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L.N. 32 of 2015

**EMBRYO PROTECTION ACT
(CAP. 524)**

Embryo Protection Authority Regulations, 2015

IN EXERCISE of the powers conferred by article 23 of the Embryo Protection Act, the Parliamentary Secretary for Health has made the following regulations:-

Citation and
commencement.

1. (1) The title of these regulations is the Embryo Protection Authority Regulations, 2015.

(2) These regulations shall be deemed to have come into force on the 1st June, 2014.

Interpretation.

2. In these regulations, unless the context otherwise requires -

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"Act" means the Embryo Protection Act;

"Authority" means the Embryo Protection Authority established by article 3 of the Act;

"Minister" means the Minister responsible for Health.

Legal
personality and
representation
of the Authority.

3. (1) The Authority shall be a body corporate having a distinct legal personality and shall be capable, subject to the provisions of the Act, of entering into contracts, of acquiring, holding and disposing of any kind of property for the purposes of its functions, of suing and being sued, and of doing all such things and entering into all such transactions as are incidental or conducive to the exercise or performance of its functions under the Act and, or these regulations.

(2) The legal representation of the Authority shall be vested in the Chairman and the Deputy Chairman:

Provided that the Authority may appoint any one or more of its members, or of the officers or employees of the Authority, to appear in the name and on behalf of the Authority in any judicial proceedings and on any act, contract, instrument or other document whatsoever.

(3) Any document purporting to be an instrument made, or issued by, the Authority and signed by the Chairman or by the Deputy Chairman shall be received in evidence and shall, until the contrary is

proved, be deemed to be an instrument made, or issued by, the Authority.

4. (1) The meetings of the Authority shall be called by the Chairman as often as may be necessary but at least once a month either on his own initiative or at the request of any two of the other members.

Meetings of
Authority.

(2) Half the number of members for the time being constituting the Authority shall form a quorum. Decisions shall be adopted by a simple majority of the votes of the members present and voting. The Chairman, or in his absence the Deputy Chairman or other person appointed to act as chairman, shall have an initial vote and in the event of an equality of votes, a casting vote. Without prejudice to the other requirements of the Act, and, or these regulations, no decision shall be valid which is not supported by at least two members of the Authority.

(3) Subject to the provisions of the Act and, or these regulations, the Authority may regulate its own procedure.

(4) Subject to the foregoing provisions of this regulation, no act or proceeding of the Authority shall be invalidated merely by reason of the existence of any vacancy among the members.

5. (1) Without prejudice to the other provisions of the Act, and, or these regulations, the appointment of officers and other employees of the Authority shall be made by the Authority. The terms and conditions of employment shall be established by the Authority with the concurrence of the Minister.

Officers and
employees of
the Authority.

(2) The Authority shall appoint and employ, at such remuneration and upon such terms and conditions as it may, in accordance with the preceding sub-regulation, determine, such officers and employees of the Authority as may from time to time be necessary for the due and efficient discharge of its functions.

(3) Where any officer is detailed for duty with the Authority, such officer shall, during the time in which such direction has effect in relation to him or her, be under the administrative authority and control of the Authority but shall for other intents and purposes remain and be considered and treated as a public officer.

(4) Without prejudice to the generality of the foregoing, a public officer detailed for duty as aforesaid -

(a) shall not during the time while such officer is so detailed -

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(i) be precluded from applying for a transfer to a department of the Government in accordance with the terms and conditions of service attached to the appointment held by that public officer at a date on which he or she was detailed for duty; or

(ii) be so employed that the remuneration and conditions of service are less favourable than those which are attached to the appointment under the Government held by that public officer at the date he or she was detailed for duty as aforesaid or which would have become attached to such appointment, during the said period, had such officer not been detailed for duty with the Authority; and

(b) shall be entitled to have the service with the Authority considered as service with the Government for the purpose of any pension, gratuity or benefit, and of any other right or privilege to which that public officer would be entitled, and shall be liable to any liability to which he or she would be liable, but for the fact that he or she is detailed for duty with the Authority.

The Executive administration and organisation of the affairs of the Authority.

6. (1) Without prejudice to the other provisions of this Act, the affairs and business of the Authority shall be the responsibility of the Authority itself but save as aforesaid, the executive conduct, administration and organisation of the Authority, including the administrative control of its officers and employees shall be the responsibility of the Director of the Authority, who shall also have such other powers as may be delegated, from time to time, by the Authority.

