

DEPARTMENT OF HEALTH

The Minister of Health has, in terms of [section 15 \(1\)](#) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act [No. 54 of 1972](#)), made the regulations in the Schedule.

SCHEDULE

ARRANGEMENT OF REGULATIONS

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| 1. | Definitions |
| 2. | General specifications |
| 3. | Essential safety requirements for toys |
| 4. | Bioavailability and concentration limits for certain elements in toys |
| 5. | Restrictions |

1. Definitions.—In these regulations, any expression defined in the Act bears that meaning and, unless the context indicates otherwise—

“bioavailability” means a measure of the physicochemical access that an element or substance has to the biological processes of the human body;

“flammable” means the ability of any object or material to burn with a blaze under specific test conditions;

“hazard” means any object or material that may be detrimental or may contain a biological, chemical or physical agent capable of causing adverse effects to the health of its user or a third party or both its user and a third party;

“ISO” means the International Standards Organization;

“normal use” means expected favourable play conditions which are in accordance with the instructions that may accompany the toy, or evident from the appearance of the toy, or established by tradition;

“reasonably foreseeable abuse” means anticipated excessive play conditions, which are not normal use, to which a toy could be subjected by a child under the age of three years;

“SANS” means the South African National Standards, a division of the South African Bureau of Standards as defined in the Standards Act, 1993 (Act No. 29 of 1993);

“the Act” means the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act [No. 54 of 1972](#)); and

“toy” means any object, product, material or part thereof designed or clearly intended for use in play or any activity by children under the age of three years, which is packaged in foodstuffs, and shall also include promotional articles intended for children.

2. General specifications.—(1) Toys that are wrapped before packaging in a foodstuff shall be properly wrapped, and the wrapping material shall not affect the chemical composition of the foodstuff.

(2) A toy shall be regarded as safe for the purposes of these regulations if, when used in a foreseeable way and having regard to the normal behaviour of children under the age of three years, it does not jeopardize the safety or health of the user or any third party.

(3) Foodstuffs that have toys packaged inside them shall be clearly labelled to indicate the presence of toys.

3. Essential safety requirements for toys.—All toys in foodstuffs shall comply with the following safety requirements:

(1) Toys that are designed to be disassembled or pieces of which may break off during normal use or during reasonably foreseeable abuse, shall not be of a size that create a hazard if they are swallowed or inhaled, or come into contact with the skin, mucous tissues or eyes.

(2) Toys shall be visually clean and free from any kind of infestation.

(3) Toys shall conform to the SANS standard on the ‘Safety of Toys’ and shall be tested to simulate reasonably foreseeable abuse in order to ensure that hazards are not generated as a result of normal wear and tear or deterioration.

(4) Testing shall be done in accordance with the appropriate test methods outlined in clauses 5.1, 5.2 and 5.3 of the ISO 8124-1:2000 standard on the ‘Safety of Toys (Part 1)’. Such tests shall be carried out in an anticipated use environment and shall be intended to expose potential hazards rather than to demonstrate the

reliability of such a toy.

- (5) Toys shall not contain flammable gases, flammable liquids or extremely flammable solids.

4. Bioavailability and concentration limits for certain elements in toys.—Metals or elements in column I of the table below with their bioavailability as outlined in column II shall not exceed the corresponding concentration limits outlined in column III if used in toys.

<i>Metal</i>	<i>Bioavailability (µg)</i>	<i>Maximum limit (g/kg)</i>
Antimony	1,4	0,6
Arsenic	0,1	0,25
Barium	25	10
Cadmium	0,6	0,75
Chromium	0,3	0,6
Lead	0,7	0,9
Mercury	0,5	0,6
Selenium	5,0	5,0

5. Restrictions.—With respect to these regulations, no person shall sell, manufacture or import for sale any foodstuff which contains toys that—

- (1) may generate potential hazards under normal use;
- (2) may be detrimental to the health of users or third parties under reasonably foreseeable abuse;
- (3) may affect the chemical composition of the foodstuff; or
- (4) do not comply with the essential safety requirements contained in these regulations.

(Signed)
ME TSHABALALA-MSIMANG
MINISTER OF HEALTH