Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Regulation Gazette **No. 10462** *Regulasiekoerant*

Vol. 601 **Pretoria, 3 July Julie 2015** **No. 38945**

AIDS HELPLINE: 0800-0123-22 Prevention is the cure

IMPORTANT
Information
from Government Printing Works

Dear Valued Customers,

Government Printing Works has implemented rules for completing and submitting the electronic Adobe Forms when you, the customer, submits your notice request.

Please take note of these guidelines when completing your form.

GPW Business Rules

1. No hand written notices will be accepted for processing, this includes Adobe forms which have been completed by hand.
2. Notices can only be submitted in Adobe electronic form format to the email submission address submit.egazette@gpw.gov.za. This means that any notice submissions not on an Adobe electronic form that are submitted to this mailbox will be **rejected**. National or Provincial gazette notices, where the Z95 or Z95Prov must be an Adobe form but the notice content (body) will be an attachment.
3. Notices brought into GPW by "walk-in" customers on electronic media can only be submitted in Adobe electronic form format. This means that any notice submissions not on an Adobe electronic form that are submitted by the customer on electronic media will be **rejected**. National or Provincial gazette notices, where the Z95 or Z95Prov must be an Adobe form but the notice content (body) will be an attachment.
4. All customers who walk in to GPW that wish to submit a notice that is not on an electronic Adobe form will be routed to the Contact Centre where the customer will be taken through the completion of the form by a GPW representative. Where a customer walks into GPW with a stack of hard copy notices delivered by a messenger on behalf of a newspaper the messenger must be referred back to the sender as the submission does not adhere to the submission rules.
5. All notice submissions that do not comply with point 2 will be charged full price for the notice submission.
6. The current cut-off of all Gazette's remains unchanged for all channels. (Refer to the GPW website for submission deadlines – www.gpwonline.co.za)
7. Incorrectly completed forms and notices submitted in the wrong format will be rejected to the customer to be corrected and resubmitted. Assistance will be available through the Contact Centre should help be required when completing the forms. (012-748 6200 or email info.egazette@gpw.gov.za)
8. All re-submissions by customers will be subject to the above cut-off times.
9. All submissions and re-submissions that miss the cut-off will be rejected to the customer to be submitted with a new publication date.
10. Information on forms will be taken as the primary source of the notice to be published. Any instructions that are on the email body or covering letter that contradicts the notice form content will be ignored.

You are therefore advised that effective from **Monday, 18 May 2015** should you not comply with our new rules of engagement, all notice requests will be rejected by our new system.

Furthermore, the fax number **012- 748 6030** will also be **discontinued** from this date and customers will only be able to submit notice requests through the email address submit.egazette@gpw.gov.za.

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eGazette

DO use the new Adobe Forms for your notice request. These new forms can be found on our website: www.gpwonline.co.za under the Gazette Services page.

DO attach documents separately in your email to GPW. (In other words, your email should have an Adobe Form plus proof of payment – 2 separate attachments – where notice content is applicable, it should also be a 3rd separate attachment)

DO specify your requested publication date.

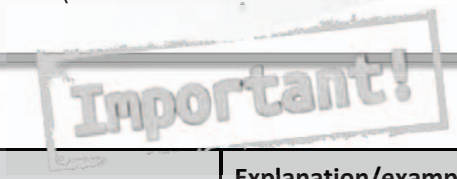
DO send us the electronic Adobe form. (There is no need to print and scan it).

DON'T submit request as a single PDF containing all other documents, i.e. form, proof of payment & notice content, it will be **FAILED** by our new system.

DON'T print and scan the electronic Adobe form.

DON'T send queries or RFQ's to the submit.egazette mailbox.

DON'T send bad quality documents to GPW. (Check that documents are clear and can be read)



Form Completion Rules

No.	Rule Description	Explanation/example
1.	All forms must be completed in the chosen language.	GPW does not take responsibility for translation of notice content.
2.	All forms must be completed in sentence case, i.e. No fields should be completed in all uppercase.	e.g. "The company is called XYZ Production Works"
3.	No single line text fields should end with any punctuation, unless the last word is an abbreviation.	e.g. "Pty Ltd.", e.g. Do not end an address field, company name, etc. with a period (.) comma (,) etc.
4.	Multi line fields should not have additional hard returns at the end of lines or the field itself.	This causes unwanted line breaks in the final output, e.g. • **Do not** type as: 43 Bloubokrand Street Putsonderwater 1923 • **Text should be entered** as: 43 Bloubokrand Street, Putsonderwater, 1923
5.	Grid fields (Used for dates, ID Numbers, Telephone No., etc.)	• Date fields are verified against format CCYY-MM-DD • Time fields are verified against format HH:MM • Telephone/Fax Numbers are not verified and allow for any of the following formats limited to 13 characters: including brackets, hyphens, and spaces ○ 0123679089 ○ (012) 3679089 ○ (012)367-9089
6.	Copy/Paste from other documents/text editors into the text blocks on forms.	• Avoid using this option as it carries the original formatting, i.e. font type, size, line spacing, etc. • Do not include company letterheads, logos, headers, footers, etc. in text block fields.

