FINDING OF EMERGENCY

The Secretary of the California Department of Food and Agriculture (Department) determined that an emergency exists: The United States Department of Agriculture (USDA) approved the California State Regulatory Plan for Hemp Production on December 21, 2021, effective January 1st, 2022, and regulations to implement the plan must be immediately adopted in order to be in place for the start of the 2022 growing season. The Department is proposing an emergency amendment and adoption of Title 3 California Code of Regulations (CCR) Sections 4890, 4900, 4901, 4902, 4930, 4934, 4935, 4936, 4940, 4941, 4942, 4943, 4944, 4946, 4950, 4950.1, 4951, and 4952, in order to comply with the State Plan approved by USDA.

Emergency Defined

"Emergency' means a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, or general welfare," Government Code Section 11342.545. If a state agency makes a finding that the adoption of a regulation is necessary to address an emergency, the regulation may be adopted as an emergency regulation. Government Code Section 11346.1(b)(1).

In this document, the Department is providing the necessary specific facts demonstrating the existence of an emergency and the need for immediate action to prevent serious harm to the general welfare of the citizens of California, pursuant to Government Code Section 11346.1(b)(2).

Government Code Section 11346.1(a)(2) requires that, at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law, the adopting agency provide a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the agency.

1

The purpose of CCR Sections 4890, 4900, 4901, 4902, 4930, 4934, 4935, 4936, 4940, 4941, 4942, 4943, 4944, 4946, 4950, 4950.1, 4951, and 4952 is to comply with the California State Regulatory Plan for Hemp Production, the USDA, the-approved state regulatory plan adopted by the Department for compliance with the USDA final federal rule on industrial hemp production. On September 18, 2020, the Department submitted the California State Regulatory Plan for Hemp Production to the USDA in accordance with the interim final rule, which was adopted by the USDA to implement the Agriculture Improvement Act of 2018. On January 19, 2021, the USDA published the final federal rule, Document number AMS-SC-19-0042, SC19-990-2 FR, Establishment of a Domestic Hemp Program.

Senate Bill (SB) 292 was approved by the Governor on October 4, 2021 and took effect on January 1, 2022. SB 292 amends existing law regarding hemp production reporting to the Farm Service Agency of the United States Department of Agriculture (USDA FSA) for registered established agricultural research institutions, hemp breeders, and growers of industrial hemp and made other minor changes to meet the requirements outlined in 2018 Farm Bill and the federal final rule.

The Department revised its proposed state regulatory plan based on the federal final rule and submitted it to the USDA for review and approval on December 20, 2021. The USDA approved the state regulatory plan, effective January 1, 2022. To stay in compliance with the federal final rule, these regulations must be implemented as early as possible, ideally near the start of the 2022 growing season so they are in place for the harvest. The growing season generally begins in March but may start earlier depending on the part of the state and cultivation activity. This does not provide sufficient time to adopt the state regulatory plan regulations via regular rulemaking. To allow California industrial hemp cultivators to manage their crops in compliance with USDA requirements and harmonize the regulations with the changes from SB 292, the regulations need to be adopted as an emergency. The information contained within this finding of emergency meets the requirements of Government Code Sections 11346.1 and 11346.5.

The Secretary is proposing to amend CCR Sections 4890, 4900, 4901, 4902, 4930, 4934, 4935, 4936, 4940, 4941, 4942, 4943, 4944, 4946, 4950, 4950.1, 4951, and 4952 pursuant to the authority in FAC Section 407: "the director may adopt such regulations as are reasonably necessary to carry out the provisions of this code which he is directed or authorized to administer or enforce."

Additionally, FAC Section 401.5 states: "The department shall also seek to enhance, protect, and perpetuate the ability of the private sector to produce food and fiber in a way that benefits the general welfare and economy of the state."

Evidence of an Emergency

Industrial hemp cultivation was federally authorized through the Federal Agricultural Act of 2014 (2014 Farm Bill) and the 2018 Farm Bill. The U.S. Domestic Hemp Production Program was established by the USDA through an interim final rule on October 31, 2019, and further amended through a final rule on January 19, 2021. The final rule took effect on March 22, 2021. Senate Bill 292 provided additional amendments to Division 24 of the California Food and Agricultural Code (FAC) to meet the requirements for state plan approval outlined in the final federal rule.

The Department adopted regulations for industrial hemp in 2019. At that time, the regulations were in compliance with USDA's interim rule for industrial hemp production. The changes in the final federal rule and FAC Division 24 due to SB 292 require changes to the current industrial hemp regulations.

Sections have been added and amended to comply with the federal final rule.

To maintain relevant producer and land information, CCR Sections 4901(a) and (e) require new registration information for each hemp cultivator and reflect changes to the

Departments submission to USDA of registration information and changes. CCR Section 4935(d) contains requirements for registrants reporting to the USDA FSA.

To comply with accurate and effective sampling and testing requirements using postdecarboxylation or similarly reliable methods, CCR Sections 4940 through 4941 have been updated for standard sampling procedures of all lots, and Sections 4901(a)(3)(E)(3)(a) and 4901(a)(4)(E)(2)(a) for procedures on performance-based sampling. Procedures for sampling agents can be found in Section 4941. Testing procedures are covered in CCR Sections 4942 through 4944.

Requirements for disposal procedures can be found in CCR Sections 4901(a)(3)(E)(4), 4901(a)(4)(E)(3), 4950, and 4950.1 for requirements on noncompliant plants and destruction, and CCR Section 4950(h) for notification to USDA on any occurrence of non-compliant plants or plant material.

CCR Section 4930(a) has new requirements for inspections of industrial hemp cultivation.

To comply with enforcement procedures, Section 4902 has ineligibility restrictions for felony convictions related to a controlled substance and material falsification of information, and Section 4951 contains requirements on negligent violations and corrective action plans.

Background

Currently, most industrial hemp products processed and manufactured in the United States heavily rely on imported material, according to the Congressional Research Service. Imports of industrial hemp material into the United States have increased over the last decade. Therefore, in order to benefit the agricultural sector and the population of California in general, the Legislature crafted and approved statutes allowing production of industrial hemp in California (these statutes can be found in FAC Division 24). With these regulations, the State of California will be able to provide effective oversight to a well-

regulated industry and high-quality industrial hemp production. Without emergency rulemaking, the agricultural sector and population of California could be affected by not being able to grow and harvest industrial hemp in compliance with current USDA requirements, because, though USDA has approved the California State Regulatory Plan for Hemp Production, the Department is yet to adopt regulations that fully implement the approved plan.

