By: Gerdes H.B. No. 1431

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

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

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

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

(e) the introduction or delivery for introduction into commerce of any article in violation of Section 431.084, 431.114, or 431.115;

(f) the dissemination of any false advertisement;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 431.412 or 431.413;

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

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

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

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

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

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

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

(a) if:

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

(2) it:

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

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

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

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

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

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

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

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

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

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

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

(b) if:

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

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

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

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

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

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

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

(c) if it is, or it bears or contains, a color additive that is unsafe under Section 431.161(a); or

(d) if it is confectionery and:

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

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

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

(B) must be labeled with a conspicuous, readily

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

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

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

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

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

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

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

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

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

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

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

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

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