No.	Rule Description	Explanation/example

7.	Rich text fields (fields that allow for text formatting)	• Font type should remain as Arial
		• Font size should remain unchanged at 9pt
		• Line spacing should remain at the default of 1.0
		• The following formatting is allowed:
		  ○ Bold
		  ○ Italic
		  ○ Underline
		  ○ Superscript
		  ○ Subscript
		• Do not use tabs and bullets, or repeated spaces in lieu of tabs and indents
		• Text justification is allowed:
		  ○ Left
		  ○ Right
		  ○ Center
		  ○ Full
		• Do not use additional hard or soft returns at the end of line/paragraphs. The paragraph breaks are automatically applied by the output software
		  ○ Allow the text to wrap automatically to the next line only use single hard return to indicate the next paragraph
		  ○ Numbered lists are allowed, but no special formatting is applied. It maintains the standard paragraph styling of the gazette, i.e. first line is indented.

	e.g. 1. The quick brown fox jumps over the lazy river. The quick brown fox jumps over the lazy river. The quick brown fox jumps over the lazy river. 2. The quick brown fox jumps over the lazy river. The quick brown fox jumps over the lazy river. The quick brown fox jumps over the lazy river.	

You can find the **new electronic Adobe Forms** on the website www.gpwonline.co.za under the Gazette Services page.

For any **queries** or **quotations**, please contact the **eGazette Contact Centre** on 012-748 6200 or email info.egazette@gpw.gov.za

Disclaimer

Government Printing Works does not accept responsibility for notice requests submitted through the discontinued channels as well as for the quality and accuracy of information, or incorrectly captured information and will not amend information supplied.
GPW will not be held responsible for notices not published due to non-compliance and/or late submission.

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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 577 **3 July 2015**

NATIONAL HEALTH ACT, 2003

REGULATIONS RELATING TO HUMAN MILK BANKS

The Minister of Health intends, in terms of section 68 of the National Health Act, 2003, (Act No.61 of 2003) and after consultation with the National Health Council, to make Regulations in the Schedule.

Interested persons are invited to submit written comments on the proposed Regulations, or any representations they may wish to make in regard thereto, to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for the attention of the Acting Director: Nutrition),within three months from the date of publication of this notice.

SCHEDULE

DEFINITIONS

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

"Act" means the National Health Act, 2003 (Act No. 61 of 2003);

"audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities and/or vendors to evaluate adherence to the written standard operating procedures, the Act and Regulations;

"collection" means the process of gathering donor human milk from human milk bank collection posts and authorised human milk banks for the purpose of processing and distribution;

"designated person" means any staff member who has been tasked with a specific set of activities for the operation of the human milk bank;

"distribution" means the transportation of donor human milk after it has been collected for processing until it has been delivered to a health establishment or non-profit organisation for use by the recipient;

"donor human milk" means human milk expressed by a mother for use by a recipient who is not the mother's own baby. No payment is given for the donated milk;

"human milk bank" means a service authorised in terms of these Regulations responsible for protection, promotion and support of breastfeeding and to recruit and collect milk from donors, process, screen, quality control, store, and distribute donated milk to meet the specific needs of infants in the community or health establishment for whom human milk is needed for optimal health;

"human milk bank collection posts means any hospital, community health centre, clinic and non-health establishment that does not have a human milk bank and which is designated by a district central human milk bank to collect and store donor human milk before it is transferred to a human milk bank for processing;

"human milk" means milk that can be obtained by means of the infant or young child suckling on the mother's breast or by the expression of milk from the breast;

"human milk donor" means any healthy lactating woman who expresses and donates her breast milk voluntarily, without financial compensation for the benefit of vulnerable infants and young children;

"infant" means a person not more than 12 months of age;

"national human milk bank network coordinating unit" means the unit in the National Department of Health responsible for implementation of strategic actions, provision of operational technical advice, coordinating human milk bank networks, research and ensuring adherence to human milk banking norms, standards and guidelines;