Project Description

CCR Section 4890 - Definitions

This section defines terms used throughout the industrial hemp regulations. It is a new section to be adopted, in which most terms have already been defined and only moved from other CCR sections. Including all definitions under Section 4890 allows the public to quickly learn where and how the terms are defined.

Terms defined are:

- "Acceptable hemp THC level" defines the THC concentration that falls within the distribution or range that includes three-tenths of one percent or less that is produced when the measurement of uncertainty is applied to the reported THC concentration. This definition was originally located in Section 4942(d).
- 2) "Cannabis" has the same meaning as defined in subdivision (e) of Section 26001 of the Business and Professions Code. This is newly defined in this section for clarity on the differentiation between cannabis and industrial hemp. This makes it clear to the public that may use the terms interchangeably.
- 3) "Central cola" means a cut stem that could develop into a bud of the flowering top of the plant. This definition is provided in the final federal rule when addressing sampling to ensure the sampler understands the different portion of the plant.
- "Criminal history report" means the Federal Bureau of Investigation's Identity History Summary. This definition was originally located in Section 4902(a)(1).
- 5) "Cultivar" means a cultivated variety of industrial hemp. This is defined per FAC Section 81000(a)(3) and has been added here for clarity as the term is used repeatedly throughout the industrial hemp regulations.

- 6) "Cultivation" means the planting, growing, irrigation, or harvesting of an industrial hemp plant or crop. This is newly defined in this section for clarity and the term is used repeatedly throughout the industrial hemp regulations.
- "Cultivation site" means contiguous land area on which the applicant plans to engage in industrial hemp cultivation, storage, or both. This definition was originally located in Section 4901(a)(1).
- 8) "Cultivator" means a person planting, cultivating, growing, irrigating, or harvesting industrial hemp plants or crop. This is newly defined in this section for clarity and the term is used repeatedly through the industrial hemp regulations.
- 9) "Destroy" or "dispose" means an activity that transitions the non-compliant product into a non-retrievable or non-ingestible form. Such activities include plowing, tilling, or disking plant material into the soil; mulching, composting, chopping, or bush mowing plant material into green manure; burning plant material; burying plant material into the earth and covering with soil. This is defined per FAC Section 81000(a)(4) and has been added here for clarity as the term is used repeatedly throughout the industrial hemp regulations.
- 10) "Disqualifying conviction" means any plea of guilty or nolo contendere, or any finding of guilt for a State or Federal felony related to a controlled substance, with exceptions. This definition was originally located in Section 4902(a)(2).
- 11)"Established agricultural research institution" means an institution of higher education, as defined in Section 101 of the federal Higher Education Act of 1965 (20 U.S.C. Sec. 1001), that grows, cultivates, or manufactures industrial hemp for purposes of agricultural or academic research. This is defined per FAC 81000(a)(5) and has been added here for clarity as the term is used repeatedly throughout the industrial hemp regulations.
- 12)"Grower" means a person that is registered with the commissioner to cultivate hemp for sale. This term is newly added here for clarity as it is used repeatedly through the industrial hemp regulations.
- 13) "Harvest" means the collection of any portion of industrial hemp plant. This term is newly added here for clarity as it is used repeatedly through the industrial hemp regulations.
- 14) "Hemp breeder" means a person that is registered with the commissioner to develop

cultivars intended for sale or research. This is defined per FAC Section 81000(a)(6) and has been added here for clarity, the term is used repeatedly throughout the industrial hemp regulations.

- 15)"Industrial hemp" or "hemp" means an agricultural product, whether growing or not, that is limited to types of the plant Cannabis sativa L. and any part of that plant, including the seeds of the plant and all derivatives, extracts, the resin extracted from any part of the plant, cannabinoids, isomers, acids, salts, and salts of isomers, with a total delta-9 tetrahydrocannabinol concentration of no more than 0.3 percent on a dry weight basis. This is defined per FAC Section 81006(a)(7). The term further specifies total delta-9 THC concentration in the definition as the testing of the industrial hemp provides for decarboxylation of THC-a to delta-9 THC. \. The term is added here for clarity and the term is used repeatedly throughout the industrial hemp regulations.
- 16) "Industrial hemp nursery stock" means any industrial hemp plant or any part of an industrial hemp plant for planting or propagation. This term is newly added here for clarity as the term is used repeatedly throughout the industrial hemp regulations.
- 17) "Key participants" includes the registrant and means any person in the entity producing industrial hemp who meets the listed criteria. This definition was originally located in Section 4902(a)(3).
- 18) "Measurement of uncertainty" means the parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement. This is defined per FAC Section 81000(a)(9) and has been added here for clarity. The term is used repeatedly throughout the industrial hemp regulations.
- 19) "Person" means any individual, partnership, association, corporation, limited liability company, or any organized group of persons whether incorporated or not. This definition was originally located in Section 4901(a)(2).
- 20) "Premises" has the same meaning as defined in subdivision (aq) of Section 26001 of the Business and Professions Code. This is defined per FAC Section 81000(a)(10) and has been added here for clarity; the term is used repeatedly through the industrial hemp regulations.
- 21) "Research plan" means a strategy devised by an established agricultural research institution, or applicant-established agricultural research institution, detailing the

institution's approach to growing or cultivating hemp for academic or agricultural research. This is defined per FAC Section 81000(a)(11) and has been added here for clarity; the term is used repeatedly throughout the industrial hemp regulations.

- 22)"THC concentration" or "percentage concentration of THC" means the postdecarboxylated value of the percentage of delta-9 THC content derived from the sum of THC and THCA content and reported on a dry weight basis to the nearest thousandth, or three decimal places. This definition was originally located in Section 4942(d).
- 23) "Tissue culture" means in vitro material introduced into culture from nodal cuttings at a particular time and from a single plant and grown in aseptic conditions to be used as a source of propagative plant material. This definition was originally located in Section 4920(a)(4)(C).
- 24) "Valid registration" means the registration is unexpired, unsuspended, and unrevoked. This definition was originally located in Section 4901(b)(1).
- 25)"Variety development plan" means a strategy devised by a hemp breeder, or applicant hemp breeder, detailing their approach to growing and developing a new cultivar for industrial hemp. This is defined per FAC 81000(a)(13) and has been added here for clarity as the term is used repeatedly though the industrial hemp regulations.

