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INHOUD

IMPORTANT ANNOUNCEMENT

Closing times PRIOR TO PUBLIC HOLIDAYS for

GOVERNMENT NOTICES, GENERAL NOTICES, REGULATION NOTICES AND PROCLAMATIONS 2011

*The closing time is **15:00** sharp on the following days:*

- **4 August,** Thursday, for the issue of Friday **12 August 2011**
- **8 December,** Thursday, for the issue of Thursday **15 December 2011**
- **14 December,** Wednesday, for the issue of Friday **23 December 2011**
- **20 December,** Tuesday, for the issue of Friday **30 December 2011**
- **28 December,** Wednesday, for the issue of Friday **6 January 2012**

Late notices will be published in the subsequent issue, if under special circumstances, a late notice is accepted, a double tariff will be charged

The copy for a SEPARATE *Government Gazette* must be handed in not later than three calendar weeks before date of publication

BELANGRIKE AANKONDIGING

Sluitingstye VOOR VAKANSIEDAE vir

GOEWERMENTS-, ALGEMENE- & REGULASIE-KENNISGEWINGS ASOOK PROKLAMASIES 2011

*Die sluitingstyd is stiptelik **15:00** op die volgende dae:*

- **4 Augustus,** Donderdag, vir die uitgawe van Vrydag **12 Augustus 2011**
- **8 Desember,** Donderdag, vir die uitgawe van Donderdag **15 Desember 2011**
- **14 Desember,** Woensdag, vir die uitgawe van Vrydag **23 Desember 2011**
- **20 Desember,** Dinsdag, vir die uitgawe van Vrydag **30 Desember 2011**
- **28 Desember,** Woensdag, vir die uitgawe van Vrydag **6 Januarie 2012**

Laat kennisgewings sal in die daaropvolgende uitgawe geplaas word. Indien 'n laat kennisgewing wel, onder spesiale omstandighede, aanvaar word, sal 'n dubbeltarief gehef word

Wanneer 'n APARTE *Staatskoerant* verlang word moet die kopie drie kalenderweke voor publikasie ingedien word

GOVERNMENT NOTICES
GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. R. 586 **22 July 2011**

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

REGULATIONS RELATING TO MEDICAL DEVICES

The Minister of Health intends, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) ("the Act"), in consultation with the Medicines Control Council, to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations in writing on the proposed regulations to the Director-General: Health, Private Bag x828, Pretoria, 0001 within three months from date of publication of this notice.

SCHEDULE

Definitions

1. In this Schedule, and any word or expression to which a meaning has been assigned in the Act shall have that meaning, and unless the context otherwise indicates—

"abbreviated assessment" means the assessment by the Council of a medical device that is already registered by a regulatory authority outside the Republic;

"Act" means the Medicines and Related Substances Act, Act No 101 of 1965, as amended;

"appropriately qualified person" means a person in possession of qualifications recognised by the Council as relevant to medical devices and

includes clinical engineers, biomedical engineers, technicians, pathologists and medical physicists;

"assessment" means the establishment by the Council of conformity of medical devices to standards of safety, quality and performance as determined by the Council;

"authorised representative" means a person designated in writing by a manufacturer or importer to represent that manufacturer or importer with regard to that manufacturer or importer's obligations under these regulations;

"custom made medical device" means a medical device made in accordance with a prescription by a qualified health care professional;

"health establishment" means a health establishment as defined under section 1 of the National Health Act, 2003 (Act No. 61 of 2003);

"instructions for use" means information provided by the manufacturer on the proper use of a medical device or any precautions to be taken in respect thereof;

"reagent" means chemical, biological or immunological components, solutions or preparations intended by the manufacturer to be used as medical devices;

"unique identification number" means a number used by the Council to identify a medical device; and

"user error" means an act that has a different result than that intended by the manufacturer or different than that expected by the operator.

Categories of medical devices

2. The following are categories of medical devices:

(a) Category C1: non-invasive medical devices which do not penetrate the body;

(b) Category C2: invasive medical devices that in whole or in part, penetrate the body, either through a body orifice or through the surface of the body;

(c) Category C3: active medical devices whose operation depend on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting energy;

(d) Category C4: combination medical devices that incorporate, as an integral part, a substance which, if used separately, can be considered to be a medicine, and which act son the human body with action ancillary to that of the medical device;

(e) Category C5: medical devices that are manufactured from or incorporating animal or human cell, tissue or derivative thereof;

(f) Category C6: medical devices used for sterilizing or disinfecting other medical devices;

(g) Category C7: medical devices used for contraception or the prevention of the transmission of sexually transmitted diseases; and

(h) Category C8: *in vitro* diagnostic medical devices which, whether used alone or in combination, are intended by the manufacturer for the *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Classes of medical devices

3. (1) Medical devices are classified as low risk, low moderate risk, moderate high risk and high risk.

(2) The Minister may, by notice in the Gazette, determine further classes of medical devices.

Prohibition on sale of medical devices which are subject to registration and are not registered

4. (1) No person shall sell any medical device which is subject to registration by virtue of a resolution published in terms of subregulation (2) unless it is registered.

(2) The Council may from time to time by resolution determine that a medical device or category or class of medical devices mentioned in the resolution shall be subject to registration in terms of these regulations.

(3) Any such resolution shall be published in the Gazette by the Registrar and shall come into operation on a date specified in that notice.

Registration of medical devices

5. (1) An application for the registration of a medical device shall be submitted on the form determined by the Council.

(2) Such an application shall be accompanied by an application fee prescribed by the Minister.

(3) If after the consideration of the application the Council is satisfied that the medical device is safe, of good quality and performs as intended, the Council shall approve the registration of such medical device.

(4) Registration under subregulation (3) may be made subject to conditions as may be determined by the Council to ensure the safety, quality and efficacy of the medical device.

(5) The Council may, for the purposes of considering an application as contemplated in subregulation (3), subject a medical device to an assessment or abbreviated assessment process.

(6) The Council may require, in relation to an application, the submission of-

(a) samples of the medical device for testing purposes;
(b) brochures or technical documentation; or
(c) any other material relating to the medical device.

(7) Custom-made medical devices are not subject to registration, but are subject to post-marketing surveillance including adverse event monitoring.

(8) When the Council has approved the registration of a medical device, the Registrar shall register such medical device and enter into the register such particulars as may required in terms of these regulations and shall issue to the applicant a certificate of registration in the form as determined by the Council.

(9) A register for medical devices shall include the following information with regard to a medical device:

(a) name and address of the applicant;
(b) name of manufacturer or importer;
(c) address of manufacturer or importer;
(d) name of the medical device;
(e) unique catalogue, list or product number;
(f) number according to an internationally recognised device nomenclature system as approved by the Council;
(g) category and class of medical device;
(h) brief description of the medical device and its use; and
(i) any other information that the Council may deem fit.

(10) The certificate contemplated in subregulation (8) shall include the following information:

(a) name and address of applicant;
(b) name and address of manufacturer;
(c) authorised representative of the applicant;
(d) name of medical device, its description and purpose;
(e) registration number;
(f) unique identification number, where practicable;

(g) number according to an internationally recognised device nomenclature system as approved by the Council;

(h) category and class of medical device; and

(i) date of issue of the certificate.

(11) The Registrar shall as soon as possible publish in the Gazette the details of medical devices registered during that year.

Notification of medical devices available on the market

6. (1) Manufacturers, importers or their authorised representatives shall, in respect of their medical devices that are available on the market in the Republic at the time of commencement of these regulations, within a period of two years, notify the Registrar of such availability by submitting the following information:

(a) name of manufacturer or importer;

(b) address of manufacturer or importer;

(c) name of medical device;

(d) unique identification number, where practicable;

(e) number according to an internationally recognised device nomenclature system as approved by the Council;

(f) category or class of medical device; and

(g) brief description of the medical device and its use.

(2) The Registrar shall allocate a notification number for a medical device in respect of which information referred to in subregulation (1) has been submitted.

(3) Notification referred to in subregulation (1) is not registration as contemplated in regulation 4.

(4) Notwithstanding subregulation (1) the Council may require a medical device to comply with any requirements that the Council may determine in order to ensure that the medical device is safe and of good quality.

Combination devices

7. A medical device that has a medicinal component in it is subject to these regulations only in respect of its component that is not a medicinal component and its medicinal component shall be dealt with as a medicine. .

Amendments and update of registration

8. (1) The particulars of registration may on application by the holder of a certificate of registration be amended by the Registrar with the approval of the Council.

(2) The application referred to in subregulation (1) shall be accompanied by an application fee as determined by Council.

Transfer of certificate of registration or licence

9. A certificate of registration or licence contemplated is regulation 10 may with the approval of the Council be transferred by the holder thereof upon application accompanied by an application fee as determined by Council to another person.

Licensing of manufacturers, exporters and importers

10. (1)The Council shall upon application accompanied by an application fee as determined by the Council, issue a licence to a manufacturer, exporter, importer or distributor of a medical device if the Council is satisfied that the manufacturing, exportation or importation of the medical device is in accordance with the good manufacturing, exportation or importation practice as determined by the Council.

(2) An application referred to in subregulation (1) shall include the following information:

(a) an indication of whether the applicant for licence is a manufacturer, an importer or a distributor;

(b) the name and contact details of the place of business of the applicant for licence;

(c) the name of an authorised representative;

(d) where the applicant for licence has contracted another party to apply for a licence on its behalf, the name and contact details of the place of business of that other party; and

(e) any other information as may be deemed necessary by the Council.

(3) Notwithstanding subregulation (1), a manufacturer, importer and distributor shall have a period of two years from the date of commencement of these regulations to obtain a licence.

(4) A licence issued under this regulation shall be valid for a period of five years and may be renewed upon payment of a renewal application fee as determined by the Council.

(5) No manufacturer, importer or distributor of a medical device shall, after two years from the date of commencement of these regulations, manufacture, import or distribute a medical device without a licence contemplated in subregulation (1).

Duties of licence holders

11. A person issued with a licence in terms of regulation 10 shall-

(a) ensure that an instruction manual in made available with each and every medical device sold;

(b) ensure that each medical device sold is labelled in accordance with these regulations and has instructions for use containing information as determined by Council including side-effects, contra-indications, warnings, and after-care maintenance; and

comply with good manufacturing practice.

Cancellation of registration or licence

12. The Council may order the Registrar to cancel the registration of a medical device issued in terms of regulation 10-

(a) in case of non-compliance with these regulations or licence conditions; or

(b) as a result of negative post market surveillance reports or misleading advertisements.

Advertisements and promotion

13. (1) Only registered medical devices or medical devices in respect of which notification in terms of regulation 6 was made may be advertised or promoted.

(2) The Council may by notice in the Gazette prohibit or restrict the advertisement and promotion of certain medical devices to the general public.

(3) No advertisement or promotion may contain a claim, statement or any other content which deviates from or is in conflict with the evidence submitted in the application for registration or which cannot be substantiated.

(4) A written advertisement for a medical device shall contain-

(a) the name of the medical device;

(b) its description;

(c) the registration number allocated to it;

(d) the licence holder's contact information; and

(e) the intended use of the medical device.

Labelling and instructions for use

14. (1) The labelling and instructions for use for medical devices shall be in at least English.

(2) The format, content and location of the label shall be appropriate to the particular device and its intended use.

(3) The label of a medical device shall, where practical, include-

(a) its name;

(b) a code linking the medical device to a number according to an internationally recognised device nomenclature system;

(c) a serial number, batch number and material number affixed to it; and

(d) its expiry date.

(4) If labelling on each medical device is not practicable, the information shall be set out in the leaflet, package insert or other information supplied with, or applicable to, one or multiple devices.

(5) Instructions for use shall-

(a) make clear the intended use of the medical device;

(b) be in plain language and, where appropriate, supplemented with drawings and diagrams so that persons reading the instructions are appropriately informed;

(c) in the case of low or moderate risk medical devices, be abbreviated if they can be used safely and as intended without any such instructions;

(d) include a clear indication of any requirement for special facilities, special training, or particular qualifications to use it;

(e) contain warnings about foreseeable user error or possible harm and severity that could result from such user error and include recommended corrective action;

(f) have sufficient details for the person using the medical device to identify it;

(g) where applicable, provide for the expiry date;

(h) where applicable, provide for special storage or handling conditions at the appropriate packaging level;

(i) provide for warnings, precautions, limitations or contra-indications;

(j) in the case of reusable devices, provide information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of de-contamination and any restriction on the number of reuses; and

(k) comply with any other requirement set from time to time by the Council.

Importation or exportation of medical devices

15. (1) A person may export medical devices at any port of exit but shall only import medical devices through any of the following ports of entry —

(a) Cape Town Airport or harbour;

(b) Port Elizabeth Airport or harbour;

(c) King Shaka International Airport or Durban harbour; and

(d) OR Tambo International Airport.

(2) A person shall only import or export-

(a) a medical device if such person is in possession of license issued in terms of regulation 10 and the medical device is registered in the Republic;

(b) an unregistered medical device if such person has been specially authorised by the Council.

