

(Legislative Supplement No. 14)

CORRIGENDUM

IN Kenya Gazette Supplement No. 17 of 2012, on page 278—

Delete the expression "LEGAL NOTICE NO. 19" and insert thereof "LEGAL NOTICE NO. 20".

LEGAL NOTICE NO. 40

THE BIOSAFETY ACT, 2009

(No. 2 of 2009)

THE BIOSAFETY (LABELING) REGULATIONS, 2012

ARRANGEMENT OF REGULATIONS

Regulations

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THE BIOSAFETY ACT, 2009

(No. 2 of 2009)

IN EXERCISE of the powers conferred by section 51 of the Biosafety Act, 2009, the Minister for Higher Education, Science and Technology, makes the following Regulations:—

THE BIOSAFETY (LABELING) REGULATIONS, 2012

1. These Regulations may be cited as the Biosafety (Labeling) Regulations, 2012. Citation.
2. In these Regulations unless the context otherwise requires— Interpretation.

"altered characteristic" of a genetically modified food means that when the genetically modified food is compared to its conventional counterpart, it is different in: composition or nutritional values, anti-nutritional factors or natural toxicants, factors known to cause allergic responses in particular sections of the population, its intended use, or any other material differences;

"Authority" means the National Biosafety Authority established under section 5 of the Act;

"competent authority" means an agency of a country outside Kenya responsible under its national law for the control or regulation of genetically modified organisms;

"conventional counterpart" means a related organism or variety, its components or products for which there is experience of establishing safety based on common use as food, feed or for processing;

"food, feed or ingredient derived from genetically modified organism" means a food, feed, or ingredient produced, in whole or in part from genetically modified organisms;

"genetic modification-free" means the complete absence of any genetically modified material, or use of a genetic modification process, in a food or food product and "non-genetically modified organism" shall be construed accordingly;

"genetically modified food or feed" means food or feed that is, or contains as an ingredient, including a processing aid, produced using modern biotechnology which—

- (a) contains novel DNA or novel protein; or
- (b) has altered characteristics;

"genetically modified organism" means an organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques;

"labeling" means any written, printed, or graphic matter that accompanies a food or is displayed near the food, including that for the purpose of promoting its sale or disposal;

"novel DNA or novel protein" means DNA or a protein which, as a result of the use of genetic modification, is different in chemical sequence or structure from DNA or protein present in counterpart food which has not been produced using genetic modification;

"operator" means a natural or legal person who places a product on the market at any stage of the production and distribution chain, but does not include the final consumer;

"placing on the market" means making a genetically modified organism available for sale;

"product" means genetically modified food, feed and ingredients as defined under these Regulations;

"traceability" means the ability to trace genetically modified organisms and products of genetically modified organisms at all stages of their placing on the market through the production and distribution chains; "unique identifier" means a simple numeric or alphanumeric code which serves to identify a genetically modified organism on the basis of the authorized transformation event from which it was developed and providing the means to retrieve specific information pertinent to that genetically modified organism.

3. The objective of these Regulations is—

Objective.

- (a) to ensure that consumers are made aware that food, feed or a product is genetically modified so that they can make informed choices; and
- (b) to facilitate the traceability of genetically modified organism products to assist in the implementation of appropriate risk management measures where necessary.

4. The labeling requirements shall include, but not be limited to—

Application.

- (a) products consisting of, or containing, genetically modified organisms; or
- (b) food or feed produced from genetically modified organisms, placed on the market in accordance with the Act.

5. These Regulations shall not apply to—

Exemptions.

- (a) food, feed or their ingredients containing approved genetically modified organisms and derived products where there is inadvertent presence of genetically modified material in proportions of less than 1% of the total weight;
- (b) highly refined food, where the effect of the refining process is to remove novel DNA or novel protein;
- (c) a processing aid or food additive, except where novel DNA or novel protein from the processing aid or food additive remains present in the food to which it has been added above the threshold level;
- (d) food intended for consumption prepared and sold from food premises and vendors.

6. Labelling and packaging of food, feed or ingredients containing genetically modified organisms or products derived from genetically modified organisms shall be considered after they have undergone appropriate food safety assessment in accordance with the Act.

Food safety assessment before Labelling.