CCR Section 4900 - Registration Fees

This section establishes the registration fee structure and schedule for applicant and renewal for growers of industrial hemp and seed breeders. As amended, the phrase "for commercial purposes" has been removed when identifying growers of industrial hemp. Registration is required for all growers of industrial hemp, including for noncommercial purposes. Removal of the commercial purposes provides clarity that all growers of industrial hemp must provide a registration and renewal fee of \$900 with the registration application in Sections 4900(a) and (b). To reflect the current breeding activities, "seed breeders" have been replaced with "hemp breeders" in CCR Sections 4900(a) and (b). Senate Bill 153 amends seed breeders to hemp breeders to demonstrate that breeding activities includes activities beyond breeding from seed sources. Throughout the industrial hemp regulations, "hemp breeders" are specified rather than "seed breeders."

CCR Section 4901 - Registration Application for Industrial Hemp

This section establishes the registration application requirements and procedures for growers of industrial hemp, hemp breeders, and established agricultural research institutions per FAC Sections 81003, 81004 and 81004.5. As amended, the definition section (4901(a)) and the definition of valid registration in 4901(b)(1) have been moved to CCR Section 4890(a).

The amended Section 4901(a) adds principal business address to the registration application for growers of industrial hemp (CCR Section 4901(a)(2)(B)), hemp breeders (CCR Section 4901(a)(3)(B)) and established agricultural research institutions (CCR Section 4901(a)(4)(B)). As part of the reporting requirement to USDA, the Department must submit information on registrants monthly, including information on the principal business address as required by Part 990.70(a)(1)(ii) in Title 7 of the Code of Federal Regulations (CFR). Adding the principal business address to the registration applications ensures that the Department can complete the required USDA reports. Any references to Section 4902(a)(2) for key participants in the registration applications and amendments (CCR Sections 4901(a)(2)(C), 4901(a)(3)(C), 4901(a)(4)(C), and 4901(b)(2)(A)) have been removed due to establishment of a definition section to be used throughout the industrial hemp regulations.

The variety development plan and research plan regulations have been amended to include testing of all plants grown to a representative sample of the plants grown or cultivated in CCR Sections 4901(a)(3)(E)(3) and 4901(a)(4)(E)(2). As revised by SB 292, the amendment ensures that the registered hemp breeders and established agricultural research institutions are proposing a sampling method that would provide a representation of all plants cultivated rather than every single plant.

As revised by SB 292, CCR Sections 4901(a)(2)(F)(2) has removed the word "department" and replaced it with "Department of Cannabis Control" as within this document "department" refers to Food and Agriculture. The Department of Cannabis Control licenses property for the cultivation of cannabis and the sites registered for

industrial hemp may not exist on those premises.

The Subsection (b) to Section 4941 ensures that the plan is specific to proposing a performance-based sampling as specified by USDA and provides further level of detail not previously in the text. Additional approval from the Department and USDA on the performance-based sampling has been removed as it is more than required by USDA. The amended regulations for variety development plan and research plan further clarify that the proposed plan of testing for industrial hemp not entering commerce would be specific to a sampling method replacing CCR Section 4941(b) and removes any adoption and approval by the Department and USDA.

For the variety development plan, there was an additional "and" in CCR Section 4901(a)(3)(E)(5), which has been removed from the end of the section.

In order to clarify research plan requirements for possession and cultivation of industrial hemp testing above the THC limit for established agricultural research institutions, CCR Section 4901(a)(4)(E)(3)(b) replaces "until the end of the study," with "the acceptable hemp THC level if the possession contributes to the development of types of industrial hemp that will fall within the acceptable hemp THC level, until the end of the study, at which point the industrial hemp testing greater than the acceptable hemp THC level must be disposed of according to Section 4901(4)(E)(3)(a)" which is required by FAC Section 81006(e)(10). The research plan requirements are further changed, as required by SB 292, by removing the measures that will be taken to prevent the unlawful use of hemp under Division 24 of the Food and Agricultural Code and this chapter (CCR Section 4901(a)(4)(E)(4).

As revised by SB 292 CCR Sections 4901(a)(3)(F)(2) and 4901(a)(4)(F)(2) the Department has removed the word "department" and replaced it with "Department of Cannabis Control" as within this document "department" refers to Food and Agriculture. The Department of Cannabis Control licenses property for the cultivation of cannabis and the sites registered for industrial hemp may not exist on those premises.

1(

The registration is non-transferrable to another person where there is a change in ownership. To clarify the occurrence of a change in ownership, CCR Section 4901(b)(1) provides that the change of ownership pertains to the business or registered plants. Without this addition, it is unclear when new registration is required for a change of ownership.

Amended Sections 4901(c)(2) and 4901(d)(1) specify calendar days where the sections refer to 30 days, as 30 calendar days is the correct amount of time to renew the registration. This timeframe is already stated earlier within the regulation but is repeated for clarity. Section 4901(d)(1) updates the reference to the definition of "key participant," due to the establishment of the definition section in Section 4980.

Section 4901(d)(4) provides for the revocation of the registration when a registrant no longer meets the registration requirements outlined in FAC Division 24 and section 4901 or fails to comply with a corrective action plan. This section has been removed as it is now placed in Section 4951(i), where more information on corrective action plan and revocation is provided.

Section 4901(g) has been added, which requires that the department and the commissioner retain information collected under Section 4901 for at least three years after collecting or receiving it per FAC Sections 81003(f), 81004(h), and 81004.5(g).

CCR Section 4902 - Criminal History Report for Industrial Hemp Registration

This section establishes timeframes and procedures for submitting criminal history reports for program eligibility determination based on controlled substance related felonies. As amended, CCR Section 4902(a), the definition section, has been moved to Section 4890(a).

The proposed regulation removes any references to the definition of "key participant" in CCR Sections 4902(a)(5) and 4902(a)(7) as this term is now defined in section 4890.

11

CCR 4930 - Inspections of Industrial Hemp.

This section requires the commissioner to randomly conduct annual inspections on registrants to verify registration information and cultivation requirements. The CCR Section 4930(a) has been amended to specify a random group of registrants to verify that the industrial hemp is not produced in violation of Division 24 of the Food and Agricultural Code and this chapter. This satisfies the requirement outlined in the final federal rule, title 7 CFR Section 990.3(a)(7), which requires annual inspections of industrial hemp producers.

