

**4-5-11 Substances considered unsafe -- Authority in department to regulate quantity and use.**

- (1)
  - (a) Any added poisonous or deleterious substance, any food additive, any pesticide chemical in or on a raw agricultural commodity or any color additive, with respect to any particular use or intended use, is considered to be unsafe for the purpose of application of Subsection 4-5-7(1) (b) unless:
    - (i) there is in effect a rule adopted pursuant to this section or Section 4-5-17 limiting the quantity of the substance; and
    - (ii) the use or intended use of the substance conforms to the terms prescribed by the rule.
  - (b) While the rules relating to the substance are in effect, a food may not, by reason of bearing or containing the substance in accordance with the rules, be considered adulterated within the meaning of Subsection 4-5-7(1)(a).
- (2) The department may make rules, which may or may not be in accordance with regulations made under the federal act, prescribing:
  - (a) tolerances, including zero tolerances, for:
    - (i) added poisonous or deleterious substances;
    - (ii) food additives;
    - (iii) pesticide chemicals in or on raw agricultural commodities; or
    - (iv) color additives;
  - (b) exemptions from tolerances in the case of pesticide chemicals in or on raw agricultural commodities; or
  - (c) conditions under which a food additive or a color additive may be safely used and exemptions when a food additive or color additive may be used solely for investigational or experimental purposes.
- (3) The department may make these rules upon its own initiative or upon the petition of any interested party. It is incumbent upon the petitioner to establish by data submitted to the department that the rule is necessary to protect the public health. If the data furnished by the petitioner is not sufficient to allow the department to determine whether the rule should be made, the department may require additional data to be submitted. Failure to comply with the request is sufficient grounds to deny the request.
- (4) In making the rules, the department shall consider, among other relevant factors, the following which the petitioner, if any, shall furnish:
  - (a) the name and all pertinent information concerning the substance including:
    - (i) where available;
    - (ii) its chemical identity and composition;
    - (iii) a statement of the conditions of the proposed use, including directions, recommendations, and suggestions;
    - (iv) specimens of proposed labeling; and
    - (v) all relevant data bearing on the physical or other technical effect and the quantity required to produce such effect;
  - (b) the probable composition of any substance formed in or on a food resulting from the use of the substance;
  - (c) the probable consumption of the substance in the diet of man and animals, taking into account any chemically or pharmacologically related substance in the diet;
  - (d) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of the substances for the uses for which they are proposed to be used, are generally recognized as appropriate for the use of animal experimentation data;

- (e) the availability of any needed practicable methods of analysis for determining the identity and quantity of:
  - (i) the substance in or on food;
  - (ii) any substance formed in or on food because of the use of the substance; and
  - (iii) the pure substance and all intermediates and impurities; and
- (f) facts supporting a contention that the proposed use of the substance will serve a useful purpose.

Amended by Chapter 157, 1990 General Session