7. (1) In labelling products consisting of or containing genetically modified organisms, operators shall ensure that—

Labelling and Packaging requirements.

- (a) for pre-packaged products, the words 'genetically modified (name of ingredient)' or 'genetically modified (name of food)' appears on the label;
- (b) for non-pre-packaged products the words 'genetically modified organisms' or 'genetically modified (name of

organism)' shall appear on, or in connection with, the display of the product.

(2) In addition to the inclusion of the words 'genetically modified' as required under sub-regulation (1), there shall be additional labeling and information requirements for genetically modified foods that have altered characteristics in relation to—

- (a) one or more significant composition or nutritional parameters having values outside the normal range of values compared to conventional counterpart food or feed or ingredient thereof not produced using modern biotechnology techniques;
- (b) the level of anti-nutritional factors or natural toxicants that are significantly different in comparison to the existing counterpart food, feed or ingredient not produced using gene technology;
- (c) the food produced using modern biotechnology that contains a new factor known to cause an allergic response in particular sections of the population;
- (d) the intended use of the food produced using modern biotechnology if it is different from the existing counterpart food produced using gene technology; or
- (e) the food derived from genetically modified organisms which contains any other characteristics or properties that differ from the conventional counterpart not mentioned in paragraph (a) to (d) above;
- (f) the genetic modification raises significant ethical, cultural and religious concerns regarding the origin of the genetic material used in the genetic modification.

Claims.

8. (1) Genetically modified organisms shall not be described or labeled in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect.

(2) Any claim on a label that a product is genetic modification free shall have a clear printed statement indicating that the claim is true and not misleading, and shall be supported by validated testing and documentation of the handling practices and procedures.

(3) Validated testing shall be carried out in appropriate accredited laboratories and analytical procedures used shall be required to be consistent with national and internationally laid down procedures and protocols.

Traceability.

9. An operator shall at all stages of placing on the market a product consisting of or containing genetically modified organisms, including bulk quantities, ensure that the following information is transmitted in writing to the subsequent operator—

- (a) that it contains or consists of genetically modified organisms; and

(b) the unique identifier assigned to those genetically modified organisms in accordance with these Regulations.

(2) At all subsequent stages of the placing on the market of the products referred to in sub-regulation (1), operators shall ensure that the information received in accordance with that sub-regulation is transmitted in writing to all other operators receiving the products along the supply chain.

(3) In the case of products consisting of or containing mixtures of genetically modified organisms to be used only and directly as food or feed or for processing, the information referred to in sub-regulation 1(b) may be replaced by a list of the unique identifiers for all those genetically modified organisms that have been used to constitute the mixtures.

(4) Each operator shall maintain a register describing the systems and procedures for each transaction to be kept for a minimum period of five years.

(5) The Authority shall establish a mechanism for development and assignment of unique identifiers where such identifiers are useful in traceability of genetically modified organisms.

10. (1) The Authority shall liaise with the relevant regulatory agency to monitor any genetically modified organisms for compliance with the requirements of these Regulations.

Monitoring
Inspection
and Compliance.

(2) Where the Authority is satisfied that a product consisting of or containing genetically modified organisms has not been labelled in accordance with Regulation 7, the inspector shall serve the operator with a notice in writing—

(a) prohibiting the placing on the market of the product until it is correctly labelled;

(b) prohibiting the removal of the product from the premises described in the notice other than to facilitate the correct labelling of the product;

(c) requiring that the product be labelled in accordance with these Regulations within such period as the inspector may deem reasonable.

(3) A notice under sub-regulation (1) may contain such conditions as the inspector is satisfied are reasonable and may be amended, suspended or revoked by a further notice in writing by the inspector at any time.

(4) A notice under this regulation shall be complied with at the cost of the operator on whom it is served.

(5) If a notice under this regulation, or an action required by the notice to be taken, is not complied with within the period specified in the notice, an inspector may arrange for it to be complied with and all reasonable costs of taking such action shall be recoverable by the Authority as a penalty due from the operator on whom the notice was served.

(6) Where the product has been placed on the market prior to the date of the notice, the inspector may require the withdrawal of the product within such period as he may reasonably believe to be necessary.

Genetically modified organisms labeling register.

11. The Authority shall maintain a register of all applications made to, and decisions made by, the Authority on labelling of genetically modified organisms.