Annual inspections may include a field inspection, in which the regulation requires the commissioner access to the cultivation sites to verify registration and cultivation requirements. Adding CCR Section 4930(b) allows the commissioner access during business hours and meets the requirement set by the regulation.

As required by FAC Sections 81004(f) and 81004.5(e), Section 4930(c) has been added, which requires registered hemp breeders and established agricultural research institutions to provide records related to the variety development or research activities under the approved plan upon request of the commissioner. This is reiterated in regulations for clarity purposes.

CCR 4934 - Planting Location Requirements.

The proposed section provides for requirements on the planting location as specified in FAC Section 81006(a)-(b). The registrant shall only plant on the registered cultivation site. Except for registered established agricultural research institution or registered hemp breeder, industrial hemp shall be grown in acreages of not less than one-tenth of an acre. All plantings shall have signage indicating they are industrial hemp. This is reiterated in regulation for clarity purposes for when planting occurs at the registered cultivation site.

CCR 4935 - Planting Report for Industrial Hemp

This section requires registrants to confirm that a planting of industrial hemp has taken place

by submitting a signed planting report within 72 hours following the completion of the planting. CCR Section 4935(a)(6) removes the redundant words "the planting."

As required by the final federal rule and FAC Section 81004.6, all registrants must report all hemp production in the state to the USDA FSA within 30 calendar days of completion of a planting. As amended, CCR Section 4935(d) removes the exemption for established agricultural research institutions from reporting to USDA FSA on all hemp production. The time frame is added to reiterate requirements by USDA FSA.

CCR 4936 - Movement of Industrial Hemp Nursery Stock.

This proposed section establishes the completion of a transfer form by the registrant to be submitted to the county or state of destination when the movement of industrial hemp nursery stock occurs. As defined CCR Section 4890, industrial hemp nursery stock is any part of the industrial hemp plant for planting or propagation. The handling and possession of industrial hemp stock requires the receiver to have registration prior to planting and assists the commissioner to verify registration and compliance of the cultivation.

No less than 72 hours prior to the movement of industrial hemp nursery stock from its registered cultivation site or a change in ownership of the industrial hemp nursery stock, the registrant shall sign and complete a transfer form, provided by the commissioner of the county where the industrial hemp nursery stock is registered. This record keeping will keep track of nursery stock as it moves and allow proper record keeping as compliant hemp nursery stock is only entering into the stream of commerce. The forms require that:

 For movement or change of ownership within California, submit the completed form to the commissioner of the destination county, if different than the county of origin, or
For interstate movement or change in ownership, submit the completed form to the destination state's department of agriculture.

The transfer form shall include the following information for record keeping:

(1) originating registrant's name, registration number, contact information, and physical

address of the origin site,

(2) receiving registrant's name, registration number, contact information, physical address of the destination site,

- (3) anticipated start and end date of the movement or date of change in ownership, and
- (4) name and number of each cultivar of plants moved or transferred to new ownership.

The bill of lading shall be provided to the Department, the commissioner, or local law enforcement upon request.

CCR 4940 - Sampling Timeframe and Pre-Harvest Notification for Industrial Hemp.

This section establishes that sampling for THC concentration shall take place no later than 11 calendar days before the anticipated harvest start date as provided on the pre-harvest report. To initiate the sampling process, the registrant submits a signed pre-harvest report to the commissioner accompanied with a sample analysis request form. In order to clarify when the information on the sample analysis request form is to be completed by the registrant, commissioner, sampler, and laboratory, CCR Section 4940(b)(3) has been amended so that the sample analysis request form must be completed during the sampling and testing process. This clarifies when the sample analysis request form is to be completed and provides for the recording of the sampling and testing activities while it is occurring.

CCR 4941 - Sampling Procedures for Testing Industrial Hemp for THC Concentration.

This section establishes the sampling requirements and procedures per FAC Section 81006(e)(3).

In order to meet the requirement outlined in 7 CFR Section 990.3(a)(2)(vii), the Department must include a training program for samplers and maintain a list of certified samplers available for the producers. To satisfy this requirement, the amended Section 4941(a)(1) specifies the sampler is no longer the commissioner, an USDA- approved sampling agent, or a federal, state, or tribal law enforcement agent authorized by USDA to collect samples, but a USDA-certified sampler. Further clarification is included, in which

the sampler cannot be a hemp registrant or key participant. Once the sampler receives certificate of training completion from USDA, the certification will be submitted to the Department where a list of USDA-certified samplers is to be made available for the registrants and the commissioners.

During sampling, the registrant must be present to observe and provide the sampler complete and unrestricted access to the property and plants. As amended, Section 4941(a)(3) provides for a registrant or an authorized representative of the registrant to observe the collection of samples and further specify that the registrant shall allow the sampler to have complete and unrestricted access to the property and the plants. The registrant may not always be an individual. To address where the registrant is a business entity, an authorized representative of the registrant is provided.

As amended, Section 4941(b) provides further details on the portion of the plant that the terminal eight inches will be collected from, specifically, the main stem of the cultivated hemp plant. This includes leaves and flowers and the terminal bud that occurs at the end of a stem, or central cola. This amends the previous description of the plant parts to be sampled, which was formerly described as only the top of the plant. The amended regulation also and meets the sample requirement specified in title 7 CFR Section 990.3(a)(2)(ii).

CCR Section 4941(b)(2) outlines the sample volume in a composite sample. Additional details are needed to address plantings with less than six plants since a contiguous planting of a variety may be less than six plants. The amended CCR Section 4941(b)(2)(a) includes sampling of plantings that have less than six plants. This ensures that sufficient plant materials can be provided to the laboratory to test and determine the THC concentration. If the planting is over 10 acres, then a formula used to calculate the number of samples to be taken for the composite sample. The text, at a confidence level of 95 percent that the plants grown will not test above the acceptable hemp THC level has been added to Section 4941(b)(2)(D), in order to clarify the confidence level used in the development of the formula.

1{

For Section 4941(b)(3), capital letters at the start of subsections (A) and (B) were switched to lowercase for continuity with the rest of the regulations.

CCR 4942 - Approved Testing Method for Testing Industrial Hemp for THC Concentration

This section establishes the approved testing methods for testing industrial hemp for THC concentration, as mandated per FAC Section 81006(e).