Post marketing surveillance

16. (1) A licence holder shall have in place a post-marketing surveillance system.

(2) A person using a medical device shall report to the Council or head of a health establishment any adverse event within 24 hours after being aware of such adverse event.

Recall of medical devices

17. (1) The Council may, on the basis of an adverse event report it received in terms of regulation 15, recall a medical device.

(2) No person shall sell a medical device that has been recalled in terms of subregulation (1).

(3) A licence holder shall inform the Council of recalls of its medical devices that occurred outside the Republic.

Disposal of medical devices

18. The head of a health establishment, a person using a medical device or licence holder shall ensure that the disposal of a medical device is, where applicable, done in accordance with manufacturer's instructions.

Persons using medical devices in health establishments

19. (1) The head of any health establishment must ensure that persons who are employed at such health establishment and who use medical devices are appropriately trained and competence to operate, use or otherwise deal with such medical devices.

(2) The head of a health establishment shall ensure that any patient using a medical device at that health establishment is appropriately informed to use such medical device.

Duties of the heads of health care facilities

20. The head of a health establishment shall ensure that-

(a) medical devices are used safely;
(b) adverse events are reported as required;
(c) medical devices are maintained according to the manufacturer's instructions;
(d) a procedure for reporting complaints relating to the use of medical devices is in place;
(e) a record is kept of-

(i) medical devices service and repairs history;
(ii) staff training records; and
(iii) adverse event reports.

Used or refurbished medical devices

21. (1) A person selling a used or refurbished medical device shall-

(a) provide the purchaser with a maintenance history of the medical device; and
(b) when required, perform all the tests required by the purchaser or the Council in order to ensure proper functioning of the device.

(2) The Council may from time to time publish guidelines in relation to the acquisition, use and safety of used or refurbished devices.

Offences

22. Any person who contravenes the provisions of these regulations shall be guilty of an offence and if found guilty, be liable to a fine or imprisonment for a period not exceeding 5 years or to both fine and such imprisonment.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH

No. R. 587 **22 July 2011**

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965): AMENDMENT

The Minister of Health, in consultation with the Medicines Control Council, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), intends to make the regulations in the Schedule.

Interested persons are invited to submit, within three months of publication of this notice, comments on the proposed regulations to the Director-General: Health, Private Bag X828, Pretoria 0001.

SCHEDULE

Amendment of Regulation 1

1. Regulation 1 of the Regulations is hereby amended by the insertion of the following definition after the definition of **"clinical trials"**:

"complementary medicine" means a medicine that is used-

(a) or intended to be used for, or manufactured or sold for use in assisting the innate healing power of a human being or animal; and
(b) in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982).

Amendment of Regulation 2

2. Regulation 2(1) of the Regulations is hereby amended by the substitution for paragraph (a) of the following paragraph:

"(a) (i) are pharmaceutically equivalent, i.e, contain the same amount of active substances in the same dosage form, meet the same or comparable standards and are intended to be administered by the same route; or

(ii) are pharmaceutical alternatives, ie contain the same active moiety but differ either in chemical form of that moiety or in the dosage form or strength, administered by the same route but are otherwise not pharmaceutically equivalent; and"

Amendment of Regulation 6

3. Regulation 6 of the Regulations is hereby amended by-

(a) the substitution for paragraph (b) of the following paragraph:

"(b) approved name and quantity of each active ingredient of the medicine contained in a dosage unit or per suitable mass or volume or unit;"

(b) the addition of the following paragraphs:

"(h) name of the final product release responsibility;
(i) date of registration; and
(j) conditions of registration, if any."

Amendment of Regulation 8

4. Regulation 8 of the regulations is hereby amended by-

(a) the substitution for paragraph (c) of subregulation (1) of the following paragraph:

" (c) the registration number of the medicine allocated in terms of section 15(6) of the Act or the application number allocated by Council in terms of the Act followed by the expression Act 101/1965;"

(b) the addition of the following paragraphs in subregulation (1):

" (z) the category of medicine immediately preceding the registration or application number;

(aa) the pharmacological classification of the medicine; and

(bb) in the case of a complementary medicine-

(i) the discipline of the medicine; and
(ii) the words: "use according to the principles of the discipline".

(c) the substitution for subregulation (2) of the following subregulation:

" (2) If the medicine package bears both an immediate container label and an outer label, the requirements of sub-regulation (1) shall apply to the outer label as well: Provided that it shall be sufficient to provide on the immediate container label-

(i) in the case of medicines intended for administration by injection and having a total volume not exceeding 5 ml, the details prescribed in paragraphs (b), (e), (m), (n), (o), (p) and (bb) of sub-regulation (1);

(i). in the case of an ointment, cream, gel or powder having a net mass not exceeding 10 grams, the details prescribed in paragraphs (b), (c), (e), (f), (n), (o), (p), (x) and (bb) of sub-regulation (1);

(iii) in the case of liquid, solution or suspension having a total volume of more than 1 ml, but not exceeding 15 ml, the details prescribed in paragraphs (b), (c), (d), (e), (n), (w), (o), (p), (x) and (bb) of sub-regulation (1);

(iv) in the case of a liquid, solution or suspension having a total volume not exceeding 1 ml, the details prescribed in paragraphs (b), (n) and (bb) of sub regulation (1);

(v) in the case of a medicine packed in blister or similar packaging, the details prescribed in paragraphs (b), (n), (o), (p) and (bb) of sub-regulation (1), repeated as frequently as is practicable."

(d) the addition in subregulation (4)(c) of the following subparagraph:

"(vii) the discipline of the medicine, if falling under category D

Amendment of Regulation 9

5. Regulation 9 of the Regulations is hereby amended by the addition in subregulation (1) of the following paragraphs:

" (t) in the case of a complementary medicine-

(i) the discipline of the medicine; and

(ii) the words: "use according to the principles of the discipline".

Amendment of Regulation 10

6. Regulation 10 of the Regulations is hereby amended by-

(a) the substitution in subregulation (1) for subparagraph (e)(v) of the following subparagraph:

" (v) the following general statement:

"Always tell your health care professional if you are taking any other medicine.

If you are pregnant or breast feeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking this medicine."

(b) the substitution in subregulation (1) for paragraph (g) of the following paragraph:

" (g) side effects, including the following general statement:

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice; "

(c) the addition of the following paragraphs in subregulation (1)

" (n) in the case of a complementary medicine-

(i) the discipline of the medicine; and

(ii) the words: "use according to the principles of the discipline".

Amendment of Regulation 11

7. Regulation 11 of the Regulations is hereby amended by the substitution for subregulation (4) of the following subregulation:

" (4) The manufacturer or wholesaler shall keep a record at the business address, of Schedule 2, 3, 4 and 5 medicines and substances in the form of invoices that will reflect."

Amendment of Regulation 12

8. Regulation 12 of the Regulations is hereby amended by the substitution for paragraphs (c) and (d) in subsection (1) of the following paragraphs:

" (c) King Shaka International Airport or Durban harbour;
(d) OR Tambo International Airport."

Amendment of Regulation 16

9. Regulation 16 of the Regulations is hereby amended by the substitution for subregulation (1) of the following subregulation:

" (1) Notwithstanding regulation 12 and subject to subregulation (3) any person entering or departing from the Republic may be in possession, for personal medicinal use, of a quantity of a Schedule, 3, 4, 5 or 6 substance, which shall not exceed a quantity required for use for a period of three months.

Amendment of Regulation 18

10. Regulation 18 of the Regulations is hereby amended by-

(a) the substitution for subregulation (1) of the following subregulation:

" (1) As contemplated in section 22C(1) of the Act, a medical practitioner, dentist or any other person registered in terms of the Health Professions Act, 1974 (Act No. 56 of 1974) or a nurse desiring to dispense or compound and dispense medicines shall apply to the Director-General for a licence to dispense or compound and dispense medicines within his or her scope of practice."

(b) the addition in subregulation (3) of the following paragraph:

" (j) the scope of practice of the applicant applying for the licence."

Amendment of regulation 22

11. Regulation 22 of the Regulations is hereby amended by the substitution in subregulation (5)(b) for subparagraph (vi) of the following subparagraph:

" (vi) category, pharmacological classification, and discipline if falling under category D."

Amendment of Regulation 23

12. Regulation 23 of the Regulations is hereby amended by the addition of the following paragraphs:

"(k) category of the medicine;
(l) pharmacological classification of the medicine;
(m) discipline of the medicine, if falling under category D."

Amendment of Regulation 25

13. Regulation 25 of the Regulations is hereby amended by-

(a) the addition in subregulation (1) of the following paragraph:

" (d) Category D = Complementary medicines intended for use in humans and animals which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine."

(b) the substitution for subsection (2) of the following subsection:

"(2) Medicines in categories A and D (human complementary medicines) are subdivided into the following pharmacological classifications:"

(c) the substitution for subregulation (3) of the following subregulation:

" (3) Medicines in categories C and D (veterinary complementary medicines) are subdivided into the following pharmacological classifications:"

Insertion of Regulation 25A

14. The following heading and regulation are inserted after regulation 25:

" **DISCIPLINES OF COMPLEMENTARY MEDICINES**

25A. Medicines in category D are subdivided into such disciplines as may be determined by the Council after consultation with the Allied Health Professions Council of South Africa."

Amendment of Regulation 26

15. The following regulations is hereby substituted for regulation 26 of the regulations:

"26. A certificate of registration substantially in the form shown below shall be issued by the Council in terms of section 15(3) after a medicine has been registered:

MEDICINES AND RELATED SUBSTANCES ACT 1965, (ACT 101 OF 1965): MEDICINE REGISTRATION CERTIFICATE

It is hereby certified that registration of the medicine described below has been approved by the Council in terms of Section 15(3)(a) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), subject to the conditions indicated.

1. Proprietary name.....

2. Registration number .....

3. Approved name of every active ingredient and quantities thereof per dosage unit or per suitable mass or volume or unit of the medicine.....

4. Dosage form .....

5. Conditions under which the medicine is registered .....

6. Name of holder of certificate of registration.....

7. Name and address of the manufacturer and the manufacturing facility... ....

8. Name of the final product release control .....

9. Name of the final product release responsibility .....

10. Conditions of registration .....

11. Date of registration .....

12. Category of medicine.....

13. Pharmacological classification medicine.....

14. Discipline of medicine, if falling under Category D.....

.....
Registrar

Issued at ..... on.. ..... 20 ....."

Amendment of Regulation 28

16. Regulation 28 of the Regulations is hereby amended by the substitution in subregulation (1) for paragraph (f) of the following paragraph:

"(f) the strength of the dosage form and the quantity of the medicine to be supplied: Provided that in the case of Schedule 6 substances the quantity to be supplied shall be expressed in figures as well as in words: Provided further that where the prescriber has failed to express the quantity in figures as well as in words, the medical practitioner, dentist, veterinarian or pharmacist dispensing the medicine may, after obtaining confirmation from the prescriber, insert the words or figures that have been omitted."

Amendment of Regulation 30

17. Regulation 30 of the Regulations is hereby amended by-

(a) the substitution for the heading of the following heading:

"REGISTER OF SPECIFIED SCHEDULE 5 OR 6 MEDICINES"

(b) the substitution for subregulation (1) of the following subsection:

" (1) A person importing, exporting, manufacturing or selling specified Schedule 5 or Schedule 6 medicines or substances shall keep a register of such medicines or substances."

Amendment of Regulation 32

18. Regulation 32 of the Regulations is hereby amended by the substitution in subsection (1) of paragraph (c) of the following paragraph:

(c) is misbranded or adulterated."

Amendment of Regulation 40

19. Regulation 40 of the Regulations is hereby amended by the addition in subregulation (1) of the following paragraphs:

"(q) in the case of a complementary medicine-
(i) the discipline of the medicine; and
(ii) the words: "use according to the principles of the discipline"."

Amendment of Regulation 48

20. Regulation 48 of the Regulations is hereby amended by-

(a) the addition in subregulation (1) of the following paragraphs:

" (u) the category of medicine;
(v) the pharmacological classification of medicine; and
(w) in the case of a complementary medicine-
(i) the discipline of the medicine; and
(ii) the words: "use according to the principles of the discipline"."

(b) the substitution for subregulation (2) of the following subregulation:

"(2) If the medicine package bears both an immediate container label and an outer label, the requirements of subregulation (1) shall apply to the outer label as well: Provided that it shall be sufficient to give on the immediate container label-

(i) in the case of medicines intended for administration by injection and having a total volume not exceeding 5 ml, the details prescribed in paragraphs (a), (b), (e), (k), (l), (m), (n) and (w) of subregulation (1);

(ii) in the case of an ointment, cream, gel or powder having a nett mass not exceeding 10 grams, the details prescribed in paragraphs (a), (b), (c), (e), (m), (n), (o), and (w) of subregulation (1);

(iii). in the case of a liquid, solution or suspension having a total volume more than 1 ml but not exceeding 15 ml, the details prescribed in paragraphs (a), (b), (c), (d), (e), (l), (m), (n), (o), and (w) of subregulation (1);

(iv) in the case of a liquid, solution or suspension having a total volume not exceeding 1 ml, the details prescribed in paragraphs (a), (b), (o), and (w) of subregulation (1);

(v) in the case of a medicine packed in blister or similar packaging, the details prescribed in paragraphs (a), (b), (m), (n), (o), and (w) of subregulation (1), repeated as frequently as is practicable."

