diet, Physical Activity and Health	Medical Research Council in collaboration with Directorate of Non Communicable Diseases
Definitions	Nutrition Society and ADSA willing to co-ordinate expert opinion for evidence-based definitions
Content / Format for mandatory information	Mrs Carol Browne Ms Jane Badham
Laboratory issues	SAAFoST in conjunction with the National Laboratory Association
Fats & Oils	Dr Pieter van Twisk Prof Marius Smuts
Nutrient reference values (MDR/RDA)	Prof Este Vorster
Annexure 6 – Nutrient Profiling	Dr Edelweiss Wentzel-Viljoen
Nutrient Function Claims	Prof Johann Jerling
Slimming claims	Prof Marianne Senekal Dr Renee Blaauw
Dossier	Prof Johann Jerling

As these regulations have been long awaited by the food industry, the nutrition health professionals and the consumers and there are no doubt many sections that are not controversial and either do not require any changes or the change adaptations may be minimal, we would like to suggest that the Department consider allowing certain sections to move forward while working groups continue to progress other sections that could then be added at a later stage. In this way we believe the Department will fulfill the urgent need for updated regulations relating to the labeling and advertising of foodstuffs and will also ensure that all the regulations are evidence-based.

Finally, we once again urge the Department to make it a priority to begin the process of developing a comprehensive national strategy for the prevention of the noncommunicable diseases and encourage the Department to ensure that the process is transparent and consultative and includes all stakeholders as per the recommendations of the World Health Organisation.

Yours sincerely

A handwritten signature in black ink that reads "R Smalberger". The signature is written in a cursive style with a large initial "R".

Mrs. René Smalberger
President: The Association for Dietetics in South Africa