

By: Perry

S.B. No. 261

A BILL TO BE ENTITLED

AN ACT

relating to the prohibited manufacture, processing, possession,
distribution, offer for sale, and sale of cell-cultured protein.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 431.002, Health and Safety Code, is
amended by adding Subdivision (5-a) to read as follows:

(5-a) "Cell-cultured protein" means a food product
derived from harvesting animal cells and artificially replicating
those cells in a growth medium to produce tissue.

SECTION 2. Section 431.021, Health and Safety Code, is
amended to read as follows:

Sec. 431.021. PROHIBITED ACTS. The following acts and the
causing of the following acts within this state are unlawful and
prohibited:

(a) the introduction or delivery for introduction into
commerce of any food, drug, device, or cosmetic that is adulterated
or misbranded;

(b) the adulteration or misbranding of any food, drug,
device, or cosmetic in commerce;

(c) the receipt in commerce of any food, drug, device, or
cosmetic that is adulterated or misbranded, and the delivery or
proffered delivery thereof for pay or otherwise;

(d) the distribution in commerce of a consumer commodity, if
such commodity is contained in a package, or if there is affixed to

1 that commodity a label that does not conform to the provisions of
2 this chapter and of rules adopted under the authority of this
3 chapter; provided, however, that this prohibition shall not apply
4 to persons engaged in business as wholesale or retail distributors
5 of consumer commodities except to the extent that such persons:

6 (1) are engaged in the packaging or labeling of such
7 commodities; or

8 (2) prescribe or specify by any means the manner in
9 which such commodities are packaged or labeled;

10 (e) the introduction or delivery for introduction into
11 commerce of any article in violation of Section [431.084](#), [431.114](#),
12 or [431.115](#);

13 (f) the dissemination of any false advertisement;

14 (g) the refusal to permit entry or inspection, or to permit
15 the taking of a sample or to permit access to or copying of any
16 record as authorized by Sections [431.042](#)-[431.044](#); or the failure to
17 establish or maintain any record or make any report required under
18 Section 512(j), (l), or (m) of the federal Act, or the refusal to
19 permit access to or verification or copying of any such required
20 record;

21 (h) the manufacture within this state of any food, drug,
22 device, or cosmetic that is adulterated or misbranded;

23 (i) the giving of a guaranty or undertaking referred to in
24 Section [431.059](#), which guaranty or undertaking is false, except by
25 a person who relied on a guaranty or undertaking to the same effect
26 signed by, and containing the name and address of the person
27 residing in this state from whom the person received in good faith

1 the food, drug, device, or cosmetic; or the giving of a guaranty or
2 undertaking referred to in Section 431.059, which guaranty or
3 undertaking is false;

4 (j) the use, removal, or disposal of a detained or embargoed
5 article in violation of Section 431.048;

6 (k) the alteration, mutilation, destruction, obliteration,
7 or removal of the whole or any part of the labeling of, or the doing
8 of any other act with respect to a food, drug, device, or cosmetic,
9 if such act is done while such article is held for sale after
10 shipment in commerce and results in such article being adulterated
11 or misbranded;

12 (l)(1) forging, counterfeiting, simulating, or falsely
13 representing, or without proper authority using any mark, stamp,
14 tag, label, or other identification device authorized or required
15 by rules adopted under this chapter or the regulations promulgated
16 under the provisions of the federal Act;

17 (2) making, selling, disposing of, or keeping in
18 possession, control, or custody, or concealing any punch, die,
19 plate, stone, or other thing designed to print, imprint, or
20 reproduce the trademark, trade name, or other identifying mark,
21 imprint, or device of another or any likeness of any of the
22 foregoing on any drug or container or labeling thereof so as to
23 render such drug a counterfeit drug;

24 (3) the doing of any act that causes a drug to be a
25 counterfeit drug, or the sale or dispensing, or the holding for sale
26 or dispensing, of a counterfeit drug;

27 (m) the using by any person to the person's own advantage,

1 or revealing, other than to the department, to a health authority,
2 or to the courts when relevant in any judicial proceeding under this
3 chapter, of any information acquired under the authority of this
4 chapter concerning any method or process that as a trade secret is
5 entitled to protection;