(c) by the addition in subsection (4)(c) of the following subparagraph:

"(vii) the discipline of the medicine, if falling in category D

Insertion of Regulations 48A and 48B

21. The following headings and regulations are inserted after regulation 48:

"ACQUISITION AND USE OF MEDICINES BY EMERGENCY SERVICES, MASTERS OF SHIPS AND OFFICERS IN CHARGE OF ANY AIRCRAFT

"48A. An official in charge of health services at a local government or a medical practitioner designated by such official may, notwithstanding these regulations, on the written request of a person in charge of emergency services, the master of the ship or the officer in charge of an aircraft, authorise the purchase, acquisition, keeping or use of a Schedule 0, Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5. or

Schedule 6 substance: Provided that the quantity shall be reasonable and on condition that such medicine is intended for emergency medicinal use only.

USE OF MEDICINES FOR EXHIBITION PURPOSES

48B. A manufacturer, importer, wholesaler, distributor or a person marketing medicines may use a medicine or scheduled substance sample for exhibition purposes or to introduce such medicine or scheduled substance to healthcare providers or the public: Provided that such samples:

(a) are only meant for such exhibition or the launch of such medicine or scheduled substance: and

(b) may not be handed out or given to any healthcare provider or member of the public."

DR A MOTSOALEDI
MINISTER OF HEALTH

DEPARTMENT OF LABOUR
DEPARTEMENT VAN ARBEID

No. R. 588 **22 July 2011**

LABOUR RELATIONS ACT, 1995

CANCELLATION OF GOVERNMENT NOTICE

BARGAINING COUNCIL FOR THE FURNITURE MANUFACTURING INDUSTRY, KWAZULU NATAL: PROVIDENT FUND AND MORTALITY BENEFIT ASSOCIATION COLLECTIVE AGREEMENT

I, MILDRED NELISIWE OLIPHANT, Minister of Labour, hereby, in terms of section 32(7) of the Labour Relations Act, 1995, cancel Government Notice No. R. 879 of 4 September 2009 with effect from .....1 August 2011.....

MN OLIPHANT
MINISTER OF LABOUR

UMNYANGO WEZABASEBENZI

No. R. 588 **22 July 2011**

UMTHETHO WOBUDLELWANO KWEZABASEBENZI KA-1995

UKUHOXISWA KWESAZISO ZIKAHULUMENI

BARGAINING COUNCIL FOR THE FURNITURE MANUFACTURING INDUSTRY, KWAZULU NATAL: ISIVUMELWANO SABAQASHI NABASEBENZI SESIKHWAMA ESIHLINZEKAYO KANYE NENHLANGANO YOKUSIZA ABASHONELWE

Mina, MILDRED NELISIWE OLIPHANT, uNgqongqoshe Wezabasebenzi ngokwesigaba-32(7) soMthetho Wobudlelwano Kwezemisebenzi we-1995, ngihoxisa iZaziso ZikaHulumeni esinguNombolo R.879 womhlaka 4 kuMandulo 2009 kusukela mhlaka .....1 kuNcwaba 2011.....

MN OLIPHANT
UNGQONGQOSHE WEZABASEBENZI

No. R. 589 **22 July 2011**

LABOUR RELATIONS ACT, 1995

BARGAINING COUNCIL FOR THE FURNITURE MANUFACTURING INDUSTRY, KWAZULU NATAL: EXTENSION TO NON-PARTIES OF THE PROVIDENT FUND AND MORTALITY BENEFIT ASSOCIATION COLLECTIVE RE-ENACTING AND AMENDING AGREEMENT

I, MILDRED NELISIWE OLIPHANT, Minister of Labour, hereby in terms of section 32(2) of the Labour Relations Act, 1995, declare that the Collective Agreement which appears in the Schedule hereto, which was concluded in the Bargaining Council for the Furniture Manufacturing Industry, Kwazulu Natal, and is binding in terms of section 31 of the Labour Relations Act, 1995, on the parties which concluded the agreement, shall be binding on the other employers and employees in that Industry with effect from .....1 August 2011..... .and for the period ending 31 July 2011.

MN OLIPHANT
MINISTER OF LABOUR

No. R. 589 **22 July 2011**

UMNYANGO WEZABASEBENZI

UMTHETHO WOBUDLELWANO KWEZABASEBENZI KA-1995

BARGAINING COUNCIL FOR THE FURNITURE MANUFACTURING INDUSTRY, KWAZULU NATAL: UKWELULELWA KWESIVUMELWANO PHAKATHI KWABAQASHI NABASEBENZI SESIKHWAMA ESIHLINZEKAYO KANYE NENHLANGANO YOKUSIZA ABASHONELWE ESAKHIWE KABUSHA FUTHI ESICHIBIYELAYO SELULELWA KULABO ABANGEYONA INGXENYE YESIVUMELWANO

Mina, MILDRED NELISIWE OLIPHANT, uNgqongqoshe WezabaSebenzi, ngokwesigaba-32(2) soMthetho Wobudlelwano WezabaSebenzi ka-1995, ngazisa ukuthi isiVumelwano sabaqashi nabasebenzi esitholakala kwiSheduli yesiNgisi exhunywe lapha, esenziwa kwi- Bargaining Council for the Furniture Manufacturing Industry, Kwazulu Natal, futhi ngokwesigaba-31 soMthetho Wezobudlelwano KwezabaSebenzi ka-1995 esibopha labo abasenzayo, sizobopha bonke abanye abaqashi nabasebenzi kuleyoMboni kusukela mhlaka-.....1 kuNcwaba 2011..... kuze kube ngu 31 kuNtulikazi 2011.

MN OLIPHANT
UNGQONGQOSHE WEZABASEBENZI

No. R. 590 **22 July 2011**

LABOUR RELATIONS ACT, 1995

BARGAINING COUNCIL FOR THE FURNITURE MANUFACTURING INDUSTRY, KWAZULU NATAL: EXTENSION OF PERIOD OF OPERATION OF THE PROVIDENT FUND AND MORTALITY BENEFIT ASSOCIATION COLLECTIVE AGREEMENT

I, MILDRED NELISIWE OLIPHANT, the Minister of Labour, hereby, in terms of section 32(6)(a)(i) of the Labour Relations Act, 1995, extend the period fixed in Government Notice No. R. ..589.....by a further period ending 31 July 2016.

MN OLIPHANT

MINISTER OF LABOUR

UMNYANGO WEZABASEBENZI

No. R. 590 **22 July 2011**

UMTHETHO WOBUDLELWANO KWEZABASEBENZI KA-1995

BARGAINING COUNCIL FOR THE FURNITURE MANUFACTURING INDUSTRY, KWAZULU NATAL: UKWELULWA KWESIKHATHI SOKUSEBENZA KWESIVUMELWANO SABAQASHI NABASEBENZI SESIKHWAMA ESIHLINZEKAYO KANYE NENHLANGANO YOKUSIZA ABASHONELWE

Mina, MILDRED NELISIWE OLIPHANT, onguNgqongqoshe Wezabasebenzi, lapha ngokwesigaba 32(6)(a)(i) soMthetho Wobudlelwano Kwezabasebenzi, ka-1995, ngimemezela ukuthi izihlinzeko zeZaziso zikaHulumeni ezingunombolo R.589. .....ziyasebenza kuze kube mhlaka 31 kuNtulikazi 2016.

MN OLIPHANT

UNGQONGQOSHE WEZABASEBENZI

SCHEDULE

BARGAINING COUNCIL FOR THE FURNITURE MANUFACTURING INDUSTRY, KWAZULU NATAL

PROVIDENT FUND AND MORTALITY BENEFIT ASSOCIATION

COLLECTIVE AGREEMENT

In accordance with the provisions of the Labour Relations Act, 1995, made and entered into by and between the

KwaZulu-Natal Furniture Manufacturers' Association

(hereinafter referred to as the "employers" or the "employers' organisation"), of the one part, and the

National Union of Furniture and Allied Workers' of South Africa

(hereinafter referred to as the "employees" or the "trade union") of the other part, being the parties to the Bargaining Council for the Furniture Manufacturing Industry, KwaZulu Natal.

CHAPTER 1

1. SCOPE OF APPLICATION OF AGREEMENT

1 The terms of this Agreement shall be observed in the Furniture Manufacturing Industry, KwaZulu Natal-

(a) by all employers who are members of the employer's organisation and by all employees who are members of the trade union, who are engaged or employed therein, respectively ;

(b) in Area A, which consists of the Magisterial Districts of Camperdown, Chatsworth, Durban, Inanda, Lower Tugela, Pietermaritzburg, Pinetown and Mount Currie ;

2 Notwithstanding the provisions of sub-clause (1), the provisions of this collective agreement shall-

(a) only apply in respect of employees for whom minimum wages are prescribed in the main collective agreement including a working Partner, Director or Member as defined under the definitions ;

(b) apply to learners in so far as they are not inconsistent with the provisions of the Skills Development Act, 92 of 1998 or any contracts entered into or any conditions fixed thereunder ;

(c) Notwithstanding the provisions of this clause, employers who carry on not more than one business within the scope of application of this collective agreement and who employ less than five employees at all times in connection with such business, shall be entitled to the phasing in concessions as contained within Clause 1(3) of the main collective agreement, provided that for the purpose of giving effect to Clause 12(1)(d) of this agreement, the contribution shall be based on the wage

prescribed for the highest paid employee in Schedule A of the main collective agreement.

(d) The provisions of Sub-Clause 2(c) shall not apply where an employer has more than four employees in his employ at the date of the coming into operation of this collective agreement, and subsequently reduces this number of employees to fewer than five.

(e) The terms of this collective agreement shall not apply to non-parties in respect of clauses 1 (1) (a), 2 and 4.

2. PERIOD OF OPERATION OF AGREEMENT

This agreement shall come into operation for the parties to this agreement as agreed upon and for non-parties on such date as may be decided upon by the Minister of Labour in terms of Section 32 of the Labour Relations Act, 1995 as amended and shall remain in force until 31 July 2016.

3. GENERAL PROVISIONS.

The provisions as contained in clauses 3 to 6, 7(1)(a)(ii) to 23 and Annexure A of the collective agreement published under Government Notice No. R. 244 of 27 February 2004, R.1139 of 8 October 2004, R. 192 of 11 March 2005, R. 1281 of 15 December 2006, R. 1172 of 14 December 2007, R. 851 of 15 August 2008 and R. 1122 of 24 October 2008 and R.879 of 04 September 2009 (as further amended and re-enacted from time to time) shall apply to employers and employees.)

4. SPECIAL PROVISIONS.

The provision as contained in clause 7(1)(a)(i) (hereinafter referred to as the "Former Agreement", as further amended and re-enacted from time to time, shall apply to employers and employees.)

5. CLAUSE 3: DEFINITIONS

1. Delete the following definition as it appears in the existing text under clause 3. Definitions :

"FSB" means the Financial Services Board.

2. Substitute the following definition of "Furniture Industry" as it appears in the existing text under clause 3. Definition, for the following :

"Furniture Manufacturing Industry": means without in any way limiting the ordinary meaning of the expression the manufacture of furniture either in whole or in part of all types of furniture irrespective of the materials used and shall include the following :

(a) Furniture :

Assembling of all items and / or components of furniture, repairing, spraying, polishing, re-polishing, wood machining, veneering, woodturning, carving, painting, staining, wood bending and laminating, the making of and / or repairing of frames, loose covers and / or cushions. Furniture manufacturing shall also include hotel, tea room or restaurant furniture, office, church, school, bar and theatre furniture, cabinets for musical instruments and radio cabinets. The veneering, laminating, papering and / or wrap of all types of doors, large or small, including the manufacturing of all items or components, whether or not such items are intended to be free standing, built in and / or affixed to a building as listed in (i) to (vii) below :

(i). dressers, cupboards, units for the housing of sinks and appliances, grocery cupboards, shelves, pigeon holes, worktops, tables, chairs, benches and pelmets ;

(ii) multipurpose cabinets which can be used either singly or in combination with each other for various purposes, including kitchen dressers, kitchen cupboards and fittings including cupboards and / or cabinets in any other part of a building ;

(iii) headboards and pedestals for beds, wardrobes and wall unit;

(iv) other cabinets and cupboards, benches, tables, chairs, benches for laboratories, shops, offices or banks ;

(v) counters, shelves and cupboards for use in bars, hotels, shops, offices or banks

(vi) the assembly of and fitting in any building of any type of furniture ;

(vii) the repairing or remedying in any building of any type of furniture ;

(b) Bedding :

The manufacture and / or processes involved in the manufacture of bedding, including all types of mattresses, spring mattresses, overlays, pillows, bolsters, spring units, bed spring mattresses and studio couches, which is designed for seating and / or conversion into a bed and of which the frame is constructed mainly of metal and the seating and / or sleeping surface consists of a mattress and / or cushion.

