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AIDS LAW PROJECT/TREATMENT ACTION CAMPAIGN: SUBMISSION ON THE REGULATIONS RELATING TO THE LABELLING AND ADVERTISING OF FOODSTUFFS[1]

The AIDS Law Project (ALP) and the Treatment Action Campaign (TAC) focus much of their work on ensuring that full and meaningful effect is given to the Bill of Rights recognition that "[e]veryone has the right to have access to … health care services" and that the "state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization" of this right.[2]

Integral to the realisation of this right, as well as the state's positive obligations in this regard, is to ensure that the public is afforded the opportunity to make educated and informed decisions about their own health, particularly insofar as this relates to a healthy diet. In part, this means ensuring the public is reasonably protected from false or misleading labels and/or advertisements which could potentially endanger their health.

With this in mind, the purpose of this submission is therefore to assist the Department of Health (DoH) in discharging its constitutional obligations in this regard. In particular, the primary aim of this submission is to assist the DoH in fine-tuning the draft Regulations Relating to the Labelling and Advertising of Foodstuffs ("the draft regulations") so that, in their final published form, they serve as an effective tool to enforce appropriate labelling and advertising, are able to withstand constitutional scrutiny, and allow the people of South Africa to make informed, evidence-based decisions about their nutrition and diet.

In this submission, we consider the following issues:

- Insufficiency and/or lack of several definitions (draft regulation 1);
- A minor technical concern in the general provisions (draft regulation 2);
- Prohibited statements (draft regulation 14);
- Small packages (draft regulation 35);

[1] Government Notice No R. 642, Government Gazette No. 30075, 20 July 2007
[2] Section 27 of the Constitution of the Republic of South Africa, 1996 ("the Constitution")

- Procedures for the approval of health claims (draft regulation 61 and guidelines 13 and 14);
- Reduction of disease risk claims (draft regulation 62);
- Enteral foods (draft guideline 14); and
- The provisions dealing with penalties.

Definitions (draft regulation 1)

Draft regulation 1 raises a number of concerns, both in respect of proposed and missing definitions. In our view, these concerns need to be addressed to ensure that there are no substantial gaps of coverage in the regulations and that there are no inherent contradictions or tensions that could undermine the regulations' impact. In particular, we are concerned about definitions relating to the following:

- Claim;
- Food constituent; and
- Health claim, medicinal claim and suitability claim;

Claim

The definition of a claim refers to a "foodstuff or a nutritional supplement." However, a definition of a nutritional supplement does not appear in the draft regulations.[3] In addition, our understanding of a foodstuff – as defined in the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 ("the Foodstuffs Act") – is that it includes a nutritional supplement. We therefore propose that the phrase "foodstuff or a nutritional supplement" be replaced by the phrase "foodstuff (including a nutritional supplement)" and that a definition of nutritional supplement be inserted. In addition, we recommend that the list provided in the definition of a claim, which is lacking in a key component (that of "health effects"), be amended accordingly.

In the result, the following reformulated definition of claim is proposed:

> "claim" in relation to a foodstuff **[or]** <u>(including a</u> nutritional supplement<u>)</u>, means any written, pictorial, visual or other descriptive matter or verbal statement, communication, representation or reference brought to the attention of the

[3] The current Labelling and Advertising Regulations define "nutrient supplement" as "any nutrient preparation intended to supplement the diet by increasing the total dietary intake of such nutrient(s)."

> public in any manner including a trade name or brand name and referring to the characteristics of a product, in particular to its nature, identity, nutritional properties, health effects, composition, quality, durability, origin or method of manufacture or production.[4]

In addition, the following definition of a nutritional supplement is proposed:

> "nutritional supplement" means any product which is not represented as a conventional food or as the sole item of a meal or diet; and –
> - Is intended to supplement a diet;
> - Is intended for ingestion in pill, capsule, tablet, powder or liquid form; and
> - Which contains any of the following dietary ingredients:
>   - A vitamin;
>   - A mineral;
>   - A herb or other botanical (other than tobacco);
>   - An amino acid;
>   - A dietary substance for use by people to supplement the diet by increasing the total dietary intake; or
>   - A concentrate, metabolite, constituent, extract, or combination of any of the above.
>
> For the purposes of these regulations, the terms "dietary supplement" and "nutrient supplement" are synonymous with "nutritional supplement".

