## CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE PROPOSED CHANGES IN THE REGULATIONS

Title 3, California Code of Regulations

Sections 4890, 4900, 4901, 4902, 4930, 4934, 4935, 4936, 4940, 4941, 4942, 4943, 4944, 4946, 4950, 4950, 1, 4951, and 4952

# ADDENDUM TO THE INITIAL STATEMENT OF REASONS/ PLAIN ENGLISH POLICY STATEMENT OVERVIEW

The previously submitted Initial Statement of Reasons is being supplemented to elaborate of the economic impact analysis and add necessity to various proposed regulations:

### **Revised Replacement Text:**

The following text has been added to these sections:

Project Description

CCR Section 4890 (a)(12) The definition of "Gross negligence" has been updated during this Notice to remove the text "clarification on the consequences for committing gross violations". This term is used in CCR Section 4951, which has been added to comply with federal law for abatement and enframement. The text removed has been struck as it includes information already in the definition and is redundant.

CCR Section 4890 (a)(22) "Recklessness" is defined as a lack of regard for the danger or consequences of one's actions. This term is used in CCR Section 4951, which has been added to comply with federal law for abatement and enframement.

CCR Section 4890 (a)(23) "Registration class" is defined as status of a registration as either a grower, hemp breeder, or established agricultural research institution. This has been added because the term is used in CCR Section 4901, and includes growers of industrial hemp, hemp

breeders and established agricultural research institutions. By using the term registration class we have a shortened terms that covers all groups.

CCR Section 4890 (a)(25) "THC concentration" or "percentage concentration of THC" or "total THC" means the post- decarboxylated 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 CCR Section 4942(d). The text "total THC" has been added as that term is used in the regulations and is defined the same as the other terms. This revision makes more specific that THC and total THC are the same. The text "<u>Tetrahydrocannabinolic acid</u>" has also been added as prior THCA was only referred to as its acronym.

CCR Section 4901 - Registration Application for Industrial Hemp

CCR Sections 4901(a)(3)(E).4 removed the text "0.3 percent" and added "the acceptable hemp THC level, given that". This changes it to complies with the measurement of uncertainty, which is defined in CCR Section 4890(a)(1).

CCR Sections 4901(a)(4)(E)2., text has been changed from "a plan for testing a representative sample of all the plants cultivated" to an earlier version with "a plan for testing a representative sample of all the plants grown". Replacing the word "cultivated" with "grown " has been determined by the department to be unnecessary so it was reverted back.

CCR Sections 4901(a)(4)(E)2.a text has been changed to remove the word "subject" from the sentence "Industrial hemp produced by registered established agricultural research institutions that does not enter the stream of commerce shall be subject sampled in accordance with...". The word "subject" has been removed as there is no type of sampling described as "subject sampling" within this document and the term could be considered confusing.

CCR Sections 4901(a)(4)(E)3.b removed the text "0.3 percent" and added "the acceptable hemp THC level, given that". This change so it complies with the measurement of uncertainty, which is defined in CCR Section 4890(a)(1).

CCR Sections 4901(a)(4)(E)4. removed the text "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, " as required by SB 292 Section 6 where it specifies that established agricultural research institutions are not subject to state and local law enforcement as a result of a negligent action.

Amended CCR Section 4901(d) adds text to clarify that a single cultivation site cannot be registered for