(2) The Director shall be appointed by the Minister in consultation with the Authority, for a period of three years and such period may be extended for further periods of three years each:

Provided that where the Director is absent from Malta or is otherwise temporarily unable to perform the functions of that office, the Authority, in consultation with the Minister, shall appoint an officer of the Authority to assume the duties of Director for the duration of such period during which the Director is so absent or otherwise unable to perform those functions.

(3) The Director shall attend all the meetings of the Authority but shall not vote at such meetings.

(4) The Director shall be responsible for the implementation of the objectives of the Authority in the exercise of its functions and,

without prejudice to the generality of the foregoing, the Director shall:

(a) be responsible for evaluating the implementation and fulfilment of the Authority's established goals, for the efficient use of its resources, and resultant benefits, and shall report directly to the Authority;

(b) develop the necessary strategies for the implementation of the objectives of the Authority;

(c) advise the Authority on any matter it may refer or on any matter which is considered necessary or expedient;

(d) perform such other duties as the Authority may assign from time to time.

7. (1) The Prime Minister may, at the request of the Authority made with the concurrence of the Minister, from time to time, direct that any public officer be detailed for duty with the Authority in such capacity and with effect from such date as may be specified in the direction.

Detailing of public officers for duty with the Authority.

(2) The period during which a direction as aforesaid shall apply to any officer specified therein shall, unless the officer retires from the public service, or otherwise ceases to hold office at an earlier date, or unless a different period is specified in the direction, end on the happening of the following events:

(a) the acceptance by such officer of an offer of permanent employment with the Authority made in accordance with the provisions of regulation 8; or

(b) the revocation by the Prime Minister of any direction made by him under this regulation in relation to such officers.

8. (1) The Authority may, with the approval of the Prime Minister, offer to any officer detailed for duty with the Authority, under any of the provisions of regulation 7, permanent employment with the Authority at a remuneration and on terms and conditions not less favourable than those enjoyed by such officer at the date of such offer.

Offer of permanent employment with the Authority to public officers detailed for duty with the Authority.

(2) The terms and conditions comprised in any offer made as aforesaid shall not be deemed to be less favourable merely because they are not in all respects identical with or superior to those enjoyed by the officer concerned at the date of such offer, if such terms and

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conditions, taken as a whole, in the opinion of the Prime Minister offer substantially equivalent or greater benefits.

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(3) Every officer who accepts permanent employment with the Authority, offered to that officer under the provisions of sub-regulation (1), shall for all purposes other than those of the Pensions Ordinance and of the Widows' and Orphans' Pensions Act, be deemed to have ceased to be in service with the Government and to have entered into service with the Authority on the date of such acceptance, and for the purposes of the said Ordinance and of the said Act, so far as applicable to that officer, service with the Authority shall be deemed to be service with the Government within the meanings thereof respectively.

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(4) Every such officer as aforesaid who, immediately before accepting permanent employment with the Authority was entitled to benefit under the Widows' and Orphans' Pensions Act, shall continue to be so entitled to benefit thereunder to all intents as if service with the Authority, were service with the Government.

(5) The Authority shall pay to the Government such contributions as may from time to time be determined by the Minister responsible for finance in respect of the cost of pensions and gratuities earned by an officer who has accepted permanent employment with the Authority as aforesaid during the period commencing on the date of such officer's acceptance.

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(6) For the purpose of the Pensions Ordinance the pensionable emoluments of such public officer on retirement shall be deemed to be the pensionable emoluments payable to an officer in Government service in a grade and at an incremental level corresponding to the post and incremental level at which the officer retires from the Authority.

(7) (a) For the purposes of this regulation posts and salary grades with the Authority shall be classified in the most nearly corresponding grades and incremental levels in the service under the Government by reference to job description, skills, responsibilities and other analogous factors.

(b) The classification referred to in paragraph (a) shall be carried out by a board composed of a chairperson appointed by the Minister responsible for finance and two other members, one appointed by the Minister responsible centrally for personnel policies in the public service and one appointed by the Authority. The classification shall be subject to the final approval of the Minister responsible for finance.

(c) Such classification shall take place within three months of any adjustment of salaries of employees in Government service and, or of employees of the Authority.

(d) No post shall be classified in a grade higher than that of Grade 3 in the service of the Government or such other grade as the Minister responsible for finance may, from time to time, determine by notice in the Gazette.