Food constituent

The term "food constituent" is defined in the draft regulations as "any biologically active substance *other than a nutrient*, which is naturally present in certain foodstuffs and with which health effects are associated."[5] Yet the defined term is only used once in the draft regulations – in draft regulation 62(a), dealing with reduction of disease risk claims. Elsewhere, numerous variations of the term are used instead. For example, the definition of "enhanced function claims" refers to "foods or their constituents". In addition, the definition of a "health claim" refers to "food or constituent of that food".[6]

Implicit or explicit in these definitions is that nutrients are ordinarily considered as constituents of foods. This much is clear in the definition of a "nutrient," which the draft regulations consider to be "any natural or synthetic substance consumed as a *constituent of a foodstuff*, which provides energy or which is needed for growth, development and maintenance of life or of which a deficit will cause characteristic biochemical or

[4] In this submission, inserted text is underlined, whereas deletions are [in bold text in square brackets].
[5] Emphasis added
[6] Further, the definition of a "nutrient" refers to a "constituent of a foodstuff", with draft regulations 45(1)(a) and 72(1)(a) referring to a "constituent of an ingredient".

physiological changes to occur."[7] Thus nutrients (and by extension, nutrient supplements) are subject to the provisions dealing with health claims and enhanced function claims.

Yet in relation to reduction of disease claims, which relies on the term "food constituent" instead of "constituent of a foodstuff", nutrients are expressly excluded. This means that any product falling within the definition of a nutrient, such as a vitamin or a mineral, would expressly be excluded from the regulation of reduction of disease risk claims. This is troubling, particularly in a context where the need for the regulation of a range of other claims in relation to nutrients has expressly been recognised.

In the result, we propose one of two options: a deletion of the definition of "food constituent" and the use of the term "constituent of a foodstuff" in the provisions dealing with reduction of disease claims. Alternatively, we propose that the following definition of "food constituent" be adopted instead:

> "food constituent" means any **[biologically active]** substance **[other than a nutrient,]** which is naturally present in **[certain]** a foodstuff**[s]** with which health effects are associated

Additionally, all the above alternative wordings should be harmonized through the use of a single consistent phrasing, so as to avoid the potential for any uncertainty.

Health claim, medicinal claim and suitability claim

In draft regulation 14(k), the term "medicinal claim" is used alongside "health claim." While the latter is indeed defined in the draft regulations, the former is neither defined in the Foodstuffs Act nor in the draft regulations. In addition, it is also not defined in the Medicines and Related Substances Act 101 of 1965 ("the Medicines Act"), to which draft regulation 14(k) refers.[8] If the term "medicinal claim" is to remain in the final regulations, it must be defined. In this regard, we propose the following:

> "medicinal claim" means any representation that states, suggests or implies that a food or constituent of a food has any property of a medicine as defined in the Medicines and Related Substances Act 101 of 1965

[7] Emphasis added
[8] Draft regulation 14(k) will be discussed more in depth below.

Additionally, and for the reasons discussed below,[9] "suitability claim" should be defined to encompass claims suggesting a particular foodstuff is suitable for a person living with or being treated for a particular disease:

> "suitability claim" means any representation that states, suggests, or implies that a food or constituent of a food is suitable for a person living with or being treated for a stated disease.

As a result of adding this definition, "health claim" should be amended as follows:

> "health claim" means any representation that states, suggests or implies that a relationship exists between a food or constituent of **[that]** a food and health, and includes but is not limited to function claims, enhanced function claims, suitability claims, reduction of disease risk claims, prebiotic claims, probiotic claims and slimming claims.