When testing industrial hemp, laboratories must test for THC concentration on a dry weight basis for each composite sample. To measure the THC concentration, laboratories dry the composite sample until the weight remains constant after drying intervals. The drying temperature must not exceed 90 degrees Celsius. In order to implement USDA's laboratory testing guidelines, the amended CCR Section 4942(a)(5) specifies a moisture content of five to 12 percent for composite samples to achieve a constant weight and provides an alternative method to determine the THC concentration on a dry weight basis. By analyzing the moisture content of the sample and factoring the measured moisture content into the THC concentration for a dry weight basis, the laboratory can determine the THC concentration, using the formula: THC concentration on dry weight basis = THC concentration of the wet sample/ (1.0 – percentage weight of the wet sample)/100). The formula is derived from other USDA approved State Plans and in consultation with CDFA Center for Analytical Chemistry.

Once the plant materials have been dried, the sample will be milled to a homogenous powder-like consistency and combined into a homogeneous powder-like consistency before analysis. The amended CCR Section 4942(a)(6) now states that the composite sample needs to be ground using a centrifugal rotor mill or a similar method to mill and combine the sample. This amendment is based on USDA's laboratory testing guidelines.

For CCR Section 4942(b)(1)-(4), the first word was switched to lowercase for continuity with the rest of the regulations.

CCR Sections 4942(c) and (d) have been moved to the definitions in Section 4890.

The CCR Section 4942(e) is now (c) due to the above sections being moved. Laboratories are required to retain samples for a minimum of 60 calendar days from the testing date. Section 4942(c)(2) has been amended to specify that the laboratory must destroy the samples between 60 and 120 calendar days from the testing date, providing a clearer understanding when the sample must be destroyed. Additional corrections are made in the citation of the Agricultural Marketing Act of 1946 and the inclusion of references to USDA's regulations and guidance for destruction method.

4943. Approved Laboratory for Testing Industrial Hemp for THC Concentration

This section establishes the testing laboratories' requirements for testing industrial hemp for THC concentration. Prior to testing industrial hemp THC concentration, the laboratory must obtain approval from the Department. The amended CCR Section 4943(a)(1) specifies that the laboratory registration requirements include registration with the United States Drug Enforcement Administration no later than December 31, 2022, as required in the final federal rule title 7 CFR Section 990.70.(a)(3)(ii)(H). Section 4943(a)(2) has been added, which requires that laboratories meet the AOAC International standard method performance requirements for Quantitation of Cannabinoids in Plant Materials of Hemp when selecting for an appropriate method. This requirement is outlined in USDA's laboratory guidelines.

The amended CCR Section 4943(b) provides the application requirements for the laboratory. The laboratory must obtain written approval from the Department before testing. By specifying approval must occur before testing, the proposed regulations make clear as to when the approval must be obtained for the testing to occur. Section 4943(b)(3) now adds an effective date for testing laboratories to provide a copy of the testing laboratory's United States Drug Enforcement Administration (DEA) registration certificate. A DEA registration certificate will be required starting December 31, 2022, as this date is specified in the federal final rule. Also, Section 4943(b)(7) has been added, which requires the laboratory to provide a copy of the laboratory sample test report to the Department in order to verify compliance with Section 4944(b)

Section 4943(c) now states that the Department, to approve or renew an approval for a laboratory to conduct THC testing, needs to receive the application following the procedures in Section 4943(b). The Department shall approve the laboratory to conduct THC testing on industrial hemp using the approved standard operating procedures for THC testing and laboratory test report. This is to clarify the laboratory must follow the procedures provided in the approved standard operating procedures and laboratory test report.

Section 4943(d) is new text that outlines the process for testing laboratories to reapply if their application for approval or renewal is denied. After the Department has provided written notification, the applicant has 30 calendar days to provide any requested information if any information was missing. Otherwise, the applicant will need to submit a new application. This allows laboratories to know the process if their applications are denied and the next steps to obtain approval.

Section 4943(e) is new text that outlines the process if an approved laboratory no longer meets the testing laboratory requirements. In this situation, the Department shall revoke the approval and provide written notification to the applicant regarding the approval revocation.

The following subsections (f)(g)(h) and (i) in Section 4943 have been renumbered as two more sections are being added.

4944. Notification of Laboratory Test Report.

This section establishes notification of laboratory testing reports that is provided to the Department. A separate test report is required for each composite sample. For the test report to meet all required information outlined in the final federal rule title 7 CFR Section 990.70 (d), CCR Section 4944(b)(8) now requires lot identification numbers as provided by U.S. Department of Agriculture Farm Service Agency.

Following the electronic notification to the Department of the laboratory test report, CCR Section 4944(d) outlines the laboratory's post-testing actions. In order to specify that the results must be provided to USDA, the regulation no long refers to this department using its acronym. Additionally, the final rule in title 7 CFR Section 990.70(d) requires that results to be submitted are the official regulatory results. Any informal testing conducted for purposes of monitoring the THC concentration is not to be reported to USDA. In order to meet this requirement, the amended CCR Section 4944(d)(1) specifies that the results for all samples required to be tested must be submitted to USDA. By including that the laboratories' reports must be sent to the USDA, the regulation ensures that the results for all samples required to be tested, CCR Section 4944(d)(1) clarifies to the laboratories that only official regulatory samples' test reports will be provided to USDA, not any informal test reports.

CCR 4946 - Final Disposition for Registered Industrial Hemp Crops.

This section establishes that the registrant may harvest a crop for which an electronic passing laboratory test report has been received as required by FAC Section 81006(e)(1).

In order to specify that only the sampled field may be harvested once a passing laboratory report is received, CCR Section 4946(a) has been amended to specify that the registrant shall harvest the sampled crop only upon receipt of an electronic copy of a passing laboratory test report. This further clarifies that a passing laboratory report is not optional for harvesting, and harvest can only be conducted for the crops, in which the field has been sampled.

As required by FAC Section 81006(e)(11), Section 4946(a)(5) has been added, which outlines that the registrants will need to provide the original copy of their passing test report to anyone transporting, purchasing, or obtaining the industrial hemp. This is reiterated in regulations to provide registrants further instructions regarding the passing test report.