"non-health establishment" means any institution registered as a non-profit organisation or registered retailer;

"Office of Standards Compliance" means the Office of Standards Compliance, established in terms of Section 78 of the Act;

"orphan" means a child who has no surviving parent caring for him or her;

"processing" means all procedures involved in the screening, pasteurization, packaging, labeling and storing of donor human milk;

"processing fees" means fees calculated by the donor milk bank for the cost of collecting, screening, processing, distributing and tracking donor milk;

"provincial human milk bank network coordinating unit" means units in Maternal, Child and Nutrition Directorates or Subdirectorates in provinces, responsible for coordinating human milk banking in their respective province;

"quality" means the conformance of donor human milk or a process with pre-established specifications or regulations;

"quality assurance management programme" means a programme that defines the policies and environment that are required to meet standards of quality and

safety and that provides confidence that the processes and donor human milk consistently conform to requirements for quality;

"recipient" means a person to whom donor human milk is administered in accordance with these Regulations;

"responsible person" means a person who is managing the day-to-day activities of the human milk bank;

"screening" means testing of potential donors for, inter alia, the absence of HIV, TB, hepatitis B and C, syphilis and lifestyle as well as the testing of an aliquot of milk from the first donation of each donor for microbial contamination, as outlined in the standard operating procedures;

"standard operating procedures" means a group of standard operating procedures (SOPs) detailing the specific policies of a human milk bank and the procedures used by staff or personnel in accordance with the guidelines, norms and standards of the national human milk bank network coordinating unit. This includes but is not limited to procedures on screening, processing, labeling, storage and distribution; and

"storage" means maintaining the donor human milk under appropriately controlled conditions for future use or until distributed.

2. Authorisation of human milk banks

(1) The Director-General may authorise an organisation or institution to establish or operate a human milk bank.

(2) An authorised human milk bank including those authorised in terms of Subsection (1) –

(a) Must have authorisation for operating the human milk bank;

(b) Must comply with the prescribed norms, standards and guidelines of the national human milk bank network coordinating unit and must provide the prescribed human milk bank services;

(c) May establish human milk bank collection posts for the delivery of human milk bank services, which is under the control of the authorised human milk bank;

(d) Must have human milk bank collection posts that are linked to the authorised human milk bank for technical and administrative purposes; and

(e) Must abide by the International Code of Marketing of Breastmilk substitutes.

(3) Existing human milk banks should apply for authorisation within 12 months after these Regulations have come into effect.

3. Application for authorisation of human milk banks

(1) An application for authorisation of a human milk bank shall be made to the Director-General.

(2) The application referred to in Sub-regulation (1) shall contain the following information:

(a) the name and nature of the applicant;

(b) location of the premises where business is to be conducted;

(c) an indication of how records and data shall be kept;

(d) the quality assurance management system to be used;

(e) details of the responsible person;

(f) names of the designated human milk bank collection posts and their contact details; and

(g) any other information the Director-General may consider necessary for the consideration of the application.

(3) The Director-General may, on application in terms of Sub-regulation (1) –

(a) request the applicant to be inspected by the national human milk bank network coordinating unit or relevant provincial human milk bank network coordinating unit;

(b) obtain such further information as he or she deems necessary for the consideration of the application;

(c) authorise, the applicant concerned as a human milk bank, subject to such conditions as he or she may determine; and

(d) where such applicantion is not approved, the Director-General shall notify the applicant in writing accordingly, stating the reason for such non-authorisation.

4. Suspension or withdrawal of authorization

(1) If the Director General is of the opinion on the strength of an inspection report and recommendation by the national human milk bank network coordinating unit or relevant provincial human milk bank network coordinating unit that there are reasonable grounds to suspect that-

(a) any premises, equipment or processes used by an authorised human milk bank is in any way hazardous to health;

(b) the authorised human milk bank organisation is not complying with the Act or these Regulations; or

(c) the authorised human milk bank after being afforded an opportunity by the provincial human milk bank network coordinating unit to rectify the situation referred to in paragraph (a), or (b) failed to rectify such situation the Director General may, suspend or withdraw the authorization.

(2) The Director-General, before suspending or withdrawing an authorisation as contemplated in Sub-regulation (1), shall afford the authorised human milk bank an opportunity to show cause why the authorisation should not be suspended or withdrawn.

(3) The suspension or withdrawal of authorisation in terms of this Regulation shall have the effect that, from the date of such suspension or revocation, the authorised human milk bank shall cease to carry out any activities referred to in Regulations 6 and 7.

