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## SUBSIDIARY LEGISLATION

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## THE ENVIRONMENTAL MANAGEMENT ACT (CAP. 191)

## REGULATIONS

(Made under sections 69 and 230(20)(o))

## THE ENVIRONMENTAL MANAGEMENT (BIOSAFETY) (AMENDMENT) REGULATIONS, 2015

Citation

1. These Regulations may be cited as the Environmental Management (Biosafety) (Amendment) Regulations, 2015, and shall be read as one with the Environmental Management (Biosafety) Regulations, 2009, hereinafter referred to as the "principal Regulations".

Amendment of

regulation 3

GN. No. 265 of 2009

2. Regulation 3 of the principal Regulations is amended by deleting the definitions of the terms "confined use" and "contained use" and substituting for them in their appropriate alphabetical order, the following:

"confined use" means any operation, undertaken by restricting a GMO and its genetic traits to a specific and defined area of the environment, that effectively limit escape or persistence of the GMO or its genetic material in the environment;

"contained use" means any operation undertaken within a facility, installation or other physical structure, which involves GMOs that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

"research" means a contained use or confined use, and the words "research activities" shall have a corresponding meaning;

"researcher" means a person who undertakes a contained use or confined use;"

Amendment of regulation 6

3. The principal Regulations are amended by deleting the whole regulation 6 and substituting for it the following:

"Strict liability

- 6.-(1) All approvals for introduction of GMO or their products shall be subject to a condition that the applicant is strictly liable for any damage caused to any person or entity.
- (2) Notwithstanding the provisions of sub-regulation (1), strict liability shall not apply to researchers and research activities."

Amendment of regulation 56

4.-(1) The principal Regulations are amended by deleting the whole regulation 56 and substituting for it the following:

"Strict liability

56.-(1) Any person or his agent who imports, transports, transits, makes use of, releases, carries out any activity in relation to GMOs or products thereof or places on the market a GMO shall be strictly liable for any harm, injury or loss caused directly or indirectly by such

G.N. No. 41 (contd.)

GMOs or their products or any activity in relation to GMOs.

- (2) Notwithstanding the provisions of sub-regulation (1), any person or his agent who develops, imports, transports GMOs or products thereof, or carries out any activity for the purpose of undertaking research shall be liable for any harm, injury or loss caused directly or indirectly by such GMOs or their products or any activity in relation to GMOs.
- (3) The harm, injury or loss includes personal injury, damage to property, financial loss and damage to the environment or to biological diversity as well as taking into account socioeconomic, cultural and ethnical concern.
- (5) In case of harm to the environment or biological diversity, compensation shall include the costs of reinstatement, rehabilitation or clean-up measures which actually are being incurred and, where applicable, the costs of preventive measures.

Application of Biosafety Manuals and guidelines

**56A**. Subject to sub-regulations (2) of regulation 56, a Practical Manual for Safe Conduct of Confined Field Trials and a Practical Manual for Containment and the National Biosafety Guidelines shall regulate researchers and research activities as prescribed under these Regulations."

Amendment of regulation 60

**5.** The principal Regulations are amended by deleting regulation 60 and substituting for it the following:

G.N. No. 41 (contd.)

"Indemnity

- 60. Any applicant shall indemnify:
- (a) any other person who deliberately release or markets GMOs or products thereof; and
- (b) any person who manufactures, processes or markets food, food ingredients or animal feed containing or delivered from GMO,

against any civil liability where the GMOs or products thereof was first developed, imported, deliberately release, used in contained conditions, or placed on the market by the applicant."

Dar es Salaam, 3<sup>rd</sup> February, 2015

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