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TOBACCO PRODUCTS CONTROL AMENDMENT BILL,

SUBMISSIONS BY GALLAHER GROUP PLC

1. **Introduction**

1.1 Gallaher Group Plc ("Gallaher") is an international tobacco company with headquarters in the UK and employs over 12,000 people worldwide. The Group has manufacturing plants in Austria, Canary Islands, Kazakhstan, Poland, Romania, Russia, South Africa, Sweden, Ukraine and the United Kingdom.

1.2 Gallaher has had an operations presence in South Africa through it's local subsidiary, Gallaher South Africa (Pty) Ltd since 2005 located in the Ekurhuleni Municipality of Gauteng which consists of a manufacturing facility of 44 000 square meters still under development. Gallaher manufactures and distributes an international portfolio of brands and employs 224 people in South Africa.

1.3 Gallaher adheres to all relevant laws and regulations around the world and has policies and procedures to ensure that the highest standards of conduct are employed in product manufacture, presentation and sale, in all business regions. Gallaher recognises that, as there are health risks associated with smoking, governments around the world have the right and the responsibility to regulate the sale, marketing and use of tobacco products. However, regulation needs to balance public health policy objectives, while at the same time allowing adults to exercise of their right to smoke. Issues surrounding product regulation, smoking and health can be best met by governments and tobacco manufacturers working together on an agreed course of action. Product regulation should be balanced, practical and proportionate. It should furthermore be based on sound scientific findings and focus on:

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1.3.1 developing an understanding of the factors that contribute to risk;

1.3.2 reducing the risks associated with tobacco usage;

1.3.3 keeping consumers regularly informed of inherent risks and any subsequent or potential reductions in risk.

1.4 Gallaher has decades of research on tobacco products and welcomes the opportunity to share the information contained in this submission on the Tobacco Products Control Amendment Bill of 1 September 2006 ("the Bill") with the Parliamentary Health Portfolio Committee.

1.5 Gallaher believes that any South African tobacco product control legislation should align with developments internationally.

2. Overview of Gallaher's Submissions

2.1 Gallaher supports the South African Ministry of Health in its endeavours to ensure good manufacturing practices for tobacco products. It also supports the Bill insofar as it seeks to ensure that smokers show consideration to others and that they avoid smoking in the presence of children.

2.2 Gallaher does, however, have certain concerns about the Bill as follows:

2.2.1 The definition of "*ingredient*" is too broad and shifts responsibility for certain ingredients of tobacco products from farmers and packaging material suppliers to tobacco manufacturers in an inappropriate way;

2.2.2 The proposed Section 3A(3) potentially makes South African standards for tobacco product manufacture applicable to tobacco products manufactured in South Africa and exported to, and sold in, foreign countries. This should be deleted from the Bill.

2.2.3 The word "*substances*" contained in the proposed Section 6(d)(i) should be substituted with the word "*ingredients*", subject to an amendment to the definition of "*ingredient*".

2.2.4 The Minister's power to make regulations in relation to standards for emissions contained in the proposed Section 6(1)(d)(i) should be limited to tar, nicotine and carbon monoxide only.

2.2.5 The power of the Minister to prescribe regulations in respect of the ignition propensity of cigarettes contained in the proposed Section 6(1)(d)(iii) should be deleted as Gallaher submits that low ignition cigarettes have relatively little ability to combat fire hazards when compared with other more effective methods

2.2.6 Before regulations can be promulgated for methods of conformity testing and compliance with any prescribed standards, investigation should be done to ascertain which international standards should apply in South Africa.

2.2.7 Tobacco product manufacturers should not be compelled to submit their proprietary or confidential information or their intellectual property to the Minister or the public as potentially envisaged in terms of the proposed Section 6(1)(f).

2.3 These concerns are dealt with in detail below. References to section numbers are to the section numbers as they would appear in the Tobacco Products Control Act, 1993 ("the Act") as amended by the Bill.

3. <u>Definition of "ingredient"</u>

3.1 The Bill defines "ingredient" as:

> *"any product component, material used to manufacture such component, residual substance from agricultural practices, storage*

and processing and substances that can migrate from packing into the product".

3.2 Gallaher submits that this definition is inappropriate because:

3.2.1 Agricultural products are controlled by farmers in accordance with agronomic procedures and good agricultural practices. They are not added by cigarette manufacturers in the production of finished goods. Tobacco manufacturers have no responsibility for agricultural products;

3.2.2 Tobacco may be treated against infestation by pests whilst stored in warehouses. These treatments are applied in accordance with strict regulations however, once again, tobacco manufacturers have no responsibility for this;

3.2.3 Tobacco manufacturers are similar to food processing companies in the sense that they buy an agricultural commodity from farmers and traders, blend it, add some ingredients and pack it for final use by consumers.