When the registrant receives a failed laboratory test report, the crop must not be

1{

harvested. The amended Section 4946(b) further specifies that hemp crops that do not receive a passing laboratory report cannot be further handled, except in accordance with Section 4950. This clarifies that handling of crops with a failed laboratory test report pertains to destruction only.

Once a registrant receives a failed laboratory report on a crop, whether it is on the first or the second test report, the registrant must destroy the crop within the specified timeframe. Section 4946(c)(1) and (2) have been amended to specify that the commissioner shall issue a notice of abatement to the registrant within 48 hours of the receipt of the electronic copy of the laboratory test report.

Section 4946(d) has been added, which requires that the registrant shall retain the original signed copy of the laboratory report for two years from the date of sampling the crop and make the original copy of the laboratory test report available to the Department, the commissioner, or law enforcement officials or their designees upon request. This is required by FAC 81006(e)(11) and is reiterated to ensure registrants retain all laboratory test reports.

CCR 4950 - Destruction of Non-Compliant Industrial Hemp Crops CCR 4950.1 - Voluntary Destruction of Industrial Hemp Crops

This section establishes the procedures and conditions under which a crop of industrial hemp must be destroyed. The amended CCR Sections 4950(a) and 4950.1(a) remove the exemption for established agricultural research institutions. Now any industrial hemp crop that does not meet the requirements of Division 24 of the Food and Agricultural Code and implementing regulations shall be destroyed in a manner compliant with Section 297B of the federal Agricultural Marketing Act of 1946 (added by Section 10113 of the federal Agriculture Improvement Act of 2018 (December 20, 2018).

The amended Section 4950(a)(1) provides the destruction timeframe for non-compliant industrial hemp to be as soon as practical, but no later than 45 calendar days after the cultivator's receipt of the notification of abatement from the commissioner unless

otherwise specified in CCR Section 4946(c). Due to the amended Section 4946, which includes the timeframes for commissioners issuing notices of abatement upon the registrant receiving failed laboratory test reports, the reference to Section 4946(c)(1) has been amended to Section 4946(c) as the entire Section 4946(c) specifies different requirements from CCR Section 4950(a)(1).

The Department is required to provide a monthly disposal report to USDA for any destruction of non-compliant plantings as specified in federal final rule title 7 CFR Section 990.70(b). For the completion of the disposal report, the amended CCR Sections 4950(b) and 4950(e) include requirements that location type and lot identification as provided by U.S. Department of Agriculture Farm Service Agency, if available, be included on the destruction plan and report.

CCR Section 4950(d) was added as required by the federal final rule title 7 CFR Section 990.3(a)(6)(i). Unless destroyed by a reverse distributor registered with the DEA or by law enforcement, the destruction shall be conducted at the planting site.

Section 4950(f) requires commissioners to confirm the completion of the destruction through an inspection. Amended CCR Section 4950(f) includes an alternative method to confirm the destruction of the crop by directing cultivators to provide pictures or videos that disposal occurred successfully. This allows the commissioners more methods and discretion when working with cultivators where a field inspection is not a feasible option in a timely manner.

The USDA requires the Department to submit a monthly disposal report. The rule title 7 CFR Section 990.70(b) specifies that the State must provide the disposal report by the first of each month for any occurrence of non-compliant plants or plant material. Amended Section 4950(h) now indicates this timeframe.

4951. Corrective Action Plan.

2′

This proposed section provides for the actions to be taken when a cultivator violates the Food and Agricultural Code Division 24 or the industrial hemp regulations.

When a cultivator negligently violates Food and Agricultural Code Division 24 or regulation, the commissioner shall issue a notice of violation and require a corrective action plan be provided by the cultivator. A negligent violation, as specified in FAC Section 81012(b), includes but is not limited to:

- (1) failing to provide a legal description of the land on which the cultivator cultivates hemp,
- (2) failing to obtain registration prior to cultivation, or
- (3) producing hemp with a THC concentration greater than the acceptable hemp THC level except that cultivators do not commit a negligent violation for producing hemp with a THC concentration greater than the acceptable hemp THC level if the crop does not have a total delta-9 tetrahydrocannabinol concentration of more than 1.0 percent on a dry weight basis.

The notice of violation, issued to the cultivator, shall describe the violations charged to the cultivator, the right to request a hearing, a corrective action plan, and, if applicable, an administrative hold.

This notice must be sent via certified mail to the last known address of the person charged and shall be considered received even if delivery is refused or the notice is not accepted at that address. The correct address is required during the registration process when growing industrial hemp and it is the responsibility of the cultivator to provide any updated contact information, including mailing address, to the commissioner.

If the commissioner determines that <u>hemp grown not in compliance with Food and</u> <u>Agricultural Code Division 24 or this chapter will negatively affect the welfare or well-being</u> <u>of the general public, it is in the public interest to issue an order for the administrative hold</u> of hemp, they may do so. The procedures for issuing an order for the administrative hold are intended to govern possession and use of industrial hemp while an enforcement matter concerning its cultivation remains pending, and the legal compliance of the crop is yet to be conclusively determined. The procedures are outlined as follow:

- The order shall provide a description of the hemp to be subject to the administrative hold.
- (2) Within twenty-four (24) hours of receipt of the order for administrative hold, the person in possession of the hemp subject to the hold shall physically segregate, safeguard and preserve all industrial hemp subject to the hold in the area designated on the licensee's premises diagram.
- (3) While the administrative hold is in effect, the person in possession of the industrial hemp is restricted from selling, donating, transferring, transporting, gifting, giving away, or destroying the industrial hemp that is subject to the hold.
- (4) Nothing herein shall prevent a registrant from continued possession, cultivation, or harvesting of the industrial hemp subject to the administrative hold. While the administrative hold is in effect, all industrial hemp subject to the hold shall be segregated from industrial hemp that is not subject to hold.
- (5) Nothing herein shall prevent a person in possession of the hemp from voluntarily surrendering industrial hemp subject to an administrative hold to the commissioner. The registrant shall identify the hemp being voluntarily surrendered. Voluntary surrender does not waive the right to a hearing and any associated rights.
- (6) Nothing herein shall prevent the person who is in possession of the hemp from inspecting it or from taking a sample according to Section 4941 and testing according to Section 4942 for evidence while in the presence of a person designated by the commissioner.

