

SECOND REGULAR SESSION

# HOUSE BILL NO. 2769

## 103RD GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE POLLITT.

6538H.01I

JOSEPH ENGLER, Chief Clerk

### AN ACT

To repeal sections 196.010, 196.045, and 196.050, RSMo, and to enact in lieu thereof five new sections relating to cell-cultured protein, with penalty provisions.

*Be it enacted by the General Assembly of the state of Missouri, as follows:*

Section A. Sections 196.010, 196.045, and 196.050, RSMo, are repealed and five new sections enacted in lieu thereof, to be known as sections 196.010, 196.016, 196.045, 196.050, and 265.443, to read as follows:

196.010. 1. For the purpose of sections 196.010 to 196.120:

(1) **The term "cell-cultured protein" means a food product derived from harvesting animal cells and artificially replicating those cells in a growth medium to produce tissue;**

(2) The term "contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations;

~~[(2)]~~ (3) The term "cosmetic" means articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles, except that such term shall not include soap;

~~[(3)]~~ (4) The term "device" except when used in subsection 2 of this section and in sections 196.015(10), 196.075(6), 196.100(3) and 196.115(3), means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the

EXPLANATION — Matter enclosed in bold-faced brackets ~~thus~~ in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

16 diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or to  
17 affect the structure or any function of the body of man or other animals;

18 ~~[(4)]~~ (5) The term "department" shall be construed to mean the department of health  
19 and senior services;

20 ~~[(5)]~~ (6) The term "drug" means (a) articles recognized in the official United States  
21 Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official  
22 National Formulary, or any supplement to any of them; and (b) articles intended for use in the  
23 diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and  
24 (c) articles, other than food, intended to affect the structure or any function of the body of man  
25 or other animals; and (d) articles intended for use as a component of any articles specified in  
26 clause (a), (b), or (c); but does not include devices or their components, parts or accessories;

27 ~~[(6)]~~ (7) The term "federal act" means the Federal Food, Drug and Cosmetic Act  
28 (Title 21 U.S.C. 301 et seq.; 52 Stat. 1040 et seq.);

29 ~~[(7)]~~ (8) The term "food" means articles used for food or drink for man or other  
30 animals, chewing gum, and articles used for components of any such article;

31 ~~[(8)]~~ (9) The term "immediate container" does not include package liners;

32 ~~[(9)]~~ (10) The term "label" means a display of written, printed, or graphic matter upon  
33 the immediate container of any article; and a requirement made by or under authority of  
34 sections 196.010 to 196.120 that any word, statement, or other information appearing on the  
35 label shall not be considered to be complied with unless such word, statement, or other  
36 information also appears on the outside container or wrapper, if any there be, of the retail  
37 package of such article, or is easily legible through the outside container or wrapper;

38 ~~[(10)]~~ (11) The term "labeling" means all labels and other written, printed, or graphic  
39 matter upon any article or any of its containers or wrappers, or accompanying such article;

40 ~~[(11)]~~ (12) The term "new drug" means any drug the composition of which is such  
41 that such drug is not generally recognized, among experts qualified by scientific training and  
42 experience to evaluate the safety of drugs, as safe for use under the conditions prescribed,  
43 recommended or suggested in the labeling thereof; or any drug the composition of which is  
44 such that such drug, as a result of investigations to determine its safety for use under such  
45 conditions, has become so recognized, but which has not, otherwise than in such  
46 investigations, been used to a material extent or for a material time under such conditions;

47 ~~[(12)]~~ (13) The term "official compendium" means the official United States  
48 Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National  
49 Formulary, or any supplement to any of them;

50 ~~[(13)]~~ (14) The term "person" includes individual, partnership, corporation, and  
51 association.

52           2. If an article is alleged to be misbranded because the labeling is misleading, then in  
53 determining whether the labeling is misleading, there shall be taken into account, among  
54 other things, not only representations made or suggested by statement, word, design, device,  
55 sound, or in any combination thereof, but also the extent to which the labeling fails to reveal  
56 facts material in the light of such representations or material with respect to consequences  
57 which may result from the use of the article to which the labeling relates under the conditions  
58 of use prescribed in the labeling thereof or under such conditions of use as are customary or  
59 usual.

60           3. The representation of a drug, in its labeling, as an antiseptic shall be considered to  
61 be a representation that it is a germicide, except in the case of a drug purporting to be, or  
62 represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or  
63 such other use as involves prolonged contact with the body.

64           4. The provisions of sections 196.010 to 196.120 regarding the selling of food, drugs,  
65 devices, or cosmetics, shall be considered to include the manufacture, production, processing,  
66 packing, exposure, offer, possession, and holding of any such article for sale and the sale,  
67 dispensing, and giving of any such article, and the supplying of any such articles in the  
68 conduct of any food, drug, or cosmetic establishment.

**196.016. 1. The sale or offering for sale of cell-cultured protein for human  
2 consumption within this state is unlawful and prohibited.**

3           **2. A violation of this section may be enforced in the same manner as a violation**  
4 **of section 196.015 is enforced under this chapter, and a person who violates this section**  
5 **shall be subject to the penalties imposed by section 196.025 for a violation of section**  
6 **196.015.**

196.045. 1. The authority to promulgate regulations for the efficient enforcement of  
2 sections 196.010 to 196.120 is hereby vested in the department of health and senior services.  
3 The department shall make the regulations promulgated under said sections conform, insofar  
4 as practicable, with those promulgated under the federal act.

5           2. Hearings authorized or required by sections 196.010 to 196.120 shall be conducted  
6 by the department of health and senior services or such officer, agent, or employee as the  
7 department may designate for the purpose.

8           3. **The department of health and senior services shall promulgate rules to**  
9 **implement section 196.016. The rules promulgated in accordance with this subsection**  
10 **may impose requirements that are not imposed under federal law, and compliance with**  
11 **section 196.016 shall be required regardless of whether the federal act or the rules**  
12 **promulgated under the federal act impose such requirements.**

13           4. Regulations shall be promulgated pursuant to the requirements of this section and  
14 chapter 536. No rule or portion of a rule promulgated under the authority of this chapter shall

15 become effective unless it has been promulgated pursuant to the provisions of section  
16 536.024.

196.050. **Except as otherwise provided in section 196.045**, in no event shall the said  
2 department of health and senior services prescribe or promulgate any regulation fixing or  
3 establishing any definitions or standards which are more rigid or more stringent than those  
4 prescribed by the federal act applying to any commodity covered by sections 196.010 to  
5 196.120 and if any product or commodity covered by said sections shall comply with the  
6 definitions and standards prescribed by the federal act for such product or commodity, such  
7 product or commodity shall be deemed in all respects to comply with sections 196.010 to  
8 196.120.

265.443. **1. As used in this section, the term "cell-cultured protein" has the same**  
2 **meaning given to the term in section 196.010.**

3 **2. A person shall not sell or offer for sale cell-cultured protein for human**  
4 **consumption.**

5 **3. To the extent another state law conflicts with this section, this section controls.**

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