5. Organisational structure of an authorised human milk bank

(1) The purpose of the authorised human milk bank shall be clearly formulated and documented. The authorised human milk bank shall state whether it is a freestanding entity or part of a hospital.

(2) All activities of an authorised milk bank shall comply with the norms, standards and guidelines to be developed by the national human milk bank network coordinating unit.

(3) The authorised human milk bank shall have a designated person(s) with expertise in infant and young child nutrition responsible for the day-to-day running of the bank and establishing standard operating procedures in accordance with the norms, standards and guidelines of the national human milk bank network coordinating unit, unless otherwise provided by the institution of which it is a part.

(4) An authorised human milk bank that is situated in a hospital will have an appointed registered health care provider who has experience in neonatology or paediatrics to be responsible for the authorised human milk bank's medical care.

(5) Authorised hospital-based human milk banks can only be situated in public or private hospitals that are designated as Mother-and-Baby friendly.

(6) An authorised milk bank which is outside a health establishment will have a appointed registered health care provider who will oversee the authorised milk bank's medical care.

(7) An authorised human milk bank shall establish a multidisciplinary committee of staff members of the organisation who will meet at least quarterly and who will provide technical guidance and assistance.

(8) The authorised human milk bank shall establish and maintain a mechanism to access medical, technical and scientific advice as needed.

(9) The responsible person shall –

(a) be responsible for the work processes of the human milk bank;

(b) plan, implement and ensure the quality of processes including human resources, materials and equipment necessary for the performance of their tasks according to the applicable policies and relevant Regulations;

(c) implement the standard operating procedures;

(d) be responsible for all operations including compliance with the Act and requirements of these Regulations;

(e) provide information to the national and relevant provincial human milk bank network coordinating unit as required in terms of these Regulations; and

(f) supervise technical staff during the period of operation of the human milk bank.

(10) Only a designated person will be directly involved in the milk bank activities as referred to in these Regulations.

(11) An authorised human milk bank may only receive payment for activities as indicated in Section 60 of the Act.

6. Duties

6.1 Duties of national human milk networking coordinating unit

(1) The national human milk networking coordinating unit shall -

(a) protect, promote and support breastfeeding;

(b) develop and review regulations, guidelines, norms and standards on human milk banks which are based on clinical evidence;

(c) advocate for the establishment of human milk banks;

(d) determine norms and standards to be prescribed for human milk banks and the review of such norms and standards;

(e) conduct inspections and certify human milk banks as compliant or non compliant with prescribed norms and standards;

(f) publish information relating to prescribed norms and standards to various interested parties within the prescribed government Regulations and guidelines;

(g) collect or request any information relating to prescribed norms and standards from authorised human milk banks and users;

(h) liaise with other regulatory authority or government or private institutions with common interests to foster collaboration and exchange information related to human milk banks;

(i) investigate complaints related to human milk banks;

(j) develop a training curriculum on human milk banking;

(k) establish a monitoring and information system on human milk banking;

(l) monitor indicators of risk as an early warning system relating to serious breaches of norms and standards and report any breaches to management without delay;

(m) identify areas and make recommendations for intervention by a national or provincial department of health or a health department of a municipality, where it is necessary, to ensure compliance with prescribed norms and standards;

(n) ensure the consistent application of the Regulations and the guidelines as prescribed;

(o) negotiate cooperation agreements with any regulatory authority in order to coordinate and harmonise norms and standards;

(p) recommend quality assurance and management systems for the human milk bank networks;

(q) coordinate research and technical development on human milk banking; and

(r) keep record of all activities undertaken at the national human milk banking network coordinating unit.

6.2 Duties of provincial human milk bank network coordinating unit

(1) The provincial human milk bank network coordinating unit shall –

(a) protect, promote and support breastfeeding;

(b) conduct inspections at all human milk banks in that province and monitor adherence to norms and standards;

(c) investigate complaints related to human milk banking in that province;

(d) ensure that equipment and other supplies are available at all human milk banks;

(e) conduct training and capacity building of human milk bank staff;

(f) conduct mentoring and supportive supervision to human milk banks;

(g) ensure that quality standards as outlined in the guidelines are strictly adhered to all the time in all Provincial human milk banks;

(h) ensure that competent persons are appointed at the reference centre;

(i) keep record of all activities undertaken at the provincial reference centre; and

(j) report to the national human milk banking network coordinating unit on all activities of the provincial human milk bank networks.