3.3 Any regulation relating to agricultural residues should concentrate on the raw material at the level of the farmer. To legislatively make tobacco product manufacturers responsible for the agricultural residues of the raw materials is shifting the responsibility from where it ought to lie, namely on tobacco farmers. Notwithstanding this, the tobacco product manufacturing companies have recognised the need for an understanding of this area through the auspices of Corporation Centre for Scientific Research Relative to Tobacco ("CORESTA") have provided guidance to growers and other suppliers of materials included in the manufacture of tobacco products on the implementation of good agricultural practice and other manufacturing practices.

3.4 Similar practices apply to packaging materials. Gallaher monitors its suppliers, however the obligation to ensure that all laws are complied with should lie with packaging material manufacturers.

3.5 Gallaher submits that a more appropriate definition of "ingredient" would be:

> *"Any product or material used in the manufacture of tobacco products excluding residual substances from agricultural practices, storage and processing and substances that can migrate from packing into the product".*

3.6 Gallaher recommends the above definition of ingredient as the most appropriate for both regulators in setting standards and for manufacturers and importers in disclosing to government authorities information about the content of tobacco products.

4. **Section 3A: Standards for Manufacturing and Export of Tobacco Products**

4.1 The new Section 3A is proposed to read as follows:

> *"(1) No person shall manufacture a tobacco product unless it complies with such standards as may be prescribed.*
>
> *(2) Every manufacturer of a tobacco product shall provide such information about the product and its emissions to the Minister and the public as may be prescribed, in the prescribed manner and within the prescribed time.*
>
> *(3) (a) No person shall export a tobacco product from the Republic unless the tobacco product meets the product and testing standards of the country of final destination.*

(b) If no such standards exist in the country of final destination, the provisions of this section apply."

4.2 Gallaher makes detailed submissions in connection with product information and emissions in paragraph 5.2.1 below.

4.3 Naturally, Gallaher meets the standards of all export countries as products could not be sold there unless those standards are met. To the extent, however, that the export country has no such standards, it is submitted that South African law should not seek to have extra-territorial effects and prescribe standards that should be imposed for products sold there. In any event Gallaher ensures its own standards are applied to such markets.

4.4 Gallaher accordingly submits that the proposed Section 3A (3) should be deleted from the Bill.

5. **Section 6(1)(d)**

5.1 As amended, Section 6(1)(d) of the Act will permit the Minister to make regulations in respect of:

"(d) the standards that a tobacco product must comply with, including –

(i) the amounts of substances that may be contained in the product or its emissions;

(ii) substances that may or may not be added to the product;

(iii) the ignition propensity of cigarettes; and

(iv) product design and composition."

5.2 Subsections (i), (ii) and (iii) are dealt with individually below:

5.2.1 **Subsection (i): Amount of substances that may be contained in the product or its emissions**

5.2.1.1 The word "substances" is an undefined term. Gallaher submits that this is likely to cause confusion and recommends that the defined term "ingredients" be substituted, subject to the change in the definition itself referred to in paragraph 3.5 of these submissions. On this basis, Gallaher would support this subsection of the Bill, provided that the Minister's powers are exercised in line with international standards as described in the following paragraphs.

5.2.1.2 There are standardised testing methods for tar, nicotine and carbon monoxide. There is also a great deal of research and publicly available information, including research performed by Gallaher, on the emissions of tar, nicotine and carbon monoxide from tobacco products. There are currently no standardised test methods other than for tar, nicotine and carbon monoxide.

5.2.1.3 In the circumstances, Gallaher submits that it is not possible for any tobacco manufacturer to provide meaningful emission data other than for tar, nicotine and carbon monoxide. Gallaher recommends that Section 6(1)(d)(i) should therefore read:

"The amounts of ***ingredients*** (substances) *that may be contained in the product or its* ***tar, nicotine and carbon monoxide****" emissions.*
(Gallaher's additions are in bold and the deleted word is in brackets)

5.2.2 **Subsection (ii): Substances that may or may not be added to the product**

5.2.2.1 Section 6(1)(d)(ii) of the Act as amended by the Bill will permit the Minister to make regulations in respect of:

"substances that may or may not be added to the product".

5.2.2.2 Gallaher repeats its submissions regarding the substitution of the word "substances" with the word "ingredients" in this proposed section.