Offences and penalties.

12. A person who contravenes the provisions of these Regulations commits an offence and is liable on conviction, to a fine not exceeding twenty million shillings or to imprisonment for a term not exceeding ten years, or both.

Made on the 7th May, 2012.

MARGARET KAMAR,

Minister for Higher Education, Science and Technology.

LEGAL NOTICE NO. 41

THE NURSES ACT

(Cap. 257)

IN EXERCISE of the powers conferred by section 4(2) and 26 of the Nurses Act, the Nursing Council of Kenya, with the approval of the Minister for Medical Services, makes the following Regulations:—

THE NURSES (NOMINATIONS AND ELECTIONS TO THE COUNCIL) REGULATIONS, 2012

PART I—PRELIMINARY

Citation.

1. These Regulations may be cited as the Nurses (Nominations and Elections to the Council) Regulations, 2012.

Interpretation.

2. In these Regulations, unless the context otherwise requires—

“Council” has the meaning assigned to it by the Act;

“elected member” means a member appointed to the Council as a result of an election in accordance with the provisions of section 4 (1) (e) (i), (ii), (iii) and (iv) of the Act;

“nominated member” means a member appointed to the Council as a result of a nomination in accordance with the provisions of section 4 (1) (e) (v), (vi), (vii) and (viii) of the Act;

“election” means election held under these Regulations for the purpose of electing members in accordance with the provisions of section 4 (1) (e) (i), (ii), (iii) and (iv) of the Act.

PART II—NOMINATIONS TO THE COUNCIL

Procedure for nomination of members to the Council.

3. (1) Within three months of a vacancy arising in the Council in respect of a nominated member or at least two months before the date on which a nominated member ceases to hold office upon expiry of the member's term, each of the organizations specified in section 4 (1) (e)

(v), (vi), (vii) and (viii) of the Act shall nominate persons for appointment to the Council in accordance with this regulation.

(2) Each of the organizations referred to in section 4 (1) (e) (v), (vi) and (vii) of the Act shall, through an open, competitive and transparent process amongst its members, nominate and submit to the Minister, the names of two persons of opposite gender who are qualified for appointment to the Council under section 4 of the Act.

(3) The organizations referred to in section 4 (1) (e) (viii) of the Act shall, through an open, competitive and transparent process amongst its members, nominate and submit to the Minister, the names of four persons, half of whom shall be of opposite gender, who are qualified for appointment to the Council under section 4 of the Act.

(4) Upon receipt of the names under paragraph (3), the Minister shall, by notice in the Gazette, appoint—

- (a) three persons consisting of one person from each set of two names submitted by the each of the three organizations under paragraph (2); and
- (b) two persons from the four names submitted by the organizations under paragraph (3),

to be members of the Board.

(5) In making the appointments under paragraph (4), the Minister shall ensure that the Council reflects the regional and other diversities of the people of Kenya and that not more than two-thirds of the members are of the same gender.

4. No person shall be appointed under regulation 3 unless such person—

- (a) is qualified in accordance with the Act; and
- (b) satisfies the requirements of Chapter six of the Constitution.

Appointment of nominated members.

PART III—ELECTIONS TO THE COUNCIL

5. (1) The Council shall, within two months of a vacancy arising in the Council or at least four months before the date on which elected members cease to hold office, appoint a person to be the returning officer for the purpose of election of members under section 4 (1) (e) (i), (ii), (iii) and (iv) of the Act.

Appointment of returning officer.

(2) Subject to these Regulations, the returning officer shall—

- (a) not be a member of the Council;
- (b) be responsible for the conduct of the elections.

6. (1) The qualifications of the various categories of elected members to be elected and the qualifications of persons entitled to nominate and to take part in the election of candidates of each of these categories shall be as specified in the First Schedule.

Qualification for election.

(2) In order to be eligible for election or to be entitled to nominate for or take part in the election a person shall be required to

have the requisite qualifications on the date to be fixed by the returning officer as the last day on which nomination papers shall be received.

Publication
of notice
of election.

7. The returning officer shall fix the last date on which nomination papers shall be received and at least twenty-one days before the date so fixed he shall cause notice of the election to be published in the Gazette and in at least two newspapers circulating in Kenya, which notice shall be as nearly as may be to Form A set out in the Second Schedule.