- (7) The hold order shall be nullified upon issuance of a decision under Section 4952(a), (b), or (q) that finds the person charged in the notice of violation was not and is not in violation as so charged.
- (8) If the notice of violation places a hold on hemp, or requires a person to cease operations, the notice of violation shall remain in effect pending the outcome of the hearings in Section 4952(a), (b), or (q).
- (9) Nothing herein shall be construed to extend required destruction timeframes and waive prohibitions on cultivation or harvest in Division 24 of the Food and Agricultural Code or this chapter.
- (10) The Commissioner shall remove a hold order upon finding that the violation that caused the hold order has been corrected.

As required in the federal final rule title, 7 CFR Section 990.6(b), <u>no more than one</u> <u>negligent violation shall be applied towards the eligibility requirement outlined in Section</u> <u>4951(k) per calendar year.</u>

Within 15 calendar days from the receipt of the notice of violation, the cultivator will be required to provide a corrective action plan to the commissioner as required by FAC Section 81012(a)(1)(A). The corrective action plan shall include:

- (1) a reasonable date, not to exceed 45 calendar days, by which the cultivator shall correct the violation,
- (2) measures to correct the violation, and
- (3) periodic reporting to the commissioner on the cultivator's compliance with the requirements of Division 24 of the Food and Agricultural Code, this chapter, and the corrective action plan for a minimum of two years from the date of the violation.

This corrective action plan shall be approved by the commissioner prior to its implementation.

Field inspections will be conducted by the commissioner to confirm compliance with the corrective action plan. The commissioner will require complete and unrestricted access during business hours to all hemp and other cannabis, whether growing or harvested, and all land, buildings, and other structures used for the cultivation, handling, and storage of all hemp and other cannabis plants, and all locations registered as a cultivation site.

If the cultivator does not comply with the corrective action plan, there will be a revocation of registration and the existing crop may be considered non-compliant and subject to destruction in accordance with Section 4950. Revocation shall be effective within 30 calendar days from the notice of violation unless appealed pursuant to Section 4952.

A grower of industrial hemp, established agricultural research institution, or hemp breeder that commits a negligent violation three times in a five-year period shall be ineligible to participate in the industrial hemp program for a period of five years beginning on the date of the finding of the third violation, as mandated by FAC Section 81012(b)(1)(B).

A negligent violation for a cultivator shall not be subject to any criminal enforcement action by the state or local government. However, the Secretary shall immediately report any violations as determined by the department or commissioner conducted with a mental state greater than negligence, including, but not limited to, intentionally, with recklessness, or with gross negligence, to the Attorney General of the United States and the Attorney General of California. Subsections (a) through (g) of this section shall not apply to such violations.

4952. Appeals.

This proposed section outlines the timeframes and procedures for appealing any notice of violation or the results of a laboratory report issued pursuant to FAC Section 81006(e). To

2{

develop the regulations, the Department reviewed the appeal practices of other regulatory agencies and programs within California, including the Department of Cannabis Control and the Department's Organic Program, Feed, Fertilizer and Livestock Drugs Regulatory Services, and Division of Measurement Standards.

A respondent may contest a notice of violation or a lab report issued pursuant to FAC Section 81006(e) within 30 calendar days from the date of the notice of violation by submitting a written request to the commissioner for a hearing before the commissioner. If the request is not made within this timeframe, the respondent waives the right to contest the notice or lab report. At the hearing, the respondent shall be given an opportunity to review the commissioner's evidence and to present evidence on his or her own behalf. A proposed decision and order shall be made by a hearing officer assigned by the commissioner within 60 calendar days of the receipt of the written request. This order shall be mailed to the respondent. The order is effective as of the date on the notice.

If the person upon whom the commissioner issued a notice of violation requested and appeared at the hearing, the person may appeal the commissioner's decision to the Secretary within 30 calendar days of the date of receiving a copy of the commissioner's decision by sending a written request to the Legal Office of Hearings and Appeals of the Department of Food and Agriculture, 1220 N Street, Room 315, Sacramento, California 95814 or via email to CDFA.LegalOffice@cdfa.ca.gov, which includes the following:

- 1. a copy of the commissioner's decision,
- 2. the notice of violation,
- 3. a clear and concise statement of the basis for the appeal, and
- 4. the signature of the appellant or his or her authorized agent.

The appellant shall file a copy of the appeal with the commissioner at the same time it is filed with the Secretary. At the time appellant files the appeal or within 10 calendar days of the filing, both the appellant and the commissioner may submit the record of the hearing and a written argument to the Secretary stating the ground for affirming, modifying, or reversing the commissioner's decision. All documents must be submitted to the Legal

Office of Hearings and Appeals of the California Department of Food and Agriculture, 1220 N Street, Suite 315, Sacramento, California 95814 or via email at CDFA.LegalOffice@cdfa.ca.gov.

The Department shall schedule an informal hearing within 45 calendar days from receipt of the request for an informal hearing. The department shall provide a notice of informal hearing to the appellant containing the following information:

(A) date, location, and time of the informal hearing, and(B) a statement to the appellant that the appellant may, but need not, be represented by counsel at any or all stages of the proceedings.

If there are any objections to the informal hearing procedure, it must be made in writing to the Legal Office of Hearings and Appeals and must be resolved by the hearing officer prior to the hearing. The hearings shall be presided over and conducted by a hearing officer designated by the Secretary. In no instance shall any employee of the Industrial Hemp Program serve as the hearing officer in any hearing conducted pursuant to this section. If the hearing officer finds substantial evidence in the record to support the commissioner's decision, the Secretary shall affirm the commissioner's decision. At the discretion of the hearing office, hearings may be conducted by teleconference.

The decision of the hearing officer shall be in writing and include a statement of the factual legal basis of the decision. The decision shall be issued within 30 calendar days after the conclusion of the hearing and may be issued orally at the conclusion of the hearing subject to written confirmation. This written decision shall be served on the respondent either by personal service, facsimile transmission, or email.

The hearing officer's decision shall be effective immediately upon first articulation under subsection (10) and shall be final and not appealable to the Secretary or any other officer of the department. However, the person charged may challenge the hearing officer's decision by filing a writ of administrative mandamus in the appropriate court pursuant to Code of Civil Procedure Section 1094.5.