General provisions (draft regulation 2)

Draft regulation 2 sets out what a person may not do with regard to the manufacture, advertising, and sale of foodstuffs. On first reading, it would appear that the intention of the drafters of this provision was to proscribe all three forms of conduct. However, the provision uses the conjunctive term "and" between draft sub-regulations (b) and (c) rather than the disjunctive "or". As it currently reads, a person is only prohibited from acting if they are simultaneously breaking sub-regulations (a), (b) AND (c) – this is clearly not the intent of the draft regulation. This relatively minor but important correction should be made, such that the "and" at the end of sub-regulation (b) is replaced by an "or":

> (a) …
> (b) advertise a foodstuff in any manner, which contains any information, claim, reference or declaration not permitted on the label in accordance with these regulations; **[and]** or
> (c) ….

Prohibited statements (draft regulation 14)

Suitable for people with a particular disease or condition

With the sole exception of draft sub-regulation (g), which deals with diabetics, there is no provision in draft regulation 14 governing claims that a foodstuff is suitable for a person

[9] See the text accompanying note 10 below

living with and/or being treated for any given disease or condition. Such claims do not currently fall within the definition of a health claim, function claim, enhanced function claim or reduction of disease risk claim. They would also not be covered by draft sub-regulation (d), which deals with "health-giving properties" and claims that a foodstuff is "healthy". As suitability claims do not fall within the ambit of the Medicines Act, these regulations are ideally placed to deal with them.[10]

The importance of regulating suitability claims is to prevent the labelling and/or advertising of foods as being suitable for persons living with and/or being treated for specific diseases in the absence of scientific evidence to back up such claims. Importantly, while certain foods may be "suitable" for some persons living with a particular disease, the suitability of these foods may be in question if certain medicines are being used to treat the particular disease. Since suitability claims are valuable for consumers, we do not propose that suitability claims be prohibited altogether, but rather that they are regulated in a scientific manner.

In our view, therefore, draft regulation 14 must be amended to prohibit – subject to certain additions to the provisions dealing with health claims – any claims stating or implying that a foodstuff is "suitable" for a person living with and/or being treated for a particular disease. The amended regulation should follow all the procedures for disclosure discussed below (as part of our comments on draft regulation 61) and be accompanied by an additional guideline specifying the dossier of information to be submitted to the DoH in respect of the suitability claim. Our proposal, to be inserted after draft regulation 14(m), thus reads as follows:

> (n) except as permitted under the procedures established in regulation XX, a claim that a food or constituent of a food is suitable for a person living with and/or being treated for any particular disease

Draft regulation 14(k)

Draft regulation 14(k) attempts to create an overlap between what is regulated by two separate statutes: the Foodstuffs Act and the Medicines Act, by implying that approved health claims may override provisions of the Medicines Act. In particular, it provides that – "subject to the provisions of the Medicines … Act" – "a label or advertisement of a

[10] See above note 9

foodstuff" may not include "the word 'cure' or any other medicinal claim, except those health claims permitted in terms of …[the draft] regulations". In other words, the draft regulations seek to permit certain health claims that "include "the word 'cure' or any other medicinal claim". This is simply not permitted by the relevant legislative framework.

In particular, the Foodstuffs Act defines a "foodstuff" as "any article or substance [except a drug as defined in the Drugs Control Act, 1965 (Act 101 of 1965)] ordinarily eaten or drunk by man or purporting to be suitable, or manufactured or sold, for human consumption …."[11] In enacting and retaining this definition, Parliament's clear intention is to ensure that those substances that are defined by the Medicines Act as medicines be regulated exclusively by that Act. Thus any regulations issued in terms of the Foodstuffs Act cannot regulate any advertising and/or labelling in respect of a substance that satisfies the definition of a medicine. Simply put, sub-regulation 14(k) oversteps the bounds of what is a permissible health claim under the Foodstuffs Act and its regulations.

As there are products that could satisfy both the definition of a medicine and a foodstuff, depending on the claims made in respect of that product, we do not propose that the regulations refrain from addressing products capable of being defined as medicines. What we do submit is that the regulations cannot permit persons to market products with claims consistent with the product's use as a medicine – as defined by the Medicines Act – when the product is being sold as a foodstuff.