(c) Upholstery :

The upholstering and / or re-upholstering of all types of furniture, or item of furniture, bedding, pelmets and mattress bases.

(d) Curtain Making :

The making, altering, repairing and / or fitting of curtains, rails, rods and pelmets.

(e) Cane Furniture :

The manufacturing of furniture made principally of wicker, cane and / or grass.

(f) Ancillary Items :

The manufacture in a factory, building and / or elsewhere in conjunction with items specified under (a) to (e) products of which wood constitutes the main component, which shall include plywood, veneer boards, chip board, laminated board, block board and / or any similar product for use in ;

(i). the erection, completion, renovation, repair, maintenance or alteration of permanent finish of buildings or structures, including but not limited to mouldings, skirting boards, panelling, shelving, banisters, partitioning and shall include doors and door frames, windows and window frames.

(g) Provided that the manufacturing of metal furniture, metal bedsteads and furniture manufactured wholly from plastic materials, shall be excluded.

6. CLAUSE 4: ADMINISTRATION.

Substitute the following existing subclause 4.2(a)

2 (a) The control and management of funds by the Council shall be vested in a Management Committee consisting of the Chairperson and Vice-Chairperson of the Council, together with four employer and four employee representatives, who shall be delegates to the Council and shall be appointed by the Council on to the Management Committee. For each representative, an alternate shall be appointed by the Council from its Members. The Chairperson and Vice-

Chairperson of the Council shall be the Chairperson and Vice-Chairperson of the Management Committee, respectively.

7. CLAUSE 5: ENFORCEMENT OF COLLECTIVE AGREEMENT.

Substitute the existing Clause 5 for the following :

1 Despite any other provisions of this collective agreement, the Council may appoint one or more persons and may request the Minister of Labour to appoint such persons as designated agents in terms of Section 33 (1) of the Act to promote , monitor and enforce compliance with this collective agreement.

2 In the event of non-compliance with this collective agreement, a designated agent may secure compliance by –

(a) publicising the contents of this Agreement.
(b) investigate complaints.
(c) conduct inspections.
(d) issue a compliance order ; or
(e) adopt any other means the Council may have approved of ; and
(f) perform any other function which is conferred on or imposed on the agent by the Council.

3 In the event that non-compliance prevails after the issuance of a compliance order in terms of sub-clause 2 (d) above, the agent must :

(a) submit a report to the Secretary of the Council, specifying that compliance had not been achieved.

4 Upon receipt of such report, the Secretary of the Council shall –

(a) Appoint an arbitrator from the list of arbitrators supplied by the CCMA to arbitrate the matter ; or

(b) take such steps as deemed necessary to give effect to any agreement reached after the compliance order was issued in resolving the matter.

(c) An arbitrator appointed in terms of this Clause shall have all the powers assigned to an arbitrator as contemplated by the Act, including but not limited to the charges and penalties as further contemplated by Section 33A of the Act read with the applicable Regulations.

5 The Secretary shall make application to certify the arbitration award or settlement agreement, whichever applies, as order of the Labour Court.

6 A designated agent appointed under Section 33 (1) of the Act, shall in addition to the powers referred to in this Clause, have the powers as assigned to designated agents as set out in Schedule 10 and Section 142 of the Act, read with the changes required by the context.

8. CLAUSE 6: DISPUTES AND DISPUTES ABOUT THE INTREPRETATION OF THIS COLLECTIVE AGREEMENT

Substitute the following for the existing Clause 6. Disputes and disputes about the interpretation of this Collective Agreement.

1 The Council shall be the body to perform dispute resolution services within the Industry - Provided that :

(a) The Council is accredited by the CCMA ; and

(b) the persons appointed to execute the dispute resolution functions are competent to do so.

(c) The Council shall adopt the Rules of the CCMA in performing its dispute resolution functions.

2 Disputes about the Interpretation of this collective agreement :

(a) If there is a dispute about the interpretation of any provisions of this collective agreement, any party to the dispute may refer the dispute to the Council.

(b) The referring party must satisfy the Council that a copy of the referral has been served on all other parties to the dispute.

(c) The Council must attempt to resolve the dispute through conciliation.

(d) The Secretary of the Council may appoint a suitable person to conciliate the dispute from the list of Commissioners made available by the CCMA from time to time, or as otherwise agreed between the parties to the dispute.

(e) In the event that the dispute remains unresolved, any party to the dispute may request the Secretary of the Council to appoint an arbitrator to arbitrate the dispute : -

(i) a similar procedure be followed as set out in sub-clause (d) above in respect of arbitration ; and

(ii) the rules of the CCMA shall apply to arbitrations under this section.

9. CLAUSE 7: EXEMPTIONS.

Substitute the existing Clause 7: Exemptions for the following :

1 General :

(a) The Council may grant exemption from any of the provisions of this collective agreement and shall be dealt with in the following manner :

(i) Parties: Any application for exemption by a Party to the collective agreement shall be dealt with as decided by the Council from time to time.

(ii) Non Parties; Any application by a non-party to the collective agreement shall be dealt with as follows :

(b) The application shall be in the prescribed form and shall include the following :

(i) the reason for the application sought ;
(ii) latest audited financial statements of the applicant ;
(iii) a business plan detailing as to how applicant is going to work towards compliance ;
(iv) schedule of names and job categories of employees so affected ;
(v) current wages earned ;
(vi) confirmation that employees and / or their representatives were consulted and there is consent towards the application.

(c) An application shall not be considered in the event that :

(i) the employees and / or their representatives are not in support of the application ;
(ii) the period for which exemption is being sought is already covered by an arbitration award.

2 Criteria to be considered in an Application for Exemption :

(a) The application shall not be in conflict with the primary objects of the Act ;
(b) the interests of the Industry shall be taken into account and whether the granting of the exemption would –

(i) unfairly impact upon fair competition between employers ;
(ii) unfairly undermine the collective bargaining process ;

(iii) encourage unfair exploitation of workers in the industry;

(iv) wage and wage related exemptions may only be granted for duration of the Agreement.

(c) Exemptions from this collective agreement shall, if granted, not exceed the duration of the collective agreement.

3 Administration :

(a) All applications for exemption, shall be forwarded to the Secretary of the Council.

(b) The Secretary of the Council shall in the case of the granting of an exemption, issue a license, jointly signed by the Chairperson and Secretary of the Council, setting out –

(i) the name of the applicant ;

(ii) the provisions of this Agreement from which exemption is granted ;

(iii) any conditions or pre-conditions attached to the said exemption so granted ;

(iv) the period for which the exemption shall be in operation;

(c) The Secretary of the Council shall :

(i) number consecutively all licenses issued ;

(ii) retain a copy of each license issued ;

(iii) forward a copy to the applicant.

(d) The Council may on good cause shown, give the holder of an exemption license 30 days' notice of withdrawal of the exemption. The holder of such exemption may appeal to the Exemptions Appeal Board and the provisions of Clause 7A shall apply read with the changes to the context.

7A. EXEMPTIONS APPEAL BOARD

1 Establishment :

(a) In terms of Section 32 of the Act, the Council shall establish an independent body to be known as the Exemptions Appeal Board, to consider and determine any appeal brought against a refusal of a non-party application for exemption by the Council.

(b) The Appeal Board, in considering the appeal, must have due regard for the views expressed by the Council, employees and / or their representatives as well as representations made by other employers within the Industry.

(c) All applications to the Appeal Board must be lodged with the Secretary of the Council by no less than 6 (six) weeks from the date of the delivery of the Council's exemption finding on the Applicant.

(d) All applications shall be in writing and heads of argument must be filed seven days prior to the convening of the hearing by the Appeals Board.

(e) All applicants shall pay a processing fee of R1,000.00 (one thousand rand).

(f) The applicants shall be required to attend the hearing, failing which the Board shall be entitled to decide on the matter in absentia.

10. CLAUSE 12: CONTRIBUTIONS.

Delete under the existing Chapter II clause 12, sub-clause 12(4) and re-number the sub-clause following accordingly

11. CLAUSE 17: MEMBERSHIP.

Substitute the following sub-clause 17(2)(b)

"(b) When a member severs his connection with the industry, and the dependants of such former member shall thereupon not be entitled to the benefits specified by clause 19 of this Chapter.".

12. CLAUSE 18: CONTRIBUTIONS.

Substitute the following sub-clause 18(1)

"(1) in respect of a member referred to clause 17 (1) (a), be diverted in equal proportions in terms of clause 12 (4) from the contributions prescribed in clause 12 (1) (a) of this Agreement ; and"

Signed at Durban on this 24th day of February 2011

G. BOSTOCK
Chairperson

S. GOVENDER
(Vice-Chairperson)

G.J.P. BLIGNAUT
Secretary of the Council

No. R. 591 **22 July 2011**

LABOUR RELATIONS ACT, 1995

LABOUR RELATIONS ACT, 1995: NATIONAL BARGAINING COUNCIL FOR THE WOOD AND PAPER SECTOR: RENEWAL OF PERIOD OF OPERATION OF DISPUTE RESOLUTION LEVY AND REGISTRATION OF EMPLOYERS COLLECTIVE AGREEMENT

I, IAN MACUN, Director: Collective Bargaining, duly authorised thereto by the Minister of Labour, hereby, in terms of section 32(6)(a)(ii), of the Labour Relations Act, 1995, renew the period fixed in Government Notice No. R. 687 of 21 July 2006, to be effective from the date of publication of this notice and for the period ending 29 February 2012.

I MACUN
DIRECTOR: COLLECTIVE BARGAINING

No. R. 591 **22 Julie 2011**

WET OP ARBEIDSVERHOUDINGE, 1995

NASIONALE BEDINGINGSRAAD VIR DIE HOUT EN PAPIER SEKTOR: HERNUWING VAN TYDPERK VAN GESKILBESLEGTIGINGS HEFFING EN REGISTRASIE VAN WERKGEWERS KOLEKTIEWE OOREENKOMS

Ek IAN MACUN, Direkteur: Kollektiewe Bedinging, verleng hierby, kragtens artikel 32(6)(a)(ii) van die Wet op Arbeidsverhoudinge, 1995, die tydperke vasgestel in Goewermentskennisgewing No. R. 687 of 21 Julie 2006, met 'n verdure tydperk was op 29 Februarie 2012 eindig.

I MACUN
DIREKTEUR: KOLLEKTIEWE BEDINGING

No. R. 592 **22 July 2011**

LABOUR RELATIONS ACT, 1995

LABOUR RELATIONS ACT, 1995: BARGAINING COUNCIL FOR THE BUILDING INDUSTRY, KIMBERLEY: RENEWAL OF PERIOD OF OPERATION OF MAIN COLLECTIVE AGREEMENT

I, **IAN MACUN**, Director: Collective Bargaining, duly authorized thereto by the Minister of Labour, hereby, in terms of section 32(6)(a)(ii) of the Labour Relations Act, 1995, declare the provisions of Government Notices Nos. R. 957 of 7 August 1998, R. 745 of 11 June 1999, R. 1365 of 15 December 2000, R. 1018 of 18 July 2003, R. 865 of 23 July 2004, R. 906 of 29 August 2008 and R. 9 of 22 January 2010 to be effective from the date of publication of this notice and for the period ending 31 July 2014.

DIRECTOR: COLLECTIVE BARGAINING

No. R. 592 **22 Julie 2011**

WET OP ARBEIDSVERHOUDINGE, 1995
BEDINGINGSRAAD VIR DIE BOUNYWERHEID, KIMBERLEY: HERNUWING VAN TYDPERK VAN HOOF KOLLEKTIEWE OOREENKOMS

Ek, **IAN MACUN**, Direkteur: Kollektiewe Bedinging, behoorlik daartoe gemagtig deur die Minister van Arbeid, 1995 verklaar hierby, kragtens artikel 32(6)(a)(ii) van die Wet op Arbeidsverhoudinge, 1995, dat die bepalings van Goewermentskennisgewings Nos R. 957 van 7 Augustus 1998, R.745 van 11 Junie 1999, R. 1365 van 15 Desember 2000, R. 1018 van 18 Julie 2003, R. 865 van 23 Julie 2004, R. 906 van 29 Augustus 2008 en R. 9 van 22 Januarie 2010 van krag is vanaf die datum van publikasie van hierdie kennisgewig en vir die tydperk wat on 31 Julie 2014 eindig.