6 (n) the using, on the labeling of any drug or device or in
7 any advertising relating to such drug or device, of any
8 representation or suggestion that approval of an application with
9 respect to such drug or device is in effect under Section [431.114](#) or
10 Section 505, 515, or 520(g) of the federal Act, as the case may be,
11 or that such drug or device complies with the provisions of such
12 sections;

13 (o) the using, in labeling, advertising or other sales
14 promotion of any reference to any report or analysis furnished in
15 compliance with Sections 431.042-431.044 or Section 704 of the
16 federal Act;

17 (p) in the case of a prescription drug distributed or
18 offered for sale in this state, the failure of the manufacturer,
19 packer, or distributor of the drug to maintain for transmittal, or
20 to transmit, to any practitioner licensed by applicable law to
21 administer such drug who makes written request for information as
22 to such drug, true and correct copies of all printed matter that is
23 required to be included in any package in which that drug is
24 distributed or sold, or such other printed matter as is approved
25 under the federal Act. Nothing in this subsection shall be
26 construed to exempt any person from any labeling requirement
27 imposed by or under other provisions of this chapter;

1 (q)(1) placing or causing to be placed on any drug or device
2 or container of any drug or device, with intent to defraud, the
3 trade name or other identifying mark, or imprint of another or any
4 likeness of any of the foregoing;

5 (2) selling, dispensing, disposing of or causing to be
6 sold, dispensed, or disposed of, or concealing or keeping in
7 possession, control, or custody, with intent to sell, dispense, or
8 dispose of, any drug, device, or any container of any drug or
9 device, with knowledge that the trade name or other identifying
10 mark or imprint of another or any likeness of any of the foregoing
11 has been placed thereon in a manner prohibited by Subdivision (1);
12 or

13 (3) making, selling, disposing of, causing to be made,
14 sold, or disposed of, keeping in possession, control, or custody,
15 or concealing with intent to defraud any punch, die, plate, stone,
16 or other thing designed to print, imprint, or reproduce the
17 trademark, trade name, or other identifying mark, imprint, or
18 device of another or any likeness of any of the foregoing on any
19 drug or container or labeling of any drug or container so as to
20 render such drug a counterfeit drug;

21 (r) dispensing or causing to be dispensed a different drug
22 in place of the drug ordered or prescribed without the express
23 permission in each case of the person ordering or prescribing;

24 (s) the failure to register in accordance with Section 510
25 of the federal Act, the failure to provide any information required
26 by Section 510(j) or (k) of the federal Act, or the failure to
27 provide a notice required by Section 510(j)(2) of the federal Act;

1 (t)(1) the failure or refusal to:

2 (A) comply with any requirement prescribed under
3 Section 518 or 520(g) of the federal Act; or

4 (B) furnish any notification or other material or
5 information required by or under Section 519 or 520(g) of the
6 federal Act;

7 (2) with respect to any device, the submission of any
8 report that is required by or under this chapter that is false or
9 misleading in any material respect;

10 (u) the movement of a device in violation of an order under
11 Section 304(g) of the federal Act or the removal or alteration of
12 any mark or label required by the order to identify the device as
13 detained;

14 (v) the failure to provide the notice required by Section
15 412(b) or 412(c), the failure to make the reports required by
16 Section 412(d)(1)(B), or the failure to meet the requirements
17 prescribed under Section 412(d)(2) of the federal Act;

18 (w) except as provided under Subchapter M of this chapter
19 and Section [562.1085](#), Occupations Code, the acceptance by a person
20 of an unused prescription or drug, in whole or in part, for the
21 purpose of resale, after the prescription or drug has been
22 originally dispensed, or sold;

23 (x) engaging in the wholesale distribution of drugs or
24 operating as a distributor or manufacturer of devices in this state
25 without obtaining a license issued by the department under
26 Subchapter I, L, or N, as applicable;

27 (y) engaging in the manufacture of food in this state or

1 operating as a warehouse operator in this state without having a
2 license as required by Section 431.222 or operating as a food
3 wholesaler in this state without having a license under Section
4 431.222 or being registered under Section 431.2211, as appropriate;