With this in mind, we propose that sub-regulation (k) be redrafted as follows:

> (k) **[subject to the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), the word "cure" or]** any **[other]** medicinal claim, except <u>as approved in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965)</u> **[those health claims permitted in terms of these regulations]**

In addition, regulation 14 needs to be supplemented by a provision that deals expressly with claims that reference medicines and medical claims. In our view, the only legitimate

[11] Note that the proposed Foodstuffs, Cosmetics and Disinfectants Amendment Bill [B35-2005] continues and updates this exclusion by defining a foodstuff as "any article or substance (except a medicine as defined in the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)) …."

cross-reference to a medicine would be in the form of an enhanced function claim. In the result, we propose the insertion of a new regulation 15(o):

> (o) except as permitted as an enhanced function claim, a claim that references a medicine, or class of medicines, registered under the Medicines and Related Substances Act 101 of 1965 by brand name, trade name or otherwise, and promotes the taking of a foodstuff or constituent of a food alongside the referenced medicine or class of medicines

Small packages (draft regulation 35)

In recognising the practical difficulties of placing information on small packages, defined as those having a total exterior surface area of 2000mm^2 or less,[12] draft regulation 35 provides a loophole which may allow unsubstantiated claims onto small packages. The loophole can easily be closed, however, by making appropriate references to the regulation dealing with bulk containers (currently draft regulation 34) without undermining the intent of draft regulation 35.

In our view, certain claims (such as health claims) must be regulated regardless of the size of the packaging in which a particular foodstuff is sold. This can be done by amending draft regulation 35 so that where any such claims are made, all the labelling requirements ordinarily associated with them are placed either on the small package itself or on the bulk stock containers out of which the small package is sold. In the result, the following amendment to draft regulation 35 is proposed:

> (1) Subject to sub-regulations (2) and (3), **[T]**the packaging of a pre-packed foodstuff that has a total exterior area of 2000mm^2 or less, including single once-off use 10g or less size packages of herbs and spices, are exempted from the requirements of labelling, except for the declaration of the name of the foodstuff, the address of the manufacturer, an appropriate date of marking, the declaration of an allergen, if applicable and the declaration according to Regulation 69 that the product has undergone irradiation if applicable.
> (2) All pre-packaged foodstuffs referred to in sub-regulation (1) and in respect of which any health claims, GI category claims or GI claims are made must satisfy all labelling requirements for such claims.
> (3) The requirements of sub-regulation (2) may be satisfied either on the packaging itself or on the relevant bulk stock container in accordance with all relevant labels and procedures as provided in regulation 34.

[12] A package measuring 20mm by 40m by 10mm – which is smaller than a box of matches – has a total exterior surface area of 2000mm^2.

Procedures for the approval of health claims (draft regulation 61 and draft guidelines 13 and 14)

The procedures established by the DoH with regard to the approval of health claims raise two concerns. First, there appears to be no statutory authority on the basis of which the regulations and/or guidelines can provide mechanisms for the approval of claims. Second, where statutory authorisation is ordinarily granted, it typically makes provision for regulations – and not guidelines – to address the identified issue. These two concerns are addressed in turn.

Lack of constitutional statutory authority upon which to approve claims

Section 15 of the Foodstuffs Act, which grants authority to the Minister of Health to promulgate regulations, does not expressly address the approval of claims in relation to the advertising of foodstuffs. In general, the various sub-sections of the provision limit the Minister's authority to proscribing, prohibiting or restricting by way of regulation. The only exception is section 15(o), which appears to be the only basis upon which the Minister may seek authority to create an approval mechanism and provides as follows:

> The Minister may make regulations … with regard to any matter which in terms of this Act may be prescribed or otherwise dealt with by regulation, and, in general, with regard to any matter which the Minster considers necessary or expedient to prescribe or regulate in order to attain or further the objects of this Act, and the generality of this provision shall not be limited by the preceding paragraphs of this subsection.