6.3 Duties of authorised human milk bank

(1) Each authorised human milk bank shall –

(a) develop plans to promote, protect and support breastfeeding and recruit donors;

(b) provide assistance to pregnant women, postpartum women, infants and lactating mothers on breastfeeding practices;

(c) have in their possession the standard operating procedures;

(d) screen, collect, select, sort, process, store donor human milk, distribute and track pasteurized human milk;

(e) ensure that recipient infant's mothers receive ongoing support to establish breastfeeding to ensure that they do not become reliant on the donor breast milk;

(f) receive, process and quality control donor human milk from milk collection posts linked to it;

(g) conduct training and capacity-building for staff at human milk bank collection posts;

(h) conduct mentoring and supervision of staff at human milk bank collection posts;

(i) perform quality control of products and processes under its jurisdiction;

(j) develop an information system which will ensure that records related to donors, recipients, products and other activities of the human milk bank are kept at all times;

(k) keep a register of human milk donors in which shall be entered at least the following particulars pertaining to each human milk donor from whom the human milk bank, organisation, or person has obtained the donor human milk –

(i) the name and surname of the donor;

(ii) the ID number, where available;

(iii) the identity of the consenting person, including name, address and telephone number;

(iv) the donor number;

(v) screening questionnaire results;

(vi) signed consent form;

(vii) results of serology tests;

(viii) date of birth and gestational age of infant; and

(ix) a record of each donation made;

(l) screen and test donors and take samples of donor human milk for testing according to the norms, standards and guidelines of the national human milk bank network coordinating unit and shall conduct these screening and testing activities on behalf of human milk bank collection posts that are linked to the authorised human milk bank testing and screening facilities and where screening and testing facilities are not available;

(m) process the donor human milk according to the norms, standards and guidelines of the national human milk bank network coordinating unit and process donor human milk from human milk bank collection posts linked to the authorised human milk bank;

(n) document the human milk banking process(es) for which the human milk bank is responsible and must include, but not be limited to:

(i) a database with date of pasteurisation, best before date, number of bottles and donor number in the batch;

(ii) date of pasteurisation, heat treatment and time;

(iii) bacteriological test results by batch; and

(iv) freezer and fridge temperatures;

(o) keep a record of statistics in respect of human milk donations, in which shall be entered at least the following information in respect of all the human milk donations and the supply of donor human milk by the human milk bank over each month:

(i) the number of human milk donors;

(ii) the volumes of donor human milk supplied;

(iii) the names, addresses and contact details of the health establishments or non-profit organisations to whom the donor human milk was supplied;

(iv) name and contact details of health care provider ordering donor human milk;

(v) pasteurization batch numbers of donor human milk supplied; and

(vi) the number of human milk donations which were discarded and the reason for which they were discarded;

(p) keep a system in place to receive, investigate, register and transmit information on a monthly basis, to the district central bank provincial human milk bank network coordinating unit according to the norms, standards and guidelines of the national human milk bank network coordinating unit about complaints about the quality and safety of donor human milk and which may be attributed to the acquisition, testing, processing, storage and distribution of donor human milk;

(q) maintain records on the distribution of donor human milk to other entities and shall send these records on a monthly basis to the relevant district central human milk bank or provincial or national human milk bank network coordinating unit in accordance with the norms, standards and guidelines of the national human milk bank network coordinating unit;

(r) make records easily accessible for inspection by the provincial or national human milk bank network coordinating unit or Office of Standards Compliance;

(s) any payment made in terms of Section 60 1(a) and (b) of the Act must be recorded – the amount paid, to whom payment was made, reason for payments and who made payment, in terms of Section 60 (4) (a) of the Act;

(t) strict confidentiality must be observed by all employees of each human milk bank with regard to all information pertaining to human milk donors and recipients pertaining to the activities in which the authorised human milk bank is involved; and

(u) establish systems that allow the traceability of donor human milk from donor to recipient.

6.4 Duties of the human milk bank collection posts

(1) Each human milk bank collection post shall –

(a) develop plans to promote, protect and support breastfeeding;

(b) provide assistance to pregnant women, postpartum women, infants and lactating mothers on breastfeeding practices;

(c) have in their possession the standard operating procedures;

(d) collect, store and pass donor human milk to the human milk bank it is linked to;

(e) receive, process and perform quality control on donor human milk from milk collection posts linked to it;

(f) perform quality control of products and record all processes undertaken under its jurisdiction to ensure product traceability; and

(g) have an information system which will ensure that that records related to donors, products and other activities of the human milk bank collection post are kept at all times.