DIREKTEUR: KOLLEKTIEWE BEDINGING

DEPARTMENT OF TRADE AND INDUSTRY
DEPARTEMENT VAN HANDEL EN NYWERHEID

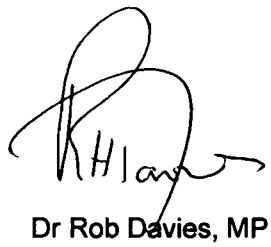
No. R. 595 **22 July 2011**

NATIONAL REGULATOR FOR COMPULSORY SPECIFICATIONS ACT (Act 5 of 2008)

PROPOSED INTRODUCTION OF A COMPULSORY SPECIFICATION FOR SAFETY GLAZING MATERIALS FOR BUILDINGS

It is hereby made known under Section 13 (4) of the National Regulator for Compulsory Specifications Act (Act 5 of 2008), that I Dr Rob Davies, the Minister of Trade and Industry intends to introduce a Compulsory Specification for *Safety Glazing Materials for Buildings*, as set out in the attached Schedule.

Any person who wishes to comment on the intention of the Minister to introduce the compulsory specification concerned, shall submit their comments in writing with the Chief Executive Officer, National Regulator for Compulsory Specifications, Private Bag X25, Brooklyn 0075, on or before the date two (2) months after the date of publication of this notice.



Dr Rob Davies, MP

Minister of Trade and Industry

SCHEDULE

PROPOSED COMPULSORY SPECIFICATION FOR SAFETY GLAZING MATERIALS FOR BUILDINGS

VC 9003

1. SCOPE

This compulsory specification covers the requirements for safety glazing materials for use in buildings in accordance with Part N of the National Building Regulations, including but not limited to

- Stock sheets of laminated safety glazing materials, i.e. sheets of safety glazing produced by a manufacturer equipped to laminate safety glass that will be cut to size by an installer;
- Toughened safety glass, i.e. panels of flat safety glazing manufactured from flat glass, cut to size, and then heat treated;
- Polymeric glazing, i.e. sheets of transparent plastics that can be cut to size;
- Any glazed product that may be subjected to human impact that is installed in and fixed to a building, such as a shower cubicle or patio door;
- Any other material claimed to be safety glazing.

2. DEFINITIONS

For the purposes of this compulsory specification the following definitions shall apply:

2.1 manufacturer:

Entity that manufactures safety glazing materials

2.2 applicant:

A manufacturer or importer applying for approval of safety glazing materials. The manufacturer or importer shall be an existing legal entity within the Republic of South Africa.

2.3 approval:

Confirmation by the NRCS that a particular type of safety glazing material satisfies the requirements of this Compulsory Specification.

2.4 NRCS:

The National Regulator for Compulsory Specifications (the Regulator) established by the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008)

2.5 Type of safety glazing material:

Safety glazing material that does not differ in essential aspects such as thickness, colour, design and method of manufacture. Types include:

- Laminated safety glass;
- Toughened safety glass;
- Toughened laminated safety glass;
- Safety film backed safety glass, including mirrors made from glass;
- Polymer based safety glazing;
- Any other type of material that is claimed to be safety glazing.

2.6 Safety glazing material:

Glazing material that is so manufactured, constructed, treated and combined with other materials and components that, if broken by human contact, the likelihood of cutting or piercing injuries that might result from such contact are minimized.

2.7 Building:

The definition of "building" contained in section 1 of the National Building Regulations and Building Standards Act 103 of 1977 shall apply.

2.8 Minister:

The Minister of Trade and Industry.

3. SPECIFIC REQUIREMENTS

3.1 Safety glazing material shall comply with SANS 1263 *Safety and security glazing materials for buildings* Part 1: *Safety performance of glazing materials under human impact.*

3.2 The applicant shall ensure that every type of safety glazing material has been approved by the NRCS in accordance with the requirements of Annex A of this compulsory specification before manufacture, import, sale or supply.

3.3 The manufacturer shall appoint a certification body recognized by the NRCS in terms of its conformity assessment policy to verify the initial compliance and ongoing

conformity of production of safety glazing material with the requirements of this compulsory specification by means of a product certification scheme conforming to Type 5 requirements according to ISO/IEC Guide 67:2004 *Conformity assessment - Fundamentals of product certification.*

3.4 The applicant shall inform the NRCS of any change in the material, method of manufacture, design or components affecting any mandatory requirement of this compulsory specification. In the event of such change/s the NRCS may, at its discretion, demand the submission of fresh evidence of conformity or a new application for approval.

3.5 In addition to the markings prescribed in SANS 1263 – 1 the NRCS approval number shall appear permanently and legibly on all safety glazing material in letters at least 2,5 mm high:

"NRCS XXXXX."

4. CONFORMITY TO REFERENCED STANDARDS

For the purposes of this compulsory specification, a new edition of a referenced standard shall become effective 12 months from the date of publication as a South African National Standard. When a new edition of a referenced standard is published, products originally approved in accordance with the previous edition of that standard may on application have their approval extended by the NRCS.

ANNEX A - APPROVAL OF SAFETY GLAZING MATERIAL

A.1 APPLICATION FOR APPROVAL

The applicant shall apply to the NRCS for approval of every type of safety glazing material. The application shall be accompanied by the following:

A.1.1 Technical specifications detailing the material composition, method of manufacturer and minimum thickness for the type of safety glazing material.

A.1.2 Details of the manufacturing plant/s where the safety glazing material is produced;

A.1.3 Evidence of conformity including test reports issued not more than 12 months before the date of submission to the NRCS by a conformity assessment body recognized in terms of the NRCS's Conformity Assessment Policy, to prove compliance with all the relevant requirements of this compulsory specification;

A.1.4 The markings to be applied to each type of safety glazing material;

A.1.5 Information for users supplied with safety glazing material including instructions for use where applicable;

A.1.6 Information to the satisfaction of the NRCS regarding the measures taken by the applicant to ensure ongoing conformity of the safety glazing material;

A.1.7 Full details of the certification body appointed to maintain ongoing surveillance as required by Clause 3.3 of this compulsory specification, and it's accreditation; and

A.1.8 Any reasonable additional information as may be requested by the NRCS.

AA.2 APPROVAL

A.2.1 The NRCS shall assess the evidence of conformity supplied by the applicant and shall decide to grant approval or not, at its sole discretion.

A.2.2 The NRCS shall assign a unique approval number to each type of safety glazing material approved.

A.2.3 The NRCS shall confirm that approval has been granted to the applicant by means of a Letter of Authority certificate bearing the approval number referred to in paragraph 3.5.

A.2.4 The approval granted with respect to safety glazing pursuant to this compulsory specification may be withdrawn by the NRCS, at any time, after the applicant has been notified in writing, if the requirements have not been met or maintained.

Annexure B

Levy calculation and Approval fees
VC9003

SCHEDULE

1) Non-perishable products - CMM

CODE	COMMODITY DESCRIPTION	UNIT	TARIFF PER UNIT
	Safety Glazing	100 kg	R1.25

No. R. 596 **22 July 2011**

NATIONAL REGULATOR FOR COMPULSORY SPECIFICATIONS ACT (Act 5 of 2008)

PROPOSED INTRODUCTION OF A NEW COMPULSORY SPECIFICATION FOR LIVE AQUACULTURED ABALONE (VC 9001)

It is hereby made known under section 13(4) of the National Regulator for Compulsory Specifications Act, (Act 5 of 2008), that the Minister of Trade and Industry, on the recommendation of the NRCS Board, intends to introduce a new Compulsory Specification for *Live Aquacultured Abalone* as set out in the attached Schedule.

Any person, who wishes to comment on the intention of the Minister to thus introduce the Compulsory Specification concerned, shall submit their comments, in writing, to the Chief Executive Officer, National Regulator for Compulsory Specifications, Private Bag X25, Brooklyn, 0075, on or before the date two (2) months after the publication of this notice.

Dr Rob Davies, MP 31/5/11
Minister of Trade and Industry

VC 9001

COMPULSORY SPECIFICATION FOR LIVE AQUACULTURED ABALONE

SCHEDULE

1 SCOPE

1.1 This Compulsory Specification applies to the harvesting, preparation, packing, conveyance and quality of live aquacultured abalone.

1.2 Wild harvested live abalone is excluded from the scope of this Compulsory Specification.

2 DEFINITIONS

2.1 For the purposes of this Compulsory Specification the definitions in SANS 729: *'Live aquaculture abalone'*, shall apply.

2.2 In addition, the following definitions shall apply:

2.2.1 applicant: a producer, packer, importer or exporter applying for approval of the product. The producer, packer, importer or exporter shall be established within the Republic of South Africa.

2.2.2 approval: confirmation by the NRCS that the product and/or facility satisfies the requirements of this Compulsory Specification.

2.2.3 conformity of production: satisfactory evidence that the harvesting, preparation, packing, or conveyance of live aquacultured abalone produced for sale continues to conform to the requirements of this Compulsory Specification.

2.2.4 DAFF: Department of Agriculture, Forestry and Fisheries

2.2.5 facility: premises where preparation and packing of live aquacultured abalone harvested according to the SAMSM&CP takes place.

2.2.6 NRCS: the National Regulator for Compulsory Specifications as established by the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008).

2.2.7 official sampling: sampling done by an official inspector as defined in and according to the SAMSM&CP.

2.2.8 SAMSM&CP: the South African Molluscan Shellfish Monitoring and Control Programme administered by DAFF.

3 GENERAL ADMINISTRATIVE REQUIREMENTS

3.1 All live aquacultured abalone products to be offered for sale shall comply with the requirements of this Compulsory Specification.

3.2 The facility for live aquacultured abalone products shall be pre-approved by the NRCS for conformity of production requirements as prescribed in Annex A.1.

3.3 The packer may not dispatch live aquacultured abalone product from the facility without a valid NRCS approvals document for the facility.

3.4 Application for approval of the product shall be made to the NRCS for every consignment of live aquacultured abalone in accordance with the requirements of Annex A.2.

3.5 The packer shall provide the NRCS with satisfactory evidence of conformity of production on request.

3.6 The packer shall inform the NRCS of any change in process of production affecting any mandatory requirement of this Compulsory Specification. In the event of such change/s the NRCS may, at its discretion, demand the submission of fresh evidence of conformity or a new application for approval.

3.7 The packer shall immediately report any failure, of whatever nature, to conform to the requirements of this Compulsory Specification to the NRCS.

3.8 The testing of live aquacultured abalone against the requirements of this Compulsory Specification shall be done by test facilities that are accredited to use the test methods as referenced in the SAMSM&CP. In the case where there are no test facilities available that are in compliance with the foregoing, the NRCS will determine which facilities can be used in terms of its conformity assessment policy. This includes testing undertaken by farms and/or packers to demonstrate conformance with this Compulsory Specification.

3.9 The NRCS shall issue health guarantees for export purposes, where required, in accordance with the requirements of the country of destination as prescribed in Annex B.

4 SPECIFIC REQUIREMENTS

4.1 The harvesting, preparation, storage, packing, conveyance, marking, labelling and quality of live aquacultured abalone, as well as the hygiene requirements for the product and for the packing facility employees, shall comply with the requirements of the latest edition of SANS 729.

4.2 Live aquacultured abalone for packing shall be obtained from sources that are officially approved by DAFF.

4.3 Farms shall be evaluated and approved annually by DAFF as per the requirements of the SAMSM&CP. Packers shall also be issued with permits on an annual basis by the dedicated authority, after official approval of the farms by the NRCS.

4.4 Land-based wet storage facilities shall conduct monthly microbiological testing of the live aquacultured abalone and water against the requirements of the SAMSM&CP.

4.5 All official sampling of live aquacultured abalone and water shall take place according to the requirements of the SAMSM&CP.

4.6 No live aquacultured abalone shall be harvested, packed or shipped for the purpose of placing on the market for human consumption, when the abalone does not meet the requirements of the SAMSM&CP or when the farm is closed by DAFF.

4.7 The facility shall be situated in an environment deemed by the NRCS to be suitable for the packing of the live aquacultured abalone product in accordance with SANS 729.

4.8 The live aquacultured abalone harvested, packed or shipped for the purpose of placing on the market for human consumption, shall not contain any chemicals, microbiological contaminants, and marine biotoxins at levels that could be detrimental to the health of the consumer as per requirements of the SAMSM&CP.

4.9 The live aquacultured abalone product shall be traceable according to the requirements of the movement document referred to in the SAMSM&CP.

5 MARKINGS

Packed live aquacultured abalone product shall be marked in accordance with the requirements of SANS 729.

ANNEX A

(Normative)

A.1 APPLICATION FOR APPROVAL OF THE FACILITY

The applicant shall apply to the NRCS for approval of the facility. The application shall be accompanied by the following:

A.1.1 Details of the facility for which approval is sought;

A.1.2 Records and documentation as evidence of implementation of a product safety management system;

A.1.3 Test results for the live aquacultured abalone and water as prescribed in SANS 729 for a minimum period of three months preceding the application (new facilities that have not been in production before the application will be given 3 to 6 months to provide documentation for A.1.2 and A.1.3);

A.1.4 Information to the satisfaction of the NRCS regarding the measures taken by the applicant to ensure ongoing conformity with the requirements of this Compulsory Specification; and

A.1.5 Any reasonable additional information requested by the NRCS.