In short, section 15(o) purports to grant the Minister the authority to promulgate any regulation so long as he or she "considers [it] necessary or expedient … to … further the objects of … [the Foodstuffs] Act."

In line with the Constitutional Court's decision in *Dawood v Minister of Home Affairs*,[13] we submit that such broad delegations of authority – without any guidance regarding their exercise – are unconstitutional. As noted by Justice O'Regan, "[t]he legislature must take care when legislation is drafted to limit the risk of an unconstitutional exercise of the discretionary powers it confers."[14] In particular, she noted that "if broad discretionary powers contain no express constraints, those who are affected by the exercise of the

[13] 2000 (3) SA 936 (CC)
[14] At paragraph 48

broad discretionary powers will not know what is relevant to the exercise of those powers or in what circumstances they are entitled to seek relief from an adverse decision."[15]

The Foodstuffs Act was last amended by the Transfer of Powers and Duties of the State President Act 97 of 1986, more than a decade prior to the coming into effect of the Constitution. The constitutional validity of section 15 has not, to our knowledge, been considered by any court. Importantly, the Foodstuffs, Cosmetics and Disinfectants Amendment Bill [B35-2005] does not, in any of the 21 proposed additions to section 15(1), propose an amendment that would expressly authorise approval mechanisms. With this in mind, we are of the view that the Foodstuffs Act's delegation of authority in terms of section 15(o) – which provides no guidance regarding the extent of the Minister's authority in this area – must be viewed as unconstitutionally vague and overbroad and in conflict with the *Dawood* decision. In the result, the Minister is unlikely to have the statutory authority to promulgate the procedures established by draft regulation 61 and draft guidelines 13 and 14.

We are concerned that the draft provisions provide no guidance to applicants or those who may be adversely affected by decisions made in terms of the procedures as to how to vindicate their rights or in what circumstances they would be entitled to seek such relief. In addition, we are concerned that draft regulation 61(c), which makes it plain that the Director-General (DG) is responsible for providing pre-market approval of enhanced function claims, is to be contrasted with draft guideline 13, which in turn makes clear that the Directorate: Food Control – based on the advice of an ad hoc expert panel appointed by the Minister – would be tasked with granting or denying such approval. While we recognise that section 25 of the Foodstuffs Act empowers the DG to delegate authority – in writing – to any officer within the DoH, we do not believe that the Minister is statutorily empowered to establish such an approval mechanism.

Our submissions in this regard should not be misunderstood to suggest that we are opposed to the creation of an expert body tasked with reviewing the scientific basis of health claims. To the contrary, we support the creation of an independent statutory body tasked with evaluating health claims – somewhat akin to the Medicines Control Council, a

[15] At paragraph 50

creation of the Medicines Act. We therefore recommend that should the Minister wish to create such an independent body, as we recommend, she should sponsor an amendment to the Foodstuffs Act which expressly creates an independent and accountable body. But unless and until this happens, the Minister is not statutorily or constitutionally entitled to establish such a mechanism to grant approvals in respect of such claims.

This does not mean, however, that the Minister is unable to regulate health claims. Instead, it simply means that the Minister can and must regulate health claims in some other manner, such as the alternative procedure proposed below:

- Draft regulation 61 should continue to require all those wishing to make enhanced function claims to submit dossiers to the Directorate: Food Control, the contents of which are specified in draft guideline 13.
- Draft guideline 13 should be amended to require dossiers to be made publicly available on the DoH website and through notice of such claims by publication in the *Government Gazette*:
  - The online publication of the dossier should include a scanned copy of the dossier, including citations for those portions which the DoH is prohibited from distributing due to copyright law;
  - Publication in the *Government Gazette* should include the claim being made, the foodstuff (including trade name) to which it relates, the name and address of the applicant, the scientific citations submitted in relation to the claim, and the web address where the dossier can be found on the DoH website.
- The applicant should be required to wait a minimum of 30 days after publication before being able to market the foodstuff in respect of which an enhanced function claim is made.
- During this time, the DG or anyone delegated by him or her should be entitled to review the dossier and determine whether to prohibit the claim or to send inspectors and make use of analysts to substantiate the claim. Importantly, it must be made clear in the regulation that the DoH's failure to act on a particular claim is not explicit or implicit approval of that claim.