5 (z) unless approved by the United States Food and Drug
6 Administration pursuant to the federal Act, the sale, delivery,
7 holding, or offering for sale of a self-testing kit designed to
8 indicate whether a person has a human immunodeficiency virus
9 infection, acquired immune deficiency syndrome, or a related
10 disorder or condition;

11 (aa) making a false statement or false representation in an
12 application for a license or in a statement, report, or other
13 instrument to be filed with or requested by the department under
14 this chapter;

15 (bb) failing to comply with a requirement or request to
16 provide information or failing to submit an application, statement,
17 report, or other instrument required by the department;

18 (cc) performing, causing the performance of, or aiding and
19 abetting the performance of an act described by Subsection (x);

20 (dd) purchasing or otherwise receiving a prescription drug
21 from a pharmacy in violation of Section 431.411(a);

22 (ee) selling, distributing, or transferring a prescription
23 drug to a person who is not authorized under state or federal law to
24 receive the prescription drug in violation of Section 431.411(b);

25 (ff) failing to deliver prescription drugs to specified
26 premises as required by Section 431.411(c);

27 (gg) failing to maintain or provide pedigrees as required by

1 Section 431.412 or 431.413;

2 (hh) failing to obtain, pass, or authenticate a pedigree as
3 required by Section 431.412 or 431.413;

4 (ii) the introduction or delivery for introduction into
5 commerce of a drug or prescription device at a flea market;

6 (jj) the receipt of a prescription drug that is adulterated,
7 misbranded, stolen, obtained by fraud or deceit, counterfeit, or
8 suspected of being counterfeit, and the delivery or proffered
9 delivery of such a drug for payment or otherwise; ~~or~~

10 (kk) the alteration, mutilation, destruction,
11 obliteration, or removal of all or any part of the labeling of a
12 prescription drug or the commission of any other act with respect to
13 a prescription drug that results in the prescription drug being
14 misbranded; or

15 (ll) the manufacture, processing, possession,
16 distribution, offer for sale, or sale of cell-cultured protein.

17 SECTION 3. Section 431.081, Health and Safety Code, is
18 amended to read as follows:

19 Sec. 431.081. ADULTERATED FOOD. A food shall be deemed to
20 be adulterated:

21 (a) if:

22 (1) it bears or contains any poisonous or deleterious
23 substance which may render it injurious to health; but in case the
24 substance is not an added substance the food shall not be considered
25 adulterated under this subdivision if the quantity of the substance
26 in the food does not ordinarily render it injurious to health;

27 (2) it:

1 (A) bears or contains any added poisonous or
2 added deleterious substance, other than one that is a pesticide
3 chemical in or on a raw agricultural commodity, a food additive, a
4 color additive, or a new animal drug which is unsafe within the
5 meaning of Section 431.161;

6 (B) is a raw agricultural commodity and it bears
7 or contains a pesticide chemical which is unsafe within the meaning
8 of Section 431.161(a);

9 (C) is, or it bears or contains, any food
10 additive which is unsafe within the meaning of Section 431.161(a);
11 provided, that where a pesticide chemical has been used in or on a
12 raw agricultural commodity in conformity with an exemption granted
13 or a tolerance prescribed under Section 431.161(a), and such raw
14 agricultural commodity has been subjected to processing such as
15 canning, cooking, freezing, dehydrating, or milling, the residue of
16 such pesticide chemical remaining in or on such processed food
17 shall, notwithstanding the provisions of Section 431.161 and
18 Section 409 of the federal Act, not be deemed unsafe if such residue
19 in or on the raw agricultural commodity has been removed to the
20 extent possible in good manufacturing practice, and the
21 concentration of such residue in the processed food, when ready to
22 eat, is not greater than the tolerance prescribed for the raw
23 agricultural commodity; or

24 (D) is, or it bears or contains, a new animal
25 drug, or a conversion product of a new animal drug, that is unsafe
26 under Section 512 of the federal Act;

27 (3) it consists in whole or in part of a diseased,

1 contaminated, filthy, putrid, or decomposed substance, or if it is
2 otherwise unfit for foods;

3 (4) it has been produced, prepared, packed or held
4 under unsanitary conditions whereby it may have become contaminated
5 with filth, or whereby it may have been rendered diseased,
6 unwholesome, or injurious to health;