A.2 APPLICATION FOR APPROVAL OF PRODUCT

The applicant shall apply to the NRCS for approval of the product. The application shall be accompanied by the following:

A.2.1 Importers and exporters shall supply details of the live aquacultured abalone product per consignment for which approval is sought and provide evidence that the product complies with SANS 729 (specific export requirements are given in Annex B);

A.2.2 The applicable rights and permits as required by SAMSM&CP;

A.2.3 Test results for the live aquacultured abalone and water as prescribed in SANS 729 for a minimum period of three months preceding the application;

A.2.4 Records and documentation as evidence of implementation of a product safety management system;

A.2.5 Movement documentation to substantiate traceability;

A.2.6 Declaration of current classification of farm with regards to the SAMSM&CP;

A.2.7 Test results as per SANS 729 and SAMSM&CP at request;

A.2.8 Details of the markings used on the packed product;

A.2.9 Information to the satisfaction of the NRCS regarding the measures taken by the applicant to ensure ongoing conformity with the requirements of this Compulsory Specification; and

A.2.10 Any reasonable additional information requested by the NRCS;

A.3 GRANTING OF APPROVAL

A.3.1 The NRCS shall issue an approvals document, as is applicable for the facility, imported products or products destined for export, to the applicant when all the requirements of this Compulsory Specification have been met.

A.3.2 The NRCS shall assign a unique number to each approvals document.

A.3.3 An approvals document shall be the sole proof of approval by the NRCS.

A.3.4 Once a facility is approved, the NRCS will issue an establishment number.

A.4 WITHDRAWAL OF APPROVAL

Any approval granted in respect of live aquacultured abalone products or the facility pursuant to this Compulsory Specification may be withdrawn at any time without prior notice, if compliance with the requirements of this Compulsory Specification has not been maintained.

ANNEX B

(Normative)

B.1 HEALTH GUARANTEES FOR EXPORT

B.1.1 The NRCS may provide health guarantees to authorities in countries to which products are exported at the request of exporters, if products have been farmed, handled and packaged in accordance with the requirements of this Compulsory Specification. In terms of requirements, all sections of the handling and processing chain are to be inspected and where appropriate, random samples have to be taken for verification purposes.

B.1.2 As required, finally prepared and packed live aquacultured abalone product shall be monitored on the basis of a random testing and surveillance programme.

B.1.3 For the issuing of health guarantees, it is required that (for every consignment):

a) the product originates from farms and is packed in facilities approved by the NRCS in terms of SANS 729;

b) the farms comply with the requirements of the SAMSM&CP;

c) the farms and the product be monitored as required by the SAMSM&CP by SAMSM&CP official inspectors;

d) all products and product codes are to be reflected in the request for export; and

e) the product covered by such a guarantee is fully traceable to its origin.

No. R. 597 **22 July 2011**

NATIONAL REGULATOR FOR COMPULSORY SPECIFICATIONS ACT (ACT 5 of 2008)

PROPOSED AMENDMENT TO THE COMPULSORY SPECIFICATION FOR MOTOR VEHICLES OF CATEGORY 01/O2

It is hereby made known under section 13 (4) of the National Regulator for Compulsory Specifications Act, (Act 5 of 2008), that Dr Rob Davies, the Minister of Trade and Industry, intends to amend the compulsory specification for *Motor Vehicles of Category O1/O2,* as set out in the attached Schedule.

Any person, who wishes to comment on the intention of the Minister to thus amend the compulsory specification concerned, shall submit their comments, in writing, to the Chief Executive Officer, National Regulator for Compulsory Specifications, Private Bag X25, Brooklyn, 0075, on or before the date two (2) months after publication of this notice.

Dr Rob Davies, MP

Minister of Trade and Industry

SCHEDULE

PROPOSED COMPULSORY SPECIFICATION FOR VEHICLES OF CATEGORY O_1 AND O_2 (CARAVANS AND LIGHT TRAILERS) - VC8026

Proposed amendments marked with *, pgs 4 &14 only

1 Scope

1.1 This specification covers the requirements for vehicle models of categories O_1 and O_2 designed or adapted for operation on a public road at speeds greater than 40 kph, including new vehicle models and vehicle models that have not previously been registered or licensed in South Africa.

1.2 The requirements of this specification, in so far as the vehicle parts already incorporated are concerned, apply in respect of an incomplete vehicle supplied for further manufacture by one manufacturer to another and the entire specification applies to the vehicle after completion thereof by the last-mentioned manufacturer.

1.3 This specification does not apply to experimental vehicles or to prototype vehicles constructed or imported by the original manufacturer or importers for the purpose of testing, assessment or development, or to agricultural trailers, unless they are subsequently sold for use on a public road in South Africa.

1.4 The relevant requirements of this specification shall take effect on the dates as specified in schedule 1.

1.5 Where a South African National Standard, including an International Standard or a UN ECE regulation adopted by South Africa as a National Standard, is incorporated by reference into this specification, only the technical requirements of the specifications for the commodity, and the tests to verify compliance, apply.

2 Definitions

For the purposes of this specification, the following definitions apply:

2.1
axle unit
set of two or more parallel axles that are so interconnected as to form a unit and the distance between adjacent axles is less than 1,2 m

2.2
caravan
trailer that provides mobile living accommodation and that has a gross vehicle mass not exceeding 3,5 t

2.3
category O
trailers

2.3.1
category O_1
single-axled trailers, other than semi-trailers, with a maximum mass not exceeding 0,75 t

2.3.2
category O_2

trailers other than category O_1, with a maximum mass not exceeding 3,5 t

2.4
equalizer
device that is connected between the towing vehicle and a trailer, and that is designed to reduce the vertical load imposed on the ball coupling by the trailer and to transfer load to the front and rear axles of the vehicle combination. The device usually takes the form of a pair of downward curved springs, one on each side of the drawbar, that are tensioned upwards when coupled to the towing vehicle.

2.5
homologation
a process for establishing the compliance of a model of vehicle and the approval being granted by the regulatory authority, prior to it being introduced for sale.

2.6
importer
a person who imports a category O vehicle, and "import" shall has a corresponding meaning

2.7
manufacturer
person who makes, produces, assembles, alters, modifies or converts a category O vehicle, and "manufacture" has a corresponding meaning

2.8 model
manufacturer's description for a series of vehicle designs that do not differ in respect of axle configuration, trailer configuration, coupling device, and braking system, or in respect of the vehicle category by which they are introduced to South Africa by a specific source

The Regulatory Authority reserves the right to decide on which variations or combinations of variation constitute a new model, and may also take cognisance to the classification system applied in the country of origin of the design

2.9
public road
road, street or thoroughfare, including the verges, or any other place, whether a thoroughfare or not, to which the public or sections of the public have the right of access and commonly use

2.10
proof of compliance
the authentic evidence of compliance with any of the requirements of this compulsory specification from a source defined in "Source of Evidence" in Annexure A

2.11
registered manufacturer, importer or builder (MIB)
any manufacturer, importer or builder required to be registered in terms of regulation 38 of the National Road Traffic Act 93/1996

2.12
regulatory authority
an organization appointed by the Minister of the Department of Trade and Industry to administer this compulsory specification on behalf of the South African Government

2.13
semi-trailer
trailer having no front axle and so designed that at least 15 % of its tare is super-imposed on and borne by a vehicle drawing such trailer

2.14
stabilizer
device that is connected between the towing vehicle and the trailer, and that is designed to reduce or

dampen any lateral (anti-snake) oscillations or vertical (anti-pitch) oscillations, or combinations thereof, of the vehicle combination. The device usually takes the form of a friction or hydraulic damping medium in either the horizontal or vertical plane, or a combination of both, and may be incorporated with an equalizer

2.15
tent trailer
trailer that has a gross vehicle mass not exceeding 3,5 t and that provides mobile living accommodation by means of a collapsible soft-topped tent that can be permanently attached to or can be removable from the trailer

2.16
trailer
vehicle that is not self-propelled and that is designed or adapted to be drawn by a motor vehicle, but does not include a side-car attached to a motor cycle

3 General requirements

3.1 Requirements for lights, lighting and warning signs

3.1.1 Lights

Lights fitted to a trailer shall comply with the relevant requirements given in the following standards:

SANS 20003/ECE R3 (SABS ECE R3:1996), *Uniform provisions concerning the approval of retro-reflecting devices for power-driven vehicles and their trailers.*

SANS 20004/ECE R4 (SABS ECE R4:1997), *Uniform provisions for the approval of devices for the illumination of rear registration plates of motor vehicles (except motor cycles) and their trailers.*

SANS 20006:2003/ECE R6, *Uniform provisions concerning the approval of direction indicators for motor vehicles and their trailers.*

SANS 20007:2002/ECE R7, *Uniform provisions concerning the approval of front and rear position (side) lamps, stop-lamps and end-outline marker lamps for motor vehicles (except motor cycles) and their trailers.*

SANS 20023/ECE R23 (SABS ECE R23:1992), *Uniform provisions concerning the approval of reversing lamps for power-driven vehicles and their trailers.*

SANS 20037:2002/ECE R37, *Uniform provisions concerning the approval of filament lamps for use in approved lamp units of power-driven vehicles and of their trailers.*

SANS 20091/ECE R91 (SABS ECE R91:1993), *Uniform provisions concerning the approval of side-marker lamps for motor vehicles and their trailers.*

3.1.2 Lighting

Lighting shall be fitted to a trailer and shall comply with the relevant requirements given in SANS 20048/ECE R48 (SABS ECE R48:1994), *Uniform provisions concerning the approval of vehicles with regard to the installation of lighting and light-signalling devices.*

The specific requirements of the said SANS 20048/ECE R48 (SABS ECE R48:1994) for **rear fog lamps** as set out in 6.11, shall be treated as **OPTIONAL** for the purpose of this compulsory specification:
Provided that, if any vehicle is fitted with such devices or lamps, they shall comply with the applicable

requirements.

The requirements for the installation of retroreflectors may be met by the use and fitting of retro-reflectors that are defined in the relevant regulations of the National Road Traffic Act, 1996 (Act 93 of 1996) and in addition, the requirements may also be met by the use and fitting of retroreflectors that are integral portions of another light lens assembly.

3.1.3 **Rear warning sign** (chevrons)

A rear warning sign shall be fitted to a trailer and shall comply with the relevant regulations of the National Road Traffic Act, 1996 (Act 93 of 1996).

3.1.4 **Emergency warning signs** (triangles)

In the case of a vehicle supplied with a warning triangle as part of the vehicle equipment, such a warning triangle shall comply with the relevant regulation of the National Road Traffic Act, 1996 (Act 93 of 1996).

3.2 Requirements for windows and partitions

Transparent partitions and windows fitted to any trailer shall be:

a) of safety glass that complies with the relevant requirements given in SANS 1191 (SABS 1191:1997), *Safety glass for vehicles – High penetration-resistant laminated safety glass for vehicles*, in SANS 1192 (SABS 1192:1994), *Safety glass for vehicles – Laminated safety glass for vehicles* or in SANS 1193 (SABS 1193:2001), *Toughened safety glass for vehicles;* or

b) of plastics safety glazing material that complies with the relevant requirements of SANS 1472**:** *2005 , *Plastics safety glazing materials for motor vehicles.*
*This may be to any category specified in A - F of clause 3.2, for rigid plastic glazing material where *so used, or to any category specified in G or H of clause 3.2, for flexible glazing material, where so *used.

3.3 Requirements for brakes and braking equipment

A trailer shall be fitted with braking equipment that complies with the relevant requirements given in SANS 20013/ECE R13 (SABS ECE R13:1996), *Uniform provisions concerning the approval of vehicles of categories M, N and O with regard to braking.*

3.4 Requirements for electrical connectors

Electrical connectors that are fitted for the purpose of towing shall comply with:

a) in the case of 12 V systems:

1) SANS 1327 (SABS 1327:1997), *Electrical connectors for towing and towed vehicles (7-pole connectors)*; or

2) SANS 11446/ISO 11446 (SABS ISO 11446:1995), *Passenger cars and light commercial vehicles with 12 V systems – 13-pole connectors between towing vehicles and trailers – Dimensions and contact allocation*; and

b) in the case of 24 V systems:

1) the said SANS 1327; or

2) SANS 12098/ISO 12098 (SABS ISO 12098:1994), *Commercial vehicles with 24 V systems –*

15-pole connectors between towing vehicles and trailers – Dimensions and contact allocation.

3.5 Requirements for couplings and drawbars on trailers with one axle or an axle unit

3.5.1 Coupling device

Excluding semi-trailers, trailers that have a gross vehicle mass not exceeding 3,5 t shall have coupling devices that comply with the relevant requirements given in SANS 20055:2003 / ECE R55, *Uniform provisions concerning the approval of mechanical coupling components of combinations of vehicles.*

3.5.2 Static vertical loading on ball couplings

The maximum and minimum static vertical load at the centre of the ball socket on the coupling head shall be determined by the manufacturer, but in no case shall it exceed 100 kg or be less than 25 kg when the trailer is loaded. When a trailer is fitted with a stabilizer or an equalizer by the manufacturer, the effect of such a device on the maximum and minimum static vertical loads shall be stated by the manufacturer.