The commissioner may deny, suspend, or revoke a registration for any violation of Division 24 of the Food and Agricultural Code or this chapter. When the commissioner denies, suspends, or revokes a registration for a violation, the commissioner shall notify the person charged with a violation, using the notice requirements outlined in Section 4951 (a). Any person who is noticed of denial, suspension, or revocation of registration may request a hearing before the Secretary within 30 calendar days of the date of receiving a copy of the commissioner's notice. The hearing shall be scheduled by the Department consistent with the provisions of Chapter 5 (commencing with Section 11500), Part 1, Division 3, Title 2 of the Government Code, and any applicable regulations enacted pursuant to these provisions. Hearings concerning the denial, suspension, or revocation of a registration shall be conducted pursuant to Chapter 5 (commencing with Section 11500) Part 1, Division 3, Title 2 of the Government Code. The standard of proof to be applied by the Department is preponderance of the evidence. The commissioner shall have the burden of proof and the burden of producing evidence.

The Department has relied upon the following information:

Authority and Reference Citations:

Authority:Sections 407 Food and Agricultural CodeReference:Sections 401.5 Food and Agricultural Code and Section 4900 of theCalifornia Code of Regulations.

Informative Digest

AOAC International Standard Method Performance Requirements (SMPR) for Quantitation of Cannabinoids in Plant Materials of Hemp (Low THC Varieties Cannabis sp.), SMPR 2019.003, October 9, 2019

Febles, Emily, USDA Approval of California's Hemp Plan, December 21, 2021

28

U.S. Domestic Hemp Production Program Final Rule, issued January 19, 2021, United States Department of Agriculture

Existing law, FAC Section 407, provides that the Secretary may adopt such regulations as are reasonably necessary to carry out the provisions of this code which the Secretary is directed or authorized to administer or enforce.

Existing law, FAC 81006, obligates the Secretary to adopt sampling procedures and approve laboratories and laboratory testing methods.

Existing Title 3 CCR Section 4900 establishes the conditions for registration and the registration fees for industrial hemp growers. This adoption provides the necessary regulatory mechanic to allow the laboratory testing of industrial hemp.

FAC Section 401.5 states: "The department shall seek to protect the general welfare and economy of the state and seek to maintain the economic well-being of agriculturally dependent rural communities in this state." The amendment of Title 3 CCR Sections 4940 and 4946 allows industrial hemp to be legally harvested.

As required by Government Code Section 11346.5(a)(3)(D), the Department has conducted an evaluation of this regulation and has determined that it is not inconsistent or incompatible with existing state regulations.

<u>CCR Sections 4890, 4900, 4901, 4902, 4930, 4934, 4935, 4936, 4940, 4941, 4942, 4943, 4944, 4946, 4950, 4950, 1, 4951, and 4952.</u>

The Department is proposing to adopt CCR Sections 4890, 4900, 4901, 4902, 4930, 4934, 4935, 4936, 4940, 4941, 4942, 4943, 4944, 4946, 4950, 4950.1, 4951, and 4952, the effect of which will result in a regulatory program in accordance with the California State Regulatory Plan for Hemp Production approved by USDA.

Mandate on Local Agencies or School Districts

The Department of Food and Agriculture has determined that amendment and adoption of Sections 4890, 4900, 4901, 4902, 4930, 4934, 4935, 4940, 4941, 4942, 4943, 4944, 4946, 4950, 4950, 1, 4951, and 4952 does not impose a mandate on local agencies or school districts. No reimbursement is required under Section 17561 of the Government Code because each **ort**y agricultural commissioner currently is reimbursed through CCR Section 4900, Industrial Hemp Registration Fees, and FAC Section 81005. There is a memorandum of understanding between the Department and California Agricultural Commissioners and Sealers Association (CACASA), the respective organization of the county agricultural commissioners. The MOU sets forth enforcement responsibilities for Division 24 among the Department and county agricultural commissioners. The MOU is intended to facilitate uniformity among county systems of enforcement, and between counties and the Department.

Economic Impact Analysis

The proposed regulations provide a comprehensive regulatory framework for industrial hemp registration and cultivation in accordance with the federal final rule established by USDA and changes from SB 292 before the next growing season.

There is no additional cost to the state for these changes. It is anticipated that this regulation will allow the growth of the industrial hemp industry in California, with an increase in the number of businesses dedicated to producing hemp and the concomitant increase in jobs.

Anticipated Benefits from This Regulatory Action

By proposing state regulations for industrial hemp cultivation that are in compliance with the federal final rule, the industrial hemp industry can continue to grow. With this regulation, the State of California will be able tocontinue to regulate a growing industry with high quality industrial hemp production.

<u>Assessment</u>

Based upon the Economic Impact Analysis, the Department has made an assessment

3(

that the proposed regulation would not eliminate jobs or existing businesses within California. The Department has made an assessment that the proposed regulation would likely lead to the creation of new jobs or businesses, and it would positively affect the expansion of businesses currently doing business within California.

As required by Government Code Section 11346.5(a)(3)(D), the Department has conducted an evaluation of this regulation and has determined that it is not inconsistent or incompatible with existing state regulations.

Estimated Cost or Savings to Public Agencies or Affected Private Individuals or Entities The Department has determined that the amendment and adoption of Sections 4890, 4900, 4901, 4902, 4930, 4934, 4935 4936, 4940, 4941, 4942, 4943, 4944, 4946, 4950, 4950.1, 4951, and 4952 does not impose a mandate on local agencies or school districts and no reimbursement is required under Section 17561 of the Government Code.

The Department also has determined that no savings or increased costs to any state agency, no reimbursable costs or savings under Part 7 (commencing with Section 17500) of Division 4 of the Government Code to local agencies or school districts, no nondiscretionary costs or savings to local agencies or school districts, and no costs or savings in federal funding to the State will result from the amendment and adoption of Sections 4890, 4900, 4901, 4902, 4930, 4934, 4935, 4936, 4940, 4941, 4942, 4943, 4944, 4946, 4950, 4950.1, 4951, and 4952.

The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. The Department has determined that the proposed actions will not have a significant adverse economic impact on housing costs or California business, including the ability of California businesses to compete with businesses in other states. The Department's determination that the action will not have a significant statewide adverse economic impact on business was based on the following:

3´

The amendment and adoption of Sections 4890, 4900, 4901, 4902, 4930, 4934, 4935, 4936, 4940, 4941, 4942, 4943, 4944, 4946, 4950, 4950.1, 4951, and 4952 will allow industrial hemp cultivators to continue growing their crops with regulations that are harmonized with the USDA federal final rule.