7. Operating procedures

7.1 Processing

(1) An authorised human milk bank shall include in their standard operating procedures -

(a) pasteurisation processes in accordance with the norms, standards and guidelines of the national human milk bank network coordinating unit;

(b) all other processes that affect quality, safety and controlled conditions; and

(c) special provision for the handling of donor human milk to be discarded.

(2) An authorised human milk bank shall have agreements and procedures in place to ensure that, in the event of termination of activities for whatever reason, stored donor human milk shall be transferred to other authorised human milk banks.

(3) An authorised human milk bank shall ensure that the equipment used, the working environment process design, validation and control conditions are in accordance with its standard operating procedures.

7.2 Storage conditions

An authorised human milk bank or a human milk bank collection post shall-

(1) ensure that all procedures associated with the storage of donated human milk are carried out documented in accordance with the norms, standards and guidelines as set out by the national human milk bank network coordinating unit;

(2) have agreements and procedures in place to ensure that, in the event of termination of activities for whatever reason, stored donor human milk shall be transferred to other authorised human milk banks; and

(3) have procedures in place to discard donor human milk that is not fit for consumption.

7.3 Labeling, documentation and packaging

An authorised human milk bank or a human milk bank collection post shall ensure that-

(a) labelling, documentation and packaging conform to the norms, standards and guidelines as set out by the national human milk bank network coordinating unit; and

(b) the following information shall be included on the container label:

(i) pasteurised donor human milk or non-pasteurised donor human milk;

(ii) donor identification code;

(iii) best before date; and

(iv) pasteurisation date.

7.4 Quality Assurance Management

A human milk bank shall take necessary measures to ensure that-

(a) a quality assurance management system is in place in accordance with the norms, standards and guidelines as set out by the national human bank network coordinating unit;

(b) the quality assurance management system referred to in paragraph (a) includes at least the following documentation:

(i) standard operating procedures and forms;

(ii) documentation on the Hazard Analysis Critical Control Point processes;

(iii) reports of process validation and equipment qualification;

(iv) training and reference materials;

(v) donor records;

(vi) information on the final destination of donor human milk; and

(vii) audit records.

(c) the information referred to in paragraph (b) is available for inspection by the national human milk bank network coordinating unit, provincial human milk bank or Office of Standards Compliance.

7.5 Distribution and dispensing

(1) An authorised human milk bank or human milk bank collection post shall ensure the quality of the donor human milk and cold chain maintenance is nor compromised during transport and or distribution.

(2) A health establishment or non-profit organisation providing donor human milk to recipients shall ensure the quality of the donor human milk and cold chain management is not compromised.

(3) Provision of donor human milk for the purpose referred to in Sub-regulation 7.5 (5) shall be restricted to hospitals, clinics, community health centres and to non-profit organisations caring for orphans.

(4) The import and export of donor human milk shall be according to the Act.

(5) A person may use donor human milk donated by a human milk donor only for such medical purposes as may be prescribed by a registered health care provider, with the following conditions receiving priority according to available supply when mother's own milk is not available:

(a) preterm infants of less than 1500g;

(b) preterm infants or ill babies of HIV positive mothers;

(c) infants, younger than 12 months old with medical condition likely to respond to donor milk;

(d) individuals older than 12 months old with medical condition likely to respond to donor milk;

(e) individuals with chronic conditions, high functioning, responding to donor milk;

(f) the recipient's mother is seriously ill or demised;

(g) the recipient's mother building up own supply – 1st three days post partum;

(h) the recipient's mother is absent – unable to visit baby and no rooming-in bed available; and

(i) other maternal contraindication - chemotherapy, serious substance abuse.

(6) No donor human milk may be ordered unless it is prescribed by a health care provider in writing on a form created for this purpose.

(7) The form referred to in paragraph (6) must be signed by the health care provider.

(8) Any institution or facility where donor human milk is administered to any living person must ensure that:

(a) policies and procedures are in place to ensure the correct identification of the recipient at the time of feeding donor human milk; and

(b) records are kept in permanent patient records of all such products administered in paragraph (a) above.

(9) The human milk bank must inform the Director-General or a person specifically designated by him or her, verbally immediately of any report received in terms of any serious or life threatening reaction or death and confirm such report in writing as soon as within 15 days after first notification.

(10) A person may not acquire donor human milk for the purpose referred to in these Regulations unless it is done –

(a) with the written consent of the person from whom the milk is acquired granted in the prescribed manner; and

(b) in accordance with prescribed conditions.