3.5.3 Height of the ball coupling device

The height of the ball coupling device fitted to a trailer, measured vertically above the ground to the centre of the ball socket and with the interior floor of the trailer horizontal and the trailer at its gross vehicle mass, shall be not less than 350 mm and not more than 465 mm, provided that any custom-built trailers that:

a) have tyre and wheel combinations with overall diameters that exceed 665 mm when measured in the unladen condition; or

b) are designed or adapted for towing behind vehicles that have a gross vehicle mass exceeding 3 500 kg

shall be excluded for the purposes of this sub-section.

3.5.4 Trailer articulation clearance

The coupling device fitted to a trailer shall be located on the drawbar as shown in figure 1.

Articulation clearance space

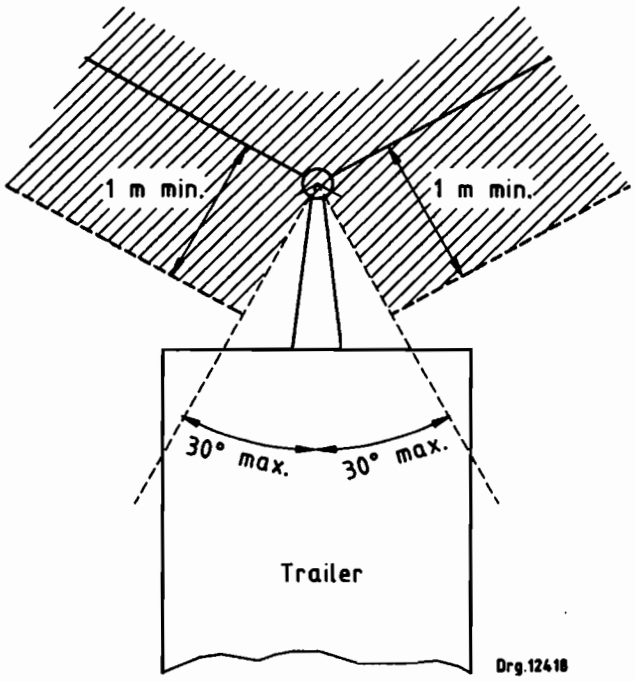


Figure 1 — Minimum articulation clearance space

3.6 Requirements for the stability of certain trailer/towing vehicle combinations whilst in motion

3.6.1 General

These requirements are only applicable to trailers with ball couplings as specified in 3.5.1 (a). Stability should be determined by calculation or other suitable means, or, in the case of a caravan, by verifying compliance with the metrological requirements of 4.1.2 (overall height), 4.1.3 (centre of gravity) and 4.1.4 (rear overhang).

3.6.2 Trailer configuration

The static vertical load on the ball coupling of the trailer shall be at the minimum value stated by the manufacturer (see 3.5.2) and stability shall be checked for two conditions of loading, given as follows:

a) with the trailer at its tare fully equipped for service in accordance with the manufacturer's specification but excluding all non-permanent equipment or stores; and

b) with the trailer at its gross vehicle mass, the load being distributed as recommended by the manufacturer.

4 Requirements concerning metrological data

4.1 Trailer dimensions

4.1.1 General

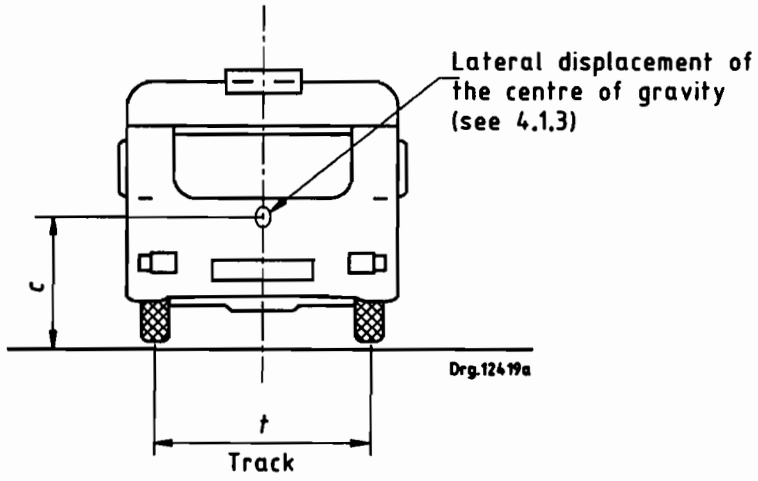
The dimensions of a trailer shall comply with the requirements of the relevant regulations of the National Road Traffic Act, 1996 (Act 93 of 1996), except as provided for in 4.1.2, 4.1.3 and 4.1.4.

4.1.2 Overall height of a caravan

The overall height of a caravan, when measured vertically above ground level, shall not exceed the lesser of 1,8 times the track of the caravan (see figure 2(a)) or 3,0 m.

4.1.3 Centre of gravity of a caravan

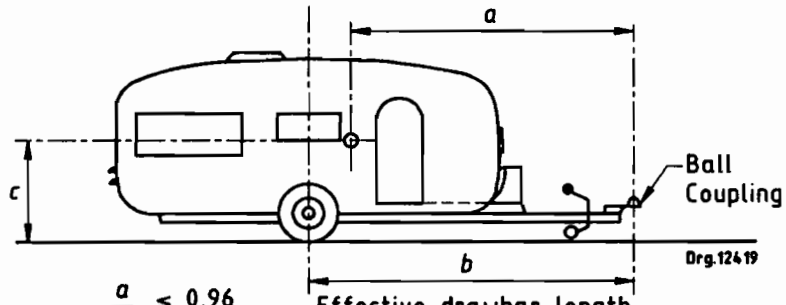
The ratio between the horizontal distances from the centre line of the ball coupling to the centre of gravity and to the centre line of the axle or axle unit of a caravan shall not exceed 0,96 (see figure 2(b)). The ratio between the height of the centre of gravity vertically above ground level to the track of a caravan shall not exceed 0,725 (see figure 2(a)).



$\frac{c}{t} \leq 0,725$

$c_{max.} = 0,725\ t$

Figure 2(a) — Vertical limitations



$\frac{a}{b} \leq 0,96$

$a_{max.} = 0,96\ b$

Figure 2(b) — Longitudinal limitations

4.1.4 Rear overhang of a trailer

The ratio of the rear overhang of a trailer to the effective drawbar length (the horizontal distance from the centre line of the axle or axle unit to the centre of the ball coupling) shall not exceed 0,7 (see figure 3), provided that the rear overhang shall not exceed 50 % of the length of the trailer body.

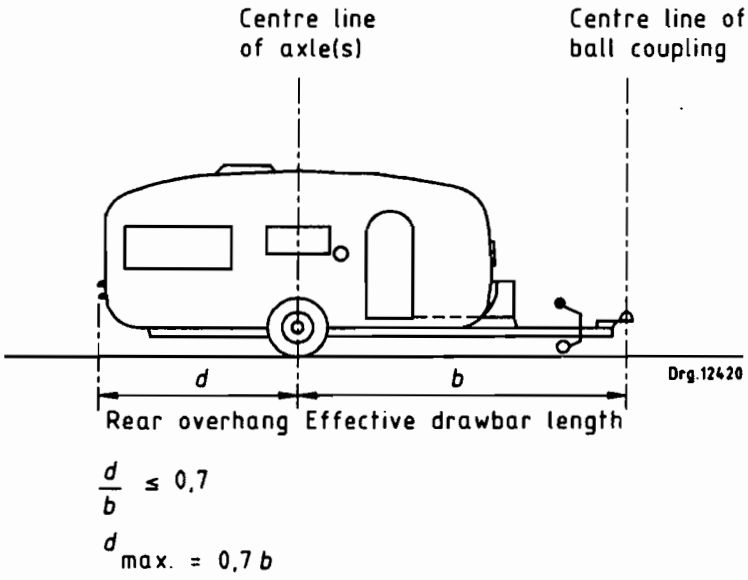


Figure 3 — Rear overhang limitations of a caravan

4.1.5 Minimum payload of a caravan

To ensure sufficient carrying capacity for movable property, the payload of the caravan (GVM minus tare) shall be not less than the total mass of user effects normally expected to be carried by the caravan (taken to be at least 15 % of the GVM), plus allowances of at least 15 kg for LPG (liquid petroleum gas) cylinders and at least 30 kg for a refrigerator, if such items are not fitted as standard equipment by the manufacturer.

4.2 Information plates

4.2.1 Data plates

A trailer shall have a data plate or data plates permanently affixed to it, or to the trailer drawbar, in a conspicuous position and visible from the left-hand side of the trailer. The information stated in the relevant regulations of the National Road Traffic Act, 1996 (Act 93 of 1996) and the wording "For public road operation" shall be legibly and permanently imprinted or stamped on the data plate(s).

4.2.2 Vehicle Identification Number (VIN)

4.2.2.1 General

A trailer shall have a vehicle identification number that complies with the relevant requirements given in SANS 3779/ISO 3779 (SABS ISO 3779:1983), *Road vehicles – Vehicle identification number (VIN) – Content and structure*, and in SANS 4030/ISO 4030 (SABS ISO 4030:1983), *Road vehicles – Vehicle identification number (VIN) – Location and attachment*, except for clause 5 of the said SANS 4030, which shall be amended in accordance with the requirements in 4.2.2.2 to 4.2.2.4.

4.2.2.2 The VIN shall be marked directly on an integral part of the vehicle; it may be either on the frame or, for integral frame body units, on a part of the body not easily removed or replaced.

4.2.2.3 The VIN shall also be marked on the data plate.

4.2.2.4 The height of the roman letters and the arabic numerals of the VIN shall be as follows:

a) at least 7 mm if marked in accordance with 4.2.2.2 (frame, body, etc.) on trailers; and

b) at least 3 mm if marked in accordance with 4.2.2.3 (data plates).

4.2.3 Axle data

4.2.3.1 Each axle on a trailer shall be provided with a data plate as given in 4.2.3.2 or 4.2.3.3, where relevant. The particulars of the information on the data plate shall be permanently and legibly imprinted or stamped and the data plate shall be permanently affixed in a conspicuous position on the axle.

4.2.3.2 Each axle of a trailer shall have a data plate that gives the following information:

a) the axle make and serial number;

b) the load capacity of the axle; and

c) the maximum rolling radius.

4.2.3.3 Where a braking system is fitted, the axle(s) of a trailer shall have a data plate that gives the information given in 4.2.3.2 and the following information:

a) the type/size of the shoe/pad, and the grade of the brake lining material, and

b) in the case of cam brakes operated by air, the brake chamber size and the brake lever length .

4.3 Measuring units

All gauges, indicators and instruments that are fitted to a trailer shall be calibrated in units as prescribed by the current applicable regulations promulgated under the Measuring Units and National Measuring Standards Act, 1973 (Act 76 of 1973).

4.4 Load-carrying capacity of tyres

Tyres for trailers shall comply with the *Compulsory specification for pneumatic tyres for passenger cars and their trailers* or the *Compulsory specification for pneumatic tyres for commercial vehicles and their trailers*, as published by Government Notice No. R1125 (Government Gazette No. 22822) of 16 November 2001 (as amended from time to time), where applicable.

5 Requirements for the control of environmental interference

5.1 Suppression of radio and television interference

All components, accessories or equipment that are fitted to a trailer and that generate and radiate electromagnetic energy shall comply with the current applicable regulations relating to interference with communications promulgated under the Telecommunications Act, 1996 (Act 103 of 1996).

5.2 Suppression of atmospheric pollution

All engines, accessories or equipment that are fitted to a trailer and that generate smoke emissions shall comply with the current regulations promulgated under the Atmospheric Pollution Prevention Act, 1965 (Act 45 of 1965).

6 Requirements for caravan equipment and components

6.1 Liquid petroleum gas containers

6.1.1 General

Provision shall be made to ensure that any LPG container(s), carried inside or outside a caravan or tent trailer, are adequately secured to prevent movement in any direction when the caravan or tent trailer is being drawn.

6.1.2 Ventilation

Permanent ventilation at a low floor level shall be provided to the outside atmosphere. The area of ventilation shall be at least the greater of 4 % of the floor area of the housing or compartment or 10 000 mm^2. The ventilation area shall have no obstruction.

6.1.3 Location

Access to the LPG container(s) shall be from the outside of a caravan or tent trailer and no LPG vapour shall be allowed to penetrate into the interior of the caravan or tent trailer.

6.1.4 Fuel storage

No component or fixture that, in normal use, could damage the LPG installation or that might ignite escaping gas, shall be installed in a fuel storage housing or a fuel storage compartment.

6.2 Provision of fire extinguishers

A caravan or tent trailer shall be provided with one or more portable 1 kg dry powder fire extinguisher(s) securely stowed in a readily accessible position which, in the case of a caravan, shall be adjacent to the main entrance door.