7 (5) it is, in whole or in part, the product of a
8 diseased animal, an animal which has died otherwise than by
9 slaughter, or an animal that has been fed upon the uncooked offal
10 from a slaughterhouse;

11 (6) its container is composed, in whole or in part, of
12 any poisonous or deleterious substance which may render the
13 contents injurious to health; [~~or~~]

14 (7) it has been intentionally subjected to radiation,
15 unless the use of the radiation was in conformity with a regulation
16 or exemption in effect in accordance with Section 409 of the federal
17 Act; or

18 (8) it contains, in whole or in part, cell-cultured
19 protein;

20 (b) if:

21 (1) any valuable constituent has been in whole or in
22 part omitted or abstracted therefrom;

23 (2) any substance has been substituted wholly or in
24 part therefor;

25 (3) damage or inferiority has been concealed in any
26 manner;

27 (4) any substance has been added thereto or mixed or

1 packed therewith so as to increase its bulk or weight, or reduce its
2 quality or strength or make it appear better or of greater value
3 than it is;

4 (5) it contains saccharin, dulcin, glucin, or other
5 sugar substitutes except in dietary foods, and when so used shall be
6 declared; or

7 (6) it be fresh meat and it contains any chemical
8 substance containing sulphites, sulphur dioxide, or any other
9 chemical preservative which is not approved by the United States
10 Department of Agriculture, the Animal and Plant Health Inspection
11 Service (A.P.H.I.S.) or by department rules;

12 (c) if it is, or it bears or contains, a color additive that
13 is unsafe under Section [431.161\(a\)](#); or

14 (d) if it is confectionery and:

15 (1) has any nonnutritive object partially or
16 completely imbedded in it; provided, that this subdivision does not
17 apply if, in accordance with department rules, the object is of
18 practical, functional value to the confectionery product and would
19 not render the product injurious or hazardous to health;

20 (2) bears or contains any alcohol, other than alcohol
21 not in excess of five percent by volume. Any confectionery that
22 bears or contains any alcohol in excess of one-half of one percent
23 by volume derived solely from the use of flavoring extracts and less
24 than five percent by volume:

25 (A) may not be sold to persons under the legal age
26 necessary to consume an alcoholic beverage in this state;

27 (B) must be labeled with a conspicuous, readily

1 legible statement that reads, "Sale of this product to a person
2 under the legal age necessary to consume an alcoholic beverage is
3 prohibited";

4 (C) may not be sold in a form containing liquid
5 alcohol such that it is capable of use for beverage purposes as that
6 term is used in the Alcoholic Beverage Code;

7 (D) may not be sold through a vending machine;

8 (E) must be labeled with a conspicuous, readily
9 legible statement that the product contains not more than five
10 percent alcohol by volume; and

11 (F) may not be sold in a business establishment
12 which derives less than 50 percent of its gross sales from the sale
13 of confectioneries; or

14 (3) bears or contains any nonnutritive substance;
15 provided, that this subdivision does not apply to a nonnutritive
16 substance that is in or on the confectionery by reason of its use
17 for a practical, functional purpose in the manufacture, packaging,
18 or storage of the confectionery if the use of the substance does not
19 promote deception of the consumer or otherwise result in
20 adulteration or misbranding in violation of this chapter; and
21 provided further, that the executive commissioner may, for the
22 purpose of avoiding or resolving uncertainty as to the application
23 of this subdivision, adopt rules allowing or prohibiting the use of
24 particular nonnutritive substances.

25 SECTION 4. Subchapter D, Chapter 433, Health and Safety
26 Code, is amended by adding Section 433.057 to read as follows:

27 Sec. 433.057. PROHIBITION ON CELL-CULTURED PROTEIN. (a)

1 In this section, "cell-cultured protein" has the meaning assigned
2 by Section 431.002.

3 (b) A person may not manufacture, process, possess,
4 distribute, offer for sale, or sell cell-cultured protein.

5 (c) To the extent another state law conflicts with this
6 section, this section controls.

7 SECTION 5. As soon as practicable after the effective date
8 of this Act, the executive commissioner of the Health and Human
9 Services Commission shall adopt any rules necessary to implement
10 the changes in law made by this Act.

11 SECTION 6. This Act takes effect September 1, 2025.