(11) Donor human milk may not be obtained from any person for any person contemplated in Sub regulation 7.5(5) –

(a) from a person who is mentally ill within the meaning of the Mental Health Care Act, 2002 (Act No. 17 of 2002); or

(b) from a person who is younger than 18 years.

7.6 Recruitment of Donors

The recruitment of human milk donors must be in accordance with the criteria set out in the guidelines of the national human milk bank network coordinating unit and the scope of practice.

7.7 Mandatory testing for human milk donors and donor human milk

(1) An authorised human milk bank shall perform a rapid HIV test on each donor of human milk.

(2) An authorised human milk bank shall not release donor human milk if there is any reason to suspect from the donor's laboratory test results, medical history, past donation record or physical condition that her milk may transmit disease.

7.8 Traceability

An authorised human milk bank must ensure that-

(a) all its activities referred to in these Regulations be traced from donor to recipient and vice versa;

(b) it has a unique donor identification system which assigns a code to each donation and to each product associated with it; and

(c) data necessary to ensure traceability at all stages is kept for a minimum of 21 years after donation or clinical use and such data may be in electronic form.

8. Inspection and control measures

(1) Each authorised human milk bank shall be inspected at least once per year according to the inspection schedule of the national or provincial human milk bank network coordinating unit or Office of Standards Compliance, whichever applies, to ensure that it complies with the requirements of these Regulations and the norms, standards and guidelines as set out by the National human milk bank network coordinating unit.

(2) Each authorised human milk bank collection post shall be inspected at least once per year according to the inspection schedule of the district human milk bank.

(3) The national and provincial human milk bank network coordinating units shall establish and maintain an accessible database of authorised human milk banks and human milk bank collection points, specifying their compliance with these Regulations, based on inspection reports.

9. Reporting

(1) A human milk bank collection post shall report to the authorised human milk bank to which it was designated.

(2) An authorised human milk bank, shall report to the provincial human milk bank coordinating unit in which it resides.

(3) Provincial human milk bank coordinating unit shall report to the national human milk bank coordinating unit.

(4) An authorised human milk bank must –

(a) inform the provincial human milk bank coordinating unit of any change in its name, address, health care provider or responsible person;

(b) inform the provincial human milk bank coordinating unit in writing in 30 days if it no longer intends to carry out the requirements referred to in these Regulations.

10. Data protection and confidentiality

(1) An authorised human milk bank or human milk bank collection post shall ensure that all data collected within the scope of these Regulations remain confidential at all times.

(2) For the purpose of Sub regulation (1), an authorised human milk bank or human milk bank collection post shall ensure that –

(a) data security measures are in place, as well as safeguards against any unauthorised data additions, deletions, or modifications to donor records;

(b) no authorised disclosure of information occurs; and

(c) anonymity and privacy of donors are protected.

11. Research

(1) All activities at authorised human milk banks and human milk bank collection posts which involve the research of donor human milk shall be in accordance with:

(a) Chapter 9 of the Act;

(b) be approved by the relevant ethics committee that guides the activities of the human milk bank; and

(c) take place under the supervision of a scientist registered as such under the terms of the Health Professions Act, 1974 (Act No. 56 of 1974).

(2) All research results shall be recorded and documented in accordance with the Act.

12. Third parties

An authorised human milk bank shall –

(a) evaluate and select third parties on the basis of their ability to meet the required standards laid down in these Regulations;

(b) shall establish a written agreement with the third party when an external activity takes place which influences the quality and safety of the donor human milk, and in particular in the following circumstances:

(i) where an authorised human milk bank, organisation or person entrusts any of the activities to a third party;

(ii) where a third party provides goods and services that affect donor milk quality and safety assurance, including their distribution;

(iii) where an authorised human milk bank or organisation process and distributes donor human milk collected by a third party;

(c) not provide services to a third party which is not accredited; and

(d) provide copies of agreements with the third party.

13. Appeals

(1) A human milk bank or an organisation, institution or person who applied for authorisation may appeal in writing to the Minister for any decision made by the Director-General in terms of any provision of these regulations in respect of such human milk bank or organisation, institution or person, as the case may be.

(2) An appeal in terms of Sub-regulation (1) must be lodged within fourteen (14) days of receipt of a notice of such decision by the human milk bank or organisation, institution, or person, as the case may be, and must clearly state –

(a) against which decisions such an appeal is lodged; and

(b) the grounds on which such an appeal is based.

(3) Any appeal in terms of these Regulations shall be lodged with the Director-General , who shall submit it to the Minister together with his or her reasons for the decision against which the appeal is lodged.