(e) Without prejudice to article 113 of the Constitution, no person may, following a classification as aforesaid, be entitled to rights under the Pensions Ordinance less favourable than those to which that person would have been entitled prior to such classification. Cap. 93.

9. (1) Where any officer is detailed for duty with the Authority by any direction under any of the provisions of regulation 7, such officer shall, during the time in which such direction has effect in relation to him be under the administrative direction and control of the Authority but shall for other intents and purposes remain and be considered and treated as a public officer. Status of public officers detailed for duty with the Authority.

(2) Without prejudice to the generality of the foregoing, a public officer detailed for duty as aforesaid -

(a) shall not during the time while such officer is so detailed:

(i) be precluded from applying for a transfer to a department of the Government in accordance with the terms and conditions of service attached to the appointment under the Government held by that public officer at a date on which he was detailed for duty; or

(ii) be so employed that the remuneration and conditions of service are less favourable than those which are attached to the appointment under the Government held by that public officer at the date he was detailed for duty as aforesaid or which would have become attached to such appointment, during the said period, had such officer not been detailed for duty with the Authority;

(b) shall be entitled to have his service with the Authority considered as service with the Government for the purpose of any pension, gratuity, or benefit under the Pensions Ordinance and the Widows' and Orphans' Pension Act, and of any other right or privilege to which that public officer would be entitled, and shall be liable to any liability to which he would be Cap. 93.
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liable, but for the fact that he is detailed for duty with the Authority.

(3) Where an application is made as provided in sub-regulation (2)(a)(i), the same consideration shall be given thereto as if the applicant had not been detailed for duty with the Authority.

(4) The Authority shall pay to the Government such contributions as may from time to time be determined by the Minister responsible for finance in respect of the cost of pensions and gratuities earned by an officer detailed for duty with the Authority as aforesaid during the period in which such officer is so detailed.

Financials of the
Authority.

10. (1) Without prejudice to the following provisions of this regulation, the Authority shall so conduct its affairs that the expenditure required for the proper performance of its functions shall, as far as practicable, be met out of its revenue.

(2) For such purpose the Authority shall levy all fees, rates and other payments prescribed in its protocols or deemed to be prescribed by or under the Act and, or these regulations, or any other law related to the powers and functions of the Authority.

(3) The Authority shall also be paid by Government out of the Consolidated Fund such sums as Parliament may from time to time authorise to be appropriated to meet the costs of specified works to be continued and for the day to day running of the Authority or otherwise carried out by the Authority:

Provided that any subvention received from Government shall be exempted from any liability for the payment of income tax and duty on documents under any law for the time being in force.

Advances from
Consolidated
Fund.

11. The Minister responsible for finance may, after consultation with the Minister, make advances to the Authority of such sums as he may agree to be required by the Authority for carrying out any of its functions under the Act, and may make such advances on such terms and conditions as he may, after consultation as aforesaid, deem appropriate. Any such advance may be made by the Minister responsible for finance out of the Consolidated Fund, and without further appropriation other than under these regulations, by warrant under his hand authorising the Accountant General to make such advance.

Estimates of the
Authority.

12. (1) The Authority shall cause to be prepared in every financial year, and shall not later than six weeks after the end of each such year adopt, estimates of the income and expenditure of the Authority for the next following financial year.

(2) In the preparation of such estimates the Authority shall take account of any funds and other moneys that may be due to be paid to it out of the Consolidated Fund during the relevant financial year, whether by virtue of these regulations or of an Appropriation Act or of any other law; and the Authority shall so prepare the said estimates as to ensure that the total revenues of the Authority are at least sufficient to meet all sums properly chargeable to its revenue account, including, but without prejudice to the generality of that expression, depreciation.

(3) The estimates shall be made out in such form and shall contain such information and such comparisons with previous years as the Minister responsible for finance may direct.

(4) A copy of the estimates shall, upon their adoption by the Authority, be sent forthwith by the Authority to the Minister and to the Minister responsible for finance.

(5) The Minister shall, at the earliest opportunity and not later than six weeks after he has received a copy of the estimates from the Authority (or if at any time during that period the House is not in session within six weeks from the beginning of the next following session), cause such estimates to be laid before the House together with a motion that the House approves the said estimates. Not less than one sitting shall be allotted for the debate in the House on such a motion; and both the motion and the approval of the estimates by the House may be with or without amendments to the estimates.