5.2.2.3 Ingredients are included in tobacco products for physical reasons i.e. (adhesives to hold the cigarette together) or cigarette paper ingredients for tar reduction purposes. Certain flavouring ingredients are added to tobacco at extremely low levels in order to add aroma and flavour. The situation regarding standards for ingredients that may or may not be added to tobacco products varies from country to country around the world. Around 25 countries have lists of ingredients that may be used in tobacco products. Some lists contain approved ingredients, while others identify those ingredients that are prohibited from use in any tobacco product. The UK was amongst the first countries in Europe to publish a list of approved tobacco ingredients which today numbers around 600 approved ingredients, up to certain levels, for product manufacture.

5.2.2.4 This comprehensive list was largely managed via a voluntary agreement between tobacco manufacturers and importers and UK Health Ministers. Tobacco companies could not produce products containing ingredients that are not on the approved list.

5.2.2.5 Other countries with approved ingredients lists include:

Austria, Belgium, Croatia, Czech Republic, France, Germany, Hungary, Lithuania, Poland, Romania, Slovakia, Slovenia, Spain, Switzerland.

5.2.2.6 The list of permitted ingredients also differs from country to country. The EU Directive 2001/37/EC concerning the manufacture, presentation and sale of tobacco products under 'Article 12 Common list of ingredients' envisaged the composition of a common list of ingredients authorised for use in tobacco products. However, it soon became clear that a common list of ingredients could not be produced until scientifically agreed criteria have been drawn up to assess any public health impact.

5.2.2.7 Gallaher is of the view that before legislation on ingredients should be passed, a comparative analysis of approved and prohibited ingredients lists from other countries such as those referred to above, should be undertaken. Accordingly, Gallaher submits that the proposed Section 6(d)(ii) should be deleted from the Bill.

5.2.3 **Subsection (iii): The Ignition Propensity of Cigarettes**

5.2.3.1 Lower ignition propensity ('LIP') is usually the term used to describe cigarettes that go out when left unattended under certain laboratory test conditions.

5.2.3.2 Some manufacturers have used banded cigarette paper to achieve compliance with recent laws introduced in Canada, New York and Vermont.

Some believe that these cigarettes, which pass the American Society for Testing and Material (ASTM) test, are less likely to ignite upholstery, bedding, furniture, etc.

5.2.3.3 To date there is no reliable evidence that cigarettes designed to pass the ASTM Test, are effective in reducing fires in the real world. Moreover, in terms of practical application, concerns have been raised about the relevancy of the 'test' as ignition propensity is significantly influenced by the contact materials. Therefore, it is important that regulators develop expertise in understanding cigarette ignition propensity and have the resources available and the ability to perform the necessary scientific evaluation required to develop and, where appropriate assess, validate and implement a LIP standard.

5.2.3.4 It is important to note that whatever standards are adopted, anything that burns, if handled carelessly, can cause a fire. Furthermore, it is imperative that standards are introduced that require furniture and bedding materials to contain fire retardants and smoke-detector and fire-alarm legislation should be made mandatory, as is the case in many countries already.

5.2.3.5 Any standards mandating LIP cigarettes should take into account and address the significant risk that consumers may behave carelessly in the belief that LIP cigarettes will pose a lower fire risk for them in day-to-day use than ordinary cigarettes.

5.2.3.5 Gallaher advocates the development of an evidence-based and holistic policy that is outcome-focussed

on achieving a significant real world reduction in fire incidence. Gallaher is willing to participate in discussions with regulators and to provide expertise and assistance as necessary..

6. **Section 6(1) (e): Methods to assess conformity, and methods of testing and measuring compliance with any prescribed standard**

6.1 In terms of this proposed section, the Minister shall be given the power to make regulations in respect of:

"methods to assess conformity, and methods of testing and measuring compliance, with any prescribed standards".

6.2 Gallaher is committed to reaching scientific consensus with any regulatory body on an approach to product assessment that has relevance to public health.

6.3 Difficulties in reaching consensus have arisen even in relation to a relatively simple standard such as that employed to determine the smoke yield from cigarettes.

6.4 The current International Standards Organisation ("ISO") methodology is under review. The World Health Organisation and others have attempted to develop other testing methodologies but as yet no agreement has been reached and no replacement has been found. Until such replacements are forthcoming it is Gallaher's belief that the existing methods continue to have merit as they will continue to provide assurances that overall smoke yields have been reduced over time.

6.5 It should be noted that the European Commission does not propose to review the current standards set out in Directive 2001/37/EC until solid evidence shows that better methods exist to replace them. Scientific and technological development in this area is encouraged. No modification to the Directive is envisaged until scientifically sound internationally agreed

alternative methodologies emerge to provide more realistic and more meaningful information.

6.6 In relation to laboratories, all manufacturers carry out a range of tests on a regular basis, generally in their own accredited laboratories to verify that the cigarettes they are producing meet certain specifications and that the information reported to governments and/or printed on the packs is accurate.