(4) The Minister may confirm, amend or revoke a decision taken by the Director-General in terms of the provisions of the Regulations and inform the human milk bank or organisation, institution or person, as the case may be, in writing of his or her decision.

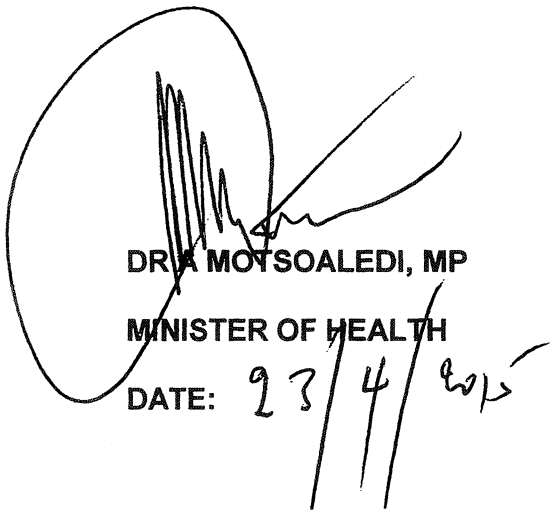
14. Delegations

(1) The Director-General may subject to such conditions he or she may determine, in writing delegate, whether general, in a particular case or cases of a particular nature, to any officer in the Department any power conferred upon him or her by or under these Regulations.

(2) Notwithstanding the provisions of Sub paragraph (1), the Director-General shall not be divested of a power delegated by him or her, and may alter or set aside any decision by an officer taken in the exercise of a power so delegated.

15. Offences and penalties

Any person who contravenes or fails to comply with any provision of these Regulations shall be guilty of an offence and liable on conviction to a fine not exceeding R40 000 and/or imprisonment for a period not exceeding two years.



DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE: 23/4/2015

IMPORTANT

Information

from Government Printing Works

Dear Valued Customers,

Government Printing Works has implemented rules for completing and submitting the electronic Adobe Forms when you, the customer, submits your notice request.

Please take note of these guidelines when completing your form.

GPW Business Rules

1. No hand written notices will be accepted for processing, this includes Adobe forms which have been completed by hand.
2. Notices can only be submitted in Adobe electronic form format to the email submission address submit.egazette@gpw.gov.za. This means that any notice submissions not on an Adobe electronic form that are submitted to this mailbox will be **rejected**. National or Provincial gazette notices, where the Z95 or Z95Prov must be an Adobe form but the notice content (body) will be an attachment.
3. Notices brought into GPW by "walk-in" customers on electronic media can only be submitted in Adobe electronic form format. This means that any notice submissions not on an Adobe electronic form that are submitted by the customer on electronic media will be **rejected**. National or Provincial gazette notices, where the Z95 or Z95Prov must be an Adobe form but the notice content (body) will be an attachment.
4. All customers who walk in to GPW that wish to submit a notice that is not on an electronic Adobe form will be routed to the Contact Centre where the customer will be taken through the completion of the form by a GPW representative. Where a customer walks into GPW with a stack of hard copy notices delivered by a messenger on behalf of a newspaper the messenger must be referred back to the sender as the submission does not adhere to the submission rules.
5. All notice submissions that do not comply with point 2 will be charged full price for the notice submission.
6. The current cut-off of all Gazette's remains unchanged for all channels. (Refer to the GPW website for submission deadlines – www.gpwonline.co.za)
7. Incorrectly completed forms and notices submitted in the wrong format will be rejected to the customer to be corrected and resubmitted. Assistance will be available through the Contact Centre should help be required when completing the forms. (012-748 6200 or email info.egazette@gpw.gov.za)
8. All re-submissions by customers will be subject to the above cut-off times.
9. All submissions and re-submissions that miss the cut-off will be rejected to the customer to be submitted with a new publication date.
10. Information on forms will be taken as the primary source of the notice to be published. Any instructions that are on the email body or covering letter that contradicts the notice form content will be ignored.

You are therefore advised that effective from **Monday, 18 May 2015** should you not comply with our new rules of engagement, all notice requests will be rejected by our new system.

Furthermore, the fax number **012- 748 6030** will also be **discontinued** from this date and customers will only be able to submit notice requests through the email address submit.egazette@gpw.gov.za.

government printing
Department: Government Printing Works
REPUBLIC OF SOUTH AFRICA

eGazette

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 748 6052, 748 6053, 748 6058
Advertisements: Tel: (012) 748 6205, 748 6208, 748 6209, 748 6210, 748 6211
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