Nomination
of candidates.

8. Each candidate for election shall be nominated on a separate nomination paper signed by not fewer than three persons having the requisite qualifications for nominating the candidate.

Nomination
papers.

9. (1) Forms of nomination papers may, on application by post or otherwise, be obtained from the returning officer at the address referred to in paragraph (3) and in making the application it should be clearly stated for what part of the election the nomination form or forms are required.

(2) Every nomination paper shall contain the name, address and registered qualification, and other requisite qualifications, of any of the candidates nominated, and the address and registered qualifications of each of the persons nominating the candidate and shall be as nearly, as may be in Form B set out in the Second Schedule.

(3) Every nomination paper shall—

- (a) be accompanied by the declaration in writing in Form C set out in the Second Schedule signed by the person nominated, acknowledging that he consents to be nominated;
- (b) be accompanied by a fee of ten thousand shillings;
- (c) be addressed to the Returning Officer, Nursing Council of Kenya, P.O. Box 20056-00200, Nairobi, and delivered to him before the hour of 4 p.m. on the last day fixed by the returning officer for the receipt of nomination papers.

(4) Any nomination paper which is not received at the address referred to in paragraph (3) before the hour and day specified in that paragraph shall be invalid.

List of nominated
candidates.

10. As soon as possible after the time fixed for the receipt of nomination papers has expired, the returning officer shall publish at the offices of the Council a list of the duly nominated candidates and shall on the same day send a copy of that list by registered post to each of the candidates.

Conduct of
the election.

11. (1) The election of elected members of the Council shall be conducted in accordance with the provisions of this regulation.

(2) If the number of duly nominated candidates in respect of any category of elected members does not exceed the number to be elected in that category the returning officer shall forthwith declare those candidates to be duly elected.

(3) If the number of duly nominated candidates in respect of any category of elected members exceeds the number to be elected in that

category the returning officer shall as soon as possible prepare ballot papers and identification envelopes which shall be as nearly as may be to Form D set out in the Second Schedule.

(4) The ballot papers shall contain the names, addresses and registered qualifications of all candidates who have been duly nominated and shall state the last day on which ballot papers may be received and the place to which they are to be returned.

(5) If no nominations are received on the appointed day the returning officer may extend the date for returning the nomination papers by fourteen days.

(6) The returning officer shall, at least twenty-one days before the last day fixed for the receipt of ballot papers, cause a ballot paper to be forwarded by post to each person qualified to vote in the election in accordance with the First Schedule at his registered address, together with an identification envelope.

(7) Votes shall not be cast or accepted except on the ballot papers provided by the returning officers.

(8) Each person qualified to vote in the election shall mark the ballot paper delivered to him with an X against the name or names of the nominated candidate or candidates (not exceeding the number to be elected) for whom he votes and shall place the ballot paper inside the identification envelope, sign the declaration on the envelope, place it inside a covering envelope, and send it by post or otherwise to the returning officer at the address stated therein.

12. (1) The returning officer shall, immediately after the last day fixed for receipt of ballot papers, ascertain the validity of the votes cast by the examination of identification envelope, open the envelope, examine and count the valid votes given for each candidate.

Counting of votes and declaration of elected members.

(2) The examination, opening and counting of the votes under paragraph (1) shall be done by the returning officer in the presence of the candidates or their duly nominated representatives, of whom seven days' notice shall have been issued to their last known address, but the absence of a candidate or his representative to whom due notice has been given shall not in any way prevent the returning officer from proceeding with the examination, opening and counting of the votes.

(3) In each of the categories for which the election is held the candidates having the greatest number of votes shall be declared elected by the returning officer.

(4) In the event of equality of votes between two or more candidates the returning officer shall determine by lot which of the candidates whose votes are equal shall be declared elected.

13. Any question arising with regard to the validity of a nomination or ballot paper shall be determined by the returning officer.

Determination by returning officer.

14. The returning officer shall forthwith deliver to every candidate a written notice of the result of the election and shall deliver to the Registrar for onward transmission to the Minister a list of candidates certified by him to have been elected showing the number of votes cast for each candidate.

Written notice of results of the election.

Validity of
election.