Sufficient statutory authority exists in section 15 of the Foodstuffs Act to create and enforce such a procedure. In addition, it should be made clear that the failure to submit a

complete dossier may be a violation of section 5 of the Foodstuffs Act, or be subject to other penalties as the Minister may provide for under section 15(5). Care must be taken in this respect, however. As discussed below, since the guidelines are unenforceable, the regulations must provide sufficient specification of the information to be submitted in the dossier, such that a failure to provide all discovered articles which contradict a proposed claim is a contravention of the regulations, not just of the guidelines.

Regulatory procedures must be in the regulations, not guidelines

As briefly mentioned above, the procedures to be utilized by the Minister, DG or Directorate: Food Control, cannot appear only in the guidelines, but must expressly be set out in the relevant regulation to which the procedure relates. At present, regulation 61 governing enhanced function claims places the responsibility for granting or denying approval on the Director General, with the procedures in terms of which approval is granted being articulated only in the unenforceable draft guidelines. In general, guidelines should be limited to explaining and expanding upon what is contained in regulations, which in turn are expressly authorised by legislation.

Reduction of disease risk claims (draft regulation 62)

In our experience, reduction of disease claims are often – whether unwittingly or deliberately – conflated with approved treatment for such diseases. In our view, therefore, draft regulations 62 needs to be amended so as to ensure that such health claims are not permitted. We therefore propose the following amendment:

> (i) the working of the reduction of disease risk claim in column II of Table 2 may not be added to, omitted, reduced, or altered in a way which will result in a change of meaning or which will result in a change of emphasis; **[and]**
> (ii) no health claim may attribute any degree of a disease risk reduction to specific dietary guidelines**[.]**; and
> (iii) no health claim may conflate reduction of disease risk with treatment of the disease.

Enteral foods (draft guideline 14)

In addition to similar concerns raised in connection with draft regulation 61 and draft guideline 13, draft guideline 14 faces additional problems. Firstly, draft guideline 14 is absent from the table of contents to the draft guidelines. Second, there is no reference to enteral foods anywhere in the draft regulations other than as part of the definition of an

enhanced function claim. Finally, there is no specific definition of the term in the Foodstuffs Act, the draft regulations or the draft guideline itself. In order to ensure proper regulation of such foodstuffs, a definition is necessary in the regulations themselves.

Provisions dealing with penalties

The Foodstuffs Act provides for offences and penalties in sections 17 and 18, further permitting the Minister – in accordance with section 15(5) – to create regulations "for any contravention of or failure to comply with its provisions, not exceeding the penalties proscribed for" in the Foodstuffs Act. Yet the regulations only provide for penalties in relation to the production of documents relating to certain allergens (draft regulation 50(d)) and the production of documents substantiating the nutritional information associated with a health or nutrition claim (draft regulation 64(5)). For its part, draft guideline 7(1)(d) also provides that a person shall be guilty of an offence for the use of misleadingly incorrect names of any bacterium.

In addition to the insufficiency of these provisions, they are also somewhat problematic. First, a non-binding guideline cannot propose to proscribe an offence. Specific authority to proscribe any conduct in regulations must first appear in the empowering statute and subsequently given detail in the regulations. Second, a separate regulation which proscribes offences and penalties should be added. Third, the proscribed conduct should be more comprehensive in its coverage so that all the regulations are enforceable and not just those relating to allergens and mandatory nutritional information. Failure to provide for any penalties leaves the regulations in a state of dubious enforceability.

Conclusion

We thank the DoH for this opportunity to provide written input on the draft regulations. Should you require any further input and/or clarifications on this submission, please contact Brian Honermann at (011) 356 4108 or by e-mail at honermannb@alp.org.za.

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