The fire extinguisher(s) shall comply with the relevant requirements given in SANS 810 (SABS 810:1992), *Portable rechargeable fire extinguishers – Dry powder type extinguishers,* or in SANS 1322 (SABS 1322:1988), *Portable, non-refillable fire extinguishers (general purpose type).*

7 Homologation requirements

7.1 Homologation

Registered manufacturers, importers and builders (MIBs) shall have each model of motor vehicle, from a specific source, covered by the scope of this compulsory specification, homologated by the regulatory authority in accordance with the requirements of Annexure A.

7.2 Rights of homologation approval

The rights of ownership of homologation approval, so granted for a vehicle model in 7.1, shall lie with the registered MIB that obtained such approval. This may only be transferable, to another registered MIB, on request of the MIB that currently owns the rights of homologation approval, and be authorised by, the regulatory authority.

A transference fee, as determined by the Minister, shall be paid to the regulatory authority.

8 Equivalent requirements

The requirements of any national standards stated in the appropriate parts given in Table 2 shall be deemed to have been met if compliance with the equivalent standards given in columns 5, 6 ,7or 8 of the same table, or any of their later amendment levels, is achieved.

Where an EEC Directive is quoted in column 5, and an amendment level is quoted in column 6, this shall mean that the Directive and its amendment up to, and including the quoted level (in column 6) is the minimum level that is acceptable.

COMPULSORY SPECIFICATION FOR CATEGORY O_1 AND O_2 VEHICLES (CARAVANS AND LIGHT TRAILERS)

SCHEDULE 1 — Operative dates

1	2	3	4	5
Subsection	**Item**	**Operative date**	**Exclusions**	**Exclusion expiry date**
	All new or newly amended subsections/items, not referred to below	2 months after final gazetting		
3.1.1	Lights to SANS 20003 SANS 20004 SANS 20006 SANS 20007 SANS 20023 SANS 20037 SANS 20091	26 March 2005		
3.1.2	Lighting to SANS 20048	26 March 2005		
3.3	Brakes and braking equipment to SANS 20013	26 March 2005		
3.5.1	Coupling devices to SANS 20055	26 September 2004		

COMPULSORY SPECIFICATION FOR VEHICLES OF CATEGORY O_1 AND O_2 (CARAVANS AND LIGHT TRAILERS)

Table 1 — Equivalent standards

1	2	3	4	5	6	7	8
Subsection	**Item**	**SANS No.**	**Date**	**EEC**		**ECE**	**Other**
				Base	**Amdts (up to and including)**		
3.1.1	Lights	20003 20004 20006 20007 20023 20037 20091	1996 1997 2003 2002 1992 2002 1993	76/757 76/760 76/759 76/758 77/539 76/761 76/758	97/29 97/31 99/15 97/30 97/32 99/17 97/30	R3.02 R4 R6.01 R7.02 R23 R37.03 R91	
3.1.2	Lighting	20048	1994	76/756	97/28	R48.02	
3.2	Safety glass	1191 1192 1193	1997 1994 2001	92/22 92/22 92/22		R43 R43 R43	
*	or Safety Glazing material (plastics)	* 1472	*2005	*92/22		*R43	
3.3	Braking	20013	1996	71/320	98/12	R13.08	
3.4	Electrical connectors	11446 12098	1995 1994				ISO 11446 ISO 12098
3.5.1	Coupling devices	20055	2003			R55.01	
4.2.2	VIN number	3779 4030	1983 1983				ISO 3779 ISO 4030
4.4	Tyres	Compulsory specifications for pneumatic tyres	2001	92/23	01/43	R30.02 R54	

Annexure A

Administrative Process - Homologation of Models of Vehicles of Category O1/O2.

1. The Applicant shall formally submit a request for homologation, for each model of vehicle intended to be manufactured or imported, in writing, to the Regulatory Authority providing information of his/her intention to homologate that model of vehicle.
2. The Regulatory Authority shall forward to the Applicant the relevant homologation application documents for each model, requested in 1 above. The application documents shall stipulate the information to be submitted to the Regulatory Authority, and these shall accompany the submitted application.
3. The Applicant shall complete the application and provide the necessary requested supporting documentation, and forward it to the Regulatory Authority. The appropriate fee for the homologation, as determined by the Minister by Notice in the Government Gazette, shall be paid to the Regulatory Authority.
4. Upon receipt of the completed application and the required documents, the Regulatory Authority shall review the documents for correctness, completeness, and authenticity. Incorrect documentation, or insufficient documentation, will be reported to the applicant, for his/her correction.
5. Once the application documentation is correct, the Regulatory Authority shall formally confirm the date and place to the Applicant for the sample vehicle to be inspected, as part of the homologation process (if not already submitted).
6. At the homologation inspection, the Regulatory Authority shall inspect the sample vehicle and verify it against all mandatory requirements and the submitted evidence of conformity in the application documents, to these requirements.
7. Any non-compliances identified in 6 above, shall be resolved by the Applicant, to the satisfaction of the Regulatory Authority.
8. Once the homologation process establishes that the vehicle model complies with all the relevant mandatory requirements, the Regulatory Authority shall issue a formal Letter of Compliance (Homologation Approval Letter), to the applicant.
9. The original application documents, and copies of supporting evidence of compliance documents, as necessary, shall be taken, and maintained as Homologation Records, by the Regulatory Authority.

Source of evidence

The evidence of compliance to any of the requirements of any referred-to standard in this compulsory specification, which requires testing to establish compliance, and a test report issuing, will only be recognized by the Regulatory Authority, from the following sources:

1) A laboratory that is part of an international or regional mutual acceptance scheme, or
2) A laboratory that is accredited to ISO/IEC 17025 by SANAS or an ILAC affiliated accreditation body, or
3) The laboratory has been successfully assessed against the requirements of ISO/IEC 17025 to the satisfaction of the Regulatory Authority.

SOUTH AFRICAN REVENUE SERVICE
SUID-AFRIKAANSE INKOMSTEDIENS

No. R. 593 **22 July 2011**

CUSTOMS AND EXCISE ACT, 1964.
AMENDMENT OF SCHEDULE NO. 1 (NO. 1/1/1427)

In terms of section 48 of the Customs and Excise Act, 1964, Part 1 of Schedule No. 1 to the said Act is hereby amended to the extent set out in the Schedule hereto.

N NENE
DEPUTY MINISTER OF FINANCE

SCHEDULE

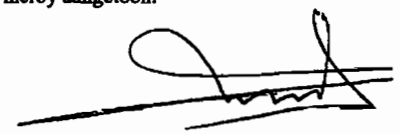
By the substitution of tariff subheading 5401.10 for the following:

Heading	Subheading	CD	Article Description	Statistical Unit	Rate of Duty			
					General	EU	EFTA	SADC
54.01	5401.10	7	- Of synthetic filaments	kg	15%	free	free	free

No. R. 593 **22 Julie 2011**

DOEANE- EN AKSYNSWET, 1964.
WYSIGING VAN BYLAE NO. 1 (NO. 1/1/1427)

Kragtens artikel 48 van die Doeane- en Aksynswet, 1964, word Deel 1 van Bylae No. 1 by bogenoemde Wet hiermee gewysig, in die mate in die Bylae hierby aangetoon.



N NENE
ADJUNKMINISTER VAN FINANSIES

BYLAE

Deur tariefsubpos 5401.10 deur die volgende te vervang:

Pos	Subpos	TS	Artikel Beskrywing	Statistiese Eenheid	Skaal van Reg			
					Algemeen	EU	EFTA	SAOG
54.01	5401.10	7	- Van sintetiese filamente	kg	15%	vry	vry	vry

CUSTOMS AND EXCISE ACT, 1964.
AMENDMENT OF SCHEDULE NO. 3 (No. 3/671)

In terms of section 75 of the Customs and Excise Act, 1964, Schedule No. 3 to the said Act is hereby amended, **with retrospective effect from 1 April 2011**, to the extent set out in the Schedule hereto.

N NENE
DEPUTY MINISTER OF FINANCE

SCHEDULE

By the substitution of tariff headings 00.00/02.00, 85.29/01.04 and 85.29/02.04 to rebate item 316.17 of the following:

Rebate Item	Tariff heading	Rebate Code	C D	Description	Extent of Rebate
316.17	00.00	02.00	04	Goods of any description (excluding mounted or populated circuit boards and display panels, irrespective of their degree of completion and any apparatus classifiable in heading 85.28), at such times, in such quantities and under such conditions as the International Trade Administration Commission may allow by specific permit, for the manufacture of reception apparatus for television incorporating a display other than a cathode-ray tube (CRT) classifiable in subheadings 8528.72.90 and 8528.73.90, whether or not combined in the same housing with radio-broadcasting receivers or sound or video recording or reproducing apparatus	Full duty
316.17	85.29	01.04	48	Display panels (excluding any apparatus classifiable in heading 85.28) not equipped or presented with mounted or populated circuit boards designed for purposes other than pixel control, and inverters, whether or not incorporating a back lighting unit but not equipped or presented with any other components, at such times, in such quantities and under such conditions as the International Trade Administration Commission may allow by specific permit, for the manufacture of reception apparatus for television, classifiable in subheadings 8528.72.90 and 8528.73.90, provided that the Commission is satisfied that the manufacturing process for reception apparatus for television includes the mounting and populating of unpopulated (blank) circuit boards	Full duty
316.17	85.29	02.04	42	Display panels (excluding any apparatus classifiable in heading 85.28), not equipped or presented with mounted or populated circuit boards designed for purposes other than pixel control, and inverters, whether or not incorporating a back lighting unit but not equipped or presented with any other components, at such times, in such quantities and under such conditions as the International Trade Administration Commission may allow by specific permit, for the manufacture of reception apparatus for television, classifiable in subheadings 8528.72.90 and 8528.73.90	Full duty less 12,2%

No. R. 594 **22 Julie 2011**

DOEANE- EN AKSYNSWET, 1964.
WYSIGING VAN BYLAE NO. 3 (No. 3/671)

Kragtens artikel 75 van die Doeane- en Aksynswet, 1964, word Bylae No. 3 by bogenoemde Wet hiermee gewysig, **met terugwerkende krag vanaf 1 April 2011**, in die mate in die Bylae hierby aangetoon.

N NENE
ADJUNKMINISTER VAN FINANSIES

BYLAE

Deur die vervanging van tariefposte 00.00/02.00, 85.29/01.04 en 85.29/02.04 by kortingitem 316.17 van die volgende:

Kortingitem	Tariefpos	Korting Kode	T S	Beskrywing	Mate van Korting
316.17	00.00	02.00	04	Goedere van enige beskrywing (uitgesonderd gemonteerde of opgeboude kringborde en beeldbuise, ongeag van hulle graad van voltooiing en enige apparaat indeelbaar in pos 85.28), teen sodanige tye, in sodanige hoeveelhede and onder sodanige omstandighede as die Internasionale Handelsadministrasie Kommissie by bepaalde permit mag toelaat, vir die vervaardiging van ontvangsapparate vir televisie wat 'n vertoon anders as 'n katodestraalbuis (KSB) inkorporeer, indeelbaar in subposte 8528.72.90 en 8528.73.90, hetsy in dieselfde omhulsel met radio-ontvangstoestelle of klank- of video-opneemapparate of -weergee-apparate gekombineer al dan nie	Volle reg
316.17	85.29	01.04	48	Vertoonpanele (uitgesonderd enige apparaat indeelbaar by pos 85.28), nie toegerus of voorgelê nie, met gemonteerde of opgeboude kringborde ontwerp vir doeleindes anders as vir pixel beheer en omkeerders, hetsy dit 'n agterbeligtingseenheid inkorporeer, al dan nie, maar nie met enige ander komponente toegerus of voorgelê nie, by sodanige tye, in sodanige hoeveelhede en onder sodanige omstandighede as die Internasionale Handelsadministrasie Kommissie by bepaalde permit mag toelaat, vir die vervaardiging van ontvangsapparate vir televisie, indeelbaar in subposte 8528.72.90 en 8528.73.90, met dien verstande dat die Kommissie tevrede is dat die vervaardigingsproses vir ontvangsapparate vir televisie die montering en opbou van blanko kringborde insluit	Volle reg
316.17	85.29	02.04	42	Vertoonpanele (uitgesonderd enige apparaat indeelbaar in pos 85.28), nie toegerus of voorgelê nie, met gemonteerde of opgeboude kringborde ontwerp vir doeleindes anders as vir pixel beheer en omkeerders, hetsy dit 'n agterbeligtingseenheid inkorporeer, al dan nie, maar nie met enige ander komponente toegerus of voorgelê nie, by sodanige tye, in sodanige hoeveelhede en onder sodanige omstandighede as die Internasionale Handelsadministrasie Kommissie by bepaalde permit mag toelaat, vir die vervaardiging van ontvangsapparate vir televisie, indeelbaar in subposte 8528.72.90 en 8528.73.90	Volle reg min 12,2%