15. (1) Any candidate unsuccessful at the poll may either personally or by agent appointed in writing, notify the returning officer within fourteen days after the declaration of the result of the elections, that he contests the validity of that part of the election in respect of which he was unsuccessful on the ground of non-compliance with the provisions of these Regulations, or of misdescription or miscount, or of the non-delivery or loss of any document.

(2) If after consideration of the contention disclosed in the notice, the returning officer is satisfied in respect of that part that the election was conducted substantially in accordance with the provisions of these Regulations and that any non-compliance, misdescription, miscount, non-delivery or loss did not affect the result of that part of the election, he may, within fourteen days of receiving the notice, so certify, and in that event he shall forward a copy of his certificate to the unsuccessful candidate, who may, within seven days of receiving that copy, appeal to the Minister.

(3) Where the returning officer does not certify in accordance with sub-regulation (2), he shall, not later than the fifteenth day after receiving the notice forward a copy thereof to the Minister together with such comments as he thinks fit.

(4) The Minister shall consider any appeal made under paragraph (2) or any notice received under paragraph (3) and his decision as to whether the result of the relevant part of the election was affected, shall be final.

Appointment of
elected members.

16. (1) Upon receipt of the names under regulation 15, the Minister shall, by notice in the Gazette, appoint the persons elected as members of the Council.

(2) No person shall be appointed under paragraph (1) unless such person—

- (a) is qualified in accordance with the Act; and
- (b) satisfies the requirements of Chapter six of the Constitution.

PART IV—MISCELLANEOUS

Election offences:

17. (1) Any person who—

- (a) commits the offence of personation, treating, undue influence or bribery as defined in the Elections Act, 2011;
- (b) makes or publishes, before or during any election, for the purpose of promoting or procuring the election of any candidate, any false statement of withdrawal of any other candidate at such election;
- (c) forges, defaces or destroys any nomination paper, or delivers to a returning officer any nomination paper knowing it to be forged;
- (d) interferes with the ballot paper by removing, destroying, concealing or mutilating, or assists in the removal, destruction, concealment or mutilation, of any such material;

- (e) directly or indirectly prints, manufactures or supplies or procures the printing, manufacture or supply of any ballot paper in connection with the election save on the authority of the Council;
 - (f) obstructs or hinders the returning officer, candidate or agent in the execution of their lawful duties;
 - (g) makes a false statement or furnishes false particulars in any statement which is required under this Act knowing the statement or particulars to be false or without reasonable grounds for believing the same to be true;
 - (h) forges, counterfeits, defaces or destroys any ballot paper or the official perforation, stamp or mark on any ballot paper or any campaign or promotional material of an opposing candidate;
 - (i) sells or offers for sale any ballot paper to any person, or purchases or offers to purchase any ballot paper from any person;
 - (j) without authority destroys, takes, opens, disposes of or otherwise interferes with any election material in use or intended to be used for the purposes of an election;
 - (k) without authority prints any ballot paper or what purports to be or is capable of being used as a ballot paper at an election;
 - (l) votes at any election when not entitled to vote; or
 - (m) votes more than once in any election,
- commits an offence.

(2) Any person who commits an offence under paragraph (1) shall be liable to a fine not exceeding ten thousand shillings or to imprisonment to a term not exceeding six months or to both such fine and imprisonment.

18. The Nurses (Elections to Council) Regulations, 1985 are hereby revoked.

Revocation of L.N.
124/1985

FIRST SCHEDULE

(r.6)

<i>Qualification of person to be elected</i>	<i>Qualifications of persons entitled to nominate and take part in election</i>
Registered midwife who is also a registered nurse practising the profession as a midwife at the time of election.	Registered midwives (i.e. those persons whose names for the time being appear on the register of midwives).
Registered community health nurse who is also a registered nurse practising the profession as a community health nurse at the time of election.	Registered community health nurses (i.e. those persons whose names for the time being appear on the register of community health nurses).
Registered psychiatric/ mental health nurse practising the profession as a psychiatric/ mental health nurse at the time of election	Registered psychiatric/ mental health nurses (i.e. those persons whose names for the time being appear on the register of psychiatric/ mental health nurses).
Registered general nurses (i.e. nurses registered in the general part of the Register), who is practising the profession as a general nurse at the time of election.	Registered general nurses (i.e. those persons whose names for the time being appear on the register of nurses).