6.7 Gallaher strongly believes that within the South Africa legislation no laboratory should be granted the approval or authorisation to check tobacco product compliance unless it possesses the ISO 17025 (or equivalent) accreditation. It is also inconceivable that any laboratory be considered for testing or verification without first being accredited in the relevant testing methods.

6.8 It is also Gallaher's strongly held view that in situations where any potential discrepancies are found, manufacturers and importers must be given a reasonable opportunity to address such discrepancies with the competent laboratory or the State authority.

6.9 Gallaher submits that further investigation is required in order to establish which international standards should apply in South Africa. Until such investigations have been undertaken, Gallaher submits that this subsection should be deleted from the Bill.

7. Section 6(1)(f): Making available prescribed information

7.1 The Minister shall be entitled to make regulations in respect of:

> *"Subject to Chapter 2 of the Constitution of the Republic of South Africa, 1996, any information that a manufacturer of a tobacco product must submit to the Minister and to the public, including information in respect of –*

(i) research conducted into a tobacco product by a manufacturer or by a person who conducted research paid for in whole or in part by a tobacco manufacturer;

(ii) the quantity of a tobacco product manufactured;

(iii) marketing expenditure; and

(iv) information on product composition, ingredients, hazardous properties and emissions".

7.2 In principle, Gallaher is prepared to make available all of the listed information subject to its rights to protect its proprietary and confidential information (including, without limitation, trade secrets) and intellectual property. Confidential information and intellectual property rights, such as the flavourings added to tobacco products that give each brand its individual and distinctive taste and aroma are of huge value. Gallaher takes enormous steps to protect this information from our competitors and counterfeiters, and such information is only known to a handful of people within the company.

7.3 Once proprietary or confidential information and/or Gallaher's intellectual property is disclosed to the public, competitors or counterfeiters it will be irretrievably lost and Gallaher will suffer significant irreparable damage. In Gallaher's view, the sections of Chapter 2 of the Constitution referred to in the proposed section 6(1)(f) are:

7.3.1 Section 14 which gives all persons a right to privacy including, without limitation, the right not to have their property searched, possessions seized or the privacy of their communications infringed;

7.3.2 Section 25 which protects property ownership rights.

7.4 Gallaher submits that it is trite law under Section 8(4) of the Constitution, that these rights apply to juristic persons including Gallaher and it's local subsidiary company as well as to natural persons. In addition, property is not limited to land in terms of Section 25(4)(b) and it is submitted that the

protection afforded by the Constitution clearly extends to intellectual property as well.

7.5 Gallaher believes that it should not be required to release proprietary or confidential information and intellectual property. Given the importance of this information to Gallaher and the extreme consequences that could result to it if the information fell into the hands of competitors or counterfeiters, Gallaher's view is that the proposed section of the Bill should make it clear that no confidential information or intellectual property need be disclosed. Accordingly, Gallaher recommends that the following Section 6(1)(g) be added and that the existing proposed Section 6(1)(g) be renumbered as Section 6(1)(h):

> *"No manufacturer of a tobacco product shall be required to submit any information which constitutes its registered or unregistered intellectual property or trade, business or industrial information with a particular economic value and which is not generally available to, or known by others".*

7.6 The proposed wording includes wording from the definition of "confidential information" contained in the Competition Act, 1998.

8. CONCLUSION

8.1 Bringing about real and meaningful reductions in the risks associated with tobacco usage involves many complex and technical issues. This is particularly true in the setting of standards to cover the composition and analysis of tobacco products when there are no scientifically sound internationally agreed alternative methodologies.

8.2 A World Health Organisation recommendation is that regulators be aware of responsibilities in developing regulations and ensure that proper procedures are followed and that the information is properly evaluated and disseminated.

8.3 Impractical and inappropriate regulation will severely impact on the tobacco product manufacturing industry in South Africa. The potential loss of jobs at Gallaher alone will be significant and it is submitted that this should not be an effect of the Bill.

8.4 Gallaher repeats its support of the Ministry of Health's efforts to appropriately regulate the manufacture and sale of tobacco products but submits that the development of product regulation should keep pace with, but not exceed, scientific understanding and development. The portions of the Bill on which Gallaher has made its submissions deal with the potential for onerous and impractical regulations.

8.5 Stakeholders such as Gallaher, as an expert in tobacco science, should play a significant role in the future development of this Bill. Gallaher has considerable experience in many of these technical issues and would welcome the opportunity to share its research and knowledge with the Ministry of Health in order to assist it in developing sensible approaches. As the science of tobacco research develops and more knowledge becomes available, consideration can be given to regulations of the sort referred to in this submission.

GALLAHER GROUP Plc

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