13. (1) No expenditure shall be made or incurred by the Authority unless it has been approved by the House as provided in regulation 11.

Expenditure to be according to approved estimates.

(2) Notwithstanding the provisions of sub-regulation (1) -

(a) until the expiration of six months from the beginning of a financial year, or until the approval of the estimates for that year by the House, whichever is the earlier date, the Authority may make or incur expenditure for carrying on its functions under the Act and these provisions not exceeding in the aggregate one-half of the amount approved by the House for the preceding financial year;

(b) expenditure approved in respect of a head or sub-head of the estimates may, with approval of the Minister given after consultation with the Minister responsible for finance, be made or incurred in respect of another head or sub-head of the estimates;

(c) in respect of the first financial year, the Authority may make or incur expenditure until the approval of the estimates for that year by the House not exceeding in the aggregate such amounts as the Minister responsible for finance may, after consultation with the Minister, allow;

(d) if in respect of any financial year it is found that the amount approved by the House is not sufficient or a need has arisen for expenditure for a purpose not provided for in the estimates, the Authority may adopt supplementary estimates for approval by the House and, pending such approval but subject to its being given, may, with the approval of the Minister responsible for finance given after consultation with the Minister, incur the relative expenditure or such part thereof as the said Minister may so approve; and in any such case the provisions of these regulations applicable to the estimates shall as near as practicable apply to the supplementary estimates.

Publication of
approved
estimates.

14. All estimates and supplementary estimates of the Authority approved by the House shall, as soon as practicable, be published in the Gazette.

Accounts and
audit.

15. (1) The Authority shall cause to be kept proper books of account and other records in respect of the Authority's operations and shall cause to be prepared a statement of accounts in respect of each financial year.

(2) The accounts of the Authority shall be audited by an auditor or auditors to be appointed by it and approved by the Minister, after consultation with the Minister responsible for finance.

Revenues and
payment by the
Authority.

16. (1) All monies accruing to the Authority shall be paid into a bank or banks appointed as bankers of the Authority by a resolution of the Authority. Such monies shall, as far as practicable, be paid into any such banks from day to day, except such sum as the Authority may authorise to be retained to meet petty disbursements and immediate cash payments.

(2) All payments out of the funds of the Authority, other than petty disbursements not exceeding a sum to be fixed by the Authority, shall be made by such officer or officers of the Authority as it shall appoint or designate for that purpose.

(3) Cheques against and withdrawals from any bank account of the Authority shall be signed by such officer of the Authority as may be appointed or designated by the Authority for that purpose and shall be countersigned by the Chairman, or such other member or officer of the Authority as may be authorised by the Authority for that

purpose.

(4) The Authority shall also make provision with respect to:

(a) the manner in which, and the officer or officers by whom, payments are to be authorised or approved;

(b) the title of any account held with the bank or banks into which the monies of the Authority are to be paid, and the transfer of funds from one account to the other;

(c) the method to be adopted in making payments out of funds of the Authority; and generally with respect to any matter which is relevant to the proper keeping and control of the accounts and books, and the control of the finance, of the Authority.

17. (1) Any officer or employee of the Authority, duly authorised by the Authority, in a reasonable time, can enter any clinic, laboratory or any other property in order to:

Enforcement powers.

(a) make the necessary inspections and, or to ensure that no infringement of the provisions of the Act, or these regulations, or of the Protocols which the Authority is entitled to enforce, or of any decision of the Authority, is being committed;

(b) have access to and collect all the necessary data or information that the Authority may require.

(2) Whosoever does not allow, or impedes, any official or employee of the Authority from duly exercising his duty under the Act and, or these regulations, and, or the Protocols, shall be guilty of an offence, and shall on conviction, be liable to an administrative fine as established in regulation 18(9), or to imprisonment for a term not exceeding twelve months, or to both such fine and imprisonment.

18. (1) Without prejudice to any other provisions under the Act and, or these regulations, or any other law which the Authority is entitled to enforce, the Authority may take the following measures in respect of any person who infringes any provision of the Act and, or these regulations, of the Protocols issued by the Authority, or of any other law which the Authority is entitled to enforce, or who fails to comply with any decision given by the Authority or with any authorisation condition:

Measures which may be taken.

(a) the imposition of an administrative fine in accordance with the provisions of this regulation,

(b) the ordering of the cessation of any act or omission which is in breach.

(2) In cases where the Authority considers that a person has seriously and repeatedly infringed the provisions of the Act and, or these regulations, or of any other law or the Protocol which the Authority is entitled to enforce, or of any decision of the Authority or of any authorisation condition, the Authority may withdraw or suspend any related authorisation granted by or under the Act and, or these regulations, or any other law which the Authority is entitled to enforce.

(3) The Authority shall, before proceeding to take any of measures under this regulation, inform the person concerned in writing, warning him of the measure that may be taken and the specific reason why it may be taken, requiring him to cease or rectify his acts or omissions and, or to make his submissions thereto within such period not being more than fifteen days, which period, without prejudice to the provisions of sub-regulation (6), may be abridged if the Authority considers that the continuance of the infringement impacts negatively the effective exercise by the Authority of its regulatory functions and, or warrants the immediate intervention of the Authority:

Provided that where the measure is an administrative fine the person concerned shall also be informed of the amount of the fine:

Provided further that when issuing a warning under this sub-regulation, the Authority may impose such conditions as it may consider reasonable in the circumstances.

(4) If the person concerned remedies the infringement within the period established by the Authority in accordance with sub-regulation (3), and agrees in writing to abide with any condition that the Authority may impose, the Authority may at its discretion desist from proceeding any further and this without prejudice to any regulatory measures that may have already been imposed.

(5) If after the lapse of the period mentioned in sub-regulation (3), the Authority considers that the person concerned has not given any valid reasons to demonstrate why no measure should be taken against him, the Authority shall notify the person concerned in writing, specifying the nature of the infringement, stating the measure being taken, and if the measure is an administrative fine, stating the amount of the fine being imposed.

(6) Notwithstanding the provisions of sub-regulation (3),

where the Authority has *prima facie* evidence that the infringement represents an immediate and serious threat to public safety, public security or public health it may take urgent *interim* measures to remedy the situation in advance of reaching a final decision, including ordering the immediate cessation of the act or omission giving cause to the infringement, requiring the cessation or delay of provision of a service or bundle of services, and the imposition of administrative fines. Administrative fines are to be considered as a civil debt:

Provided that the person against whom such measures are contemplated shall, thereafter, be given a reasonable opportunity to state his view of the facts and propose any remedies:

Provided further that the *interim* measures shall be valid for a maximum period of three months, subject to an extension of a further period of three months, in circumstances where enforcement procedures have not been completed.

(7) The Authority shall give its reasons for any decision taken under this regulation.

(8) Notwithstanding the provisions of any law, no precautionary warrant or order shall be issued by any court restraining the Authority from the exercise of any of the powers conferred upon it under this regulation.

(9) An administrative fine imposed shall not, unless provided otherwise by or under the Act, exceed three hundred and forty-nine thousand and four hundred euro (€349,400) for each infringement or failure to comply and, or eleven thousand and six hundred euro (€11,600) for each day of infringement or non-compliance as the case may be:

Provided that if the act or omission which constitutes an infringement is committed by an undertaking and the Authority considers that such act or omission has especially significant effects to the detriment of the clients and, or patients, the stated amount that may be imposed as an administrative fine may be increased to an amount that is not more than five per cent of the turnover of the undertaking in the calendar year immediately preceding the year when the infringement was committed:

Provided further that any daily fine imposed may be back-dated to the date of the commission, or commencement of, the infringement.

(10) In determining the amount of an administrative fine, regard shall be had in particular to the nature and extent of the infringement, its duration and its impact.

(11) The Authority shall establish the administrative fines that may be imposed by it for breaches of the Protocols issued and any other regulations made by the Authority:

Provided that the amount of the fines that may be so prescribed shall not exceed the maximum amounts referred to under sub-regulation (9).

(12) Where an administrative infringement of any provision of the Act and, or these regulations, or any other law which the Authority is entitled to enforce is committed by a body corporate and is proved to have been committed with the consent or involvement of, or to be attributable to, any gross negligence on the part of a person being a director, manager, secretary or other officer however so described of the body corporate or a person who was purporting to act in any such capacity, that person, as well as the body corporate, shall be liable to be proceeded against and found guilty as if he was responsible for the said infringement:

Provided that the body corporate as well as the individual person shall be responsible *in solidum* for the payment of the administrative fines.