SECOND SCHEDULE

(r.7, 8 & 11)

THE NURSES ACT

(Cap.257)

FORM A

NOTICE OF ELECTIONS TO THE NURSING COUNCIL OF KENYA

Notice is given that under the provisions of section 4 (l) (e) of the Nurses Act, and regulation 7 of these Regulations, an election will be held for the following vacancies in the Council—

- (a) one registered midwife, to be elected by registered midwives;
- (b) one registered community health nurse, to be elected by registered community health nurses;
- (c) one registered psychiatric/ mental health nurse, to be elected by registered psychiatric/ mental health nurses;
- (d) one registered general nurse, elected by registered general nurses.

Nominations are invited from Kenya Registered Midwives, Kenya Registered Community Health Nurses, Kenya Registered Psychiatric/ Mental Health Nurses and Kenya Registered General Nurses.

The nomination should reach the Returning Officer, c/o The Nursing Council of Kenya, P. O. Box 20056-00200, Nairobi, not later than.....

FORM B

NOMINATION PAPER FOR ELECTION OF REGISTERED NURSES TO THE
NURSING COUNCIL OF KENYA

Note.—Only a nurse registered and qualified in the area of speciality in which the candidate to be nominated is seeking election may sign this paper as a nominator.

We, the undersigned being nurses whose names appear on the register of nurses as.....for the Republic of Kenya hereby nominate.....of whose registration number is.....and who is employed at where he/she is engaged in

FULL NAME (BLOCK LETTERS)

ADDRESS

REGISTERED QUALIFICATIONS AND NUMBERS

USUAL SIGNATURE

Date.....

This nomination paper must be signed by not less than three nominators and must be received by the Returning Officer, the Nursing Council of Kenya, and P.O. Box 20056-00200, Nairobi, Kenya not later than 4 p.m. on.....

- (a) Here insert full name of candidate as given in the register.
- (b) Here insert candidate's address.
- (c) Here insert candidate's registration number.
- (d) Here insert candidate's place of employment and his postal address.
- (e) Here insert candidate's present post.

FORM C

(FORM OF DECLARATION TO BE ISSUED WITH NOMINATION PAPERS FOR
USE BY NOMINATED CANDIDATE)

ELECTION TO THE NURSING COUNCIL OF KENYA

Date

I, (*) consent to be nominated as a candidate for election as representative of the nurses registered in the (!).....to serve on the Nursing Council of Kenya.

I declare that the statement in the nomination paper regarding my qualifications is correct.

Signature Registration Number.....
 Address

(*) Here insert full name, in block letters.

(!) Here insert "General Part of the Register";

or "part of the Register for Psychiatric/ Mental Health Nurses";

or "Register of Community Health Nurses";

or "Register of midwives".

as the case may be.

This declaration form, *which must accompany the nomination paper*, must be received by the Returning Officer, not later than

To: The Returning Officer,
 Nursing Council of Kenya,
 P.O. Box 20056-00200, Nairobi.

FORM D
 BALLOT PAPERS

BALLOT PAPER I
 ELECTION OF ONE REGISTERED MIDWIFE NURSE

*Electors Names of candidates Present post and Registered
 Mark X nominated address of candidate qualifications and
 nominated Number*

BALLOT PAPER II
 ELECTION OF ONE REGISTERED COMMUNITY HEALTH NURSE

*Electors Names of candidate Present post and Registered
 Mark X nominated address of candidate qualifications and
 nominated Number*

BALLOT PAPER III
 ELECTION OF ONE REGISTERED PSYCHIATRIC/ MENTAL HEALTH NURSE

*Electors Names of candidates Present post and Registered
 Mark X nominated address of candidate qualifications and
 nominated Number*

BALLOT PAPER IV
 ELECTION OF TWO REGISTERED GENERAL NURSES

*Electors Names of candidate Present post and Registered
 Mark X nominated address of candidates qualifications and
 nominated Number*

IDENTIFICATION ENVELOPE

I, the undersigned, declare that I am the person to whom the enclosed ballot paper is addressed as above; that I am registered on the part of the register, and that I have not marked any other ballot paper in this part of the election.

Signature.....

Dated the 10th May, 2012.

ELIZABETH OYWER,
*Registrar,
Nursing Council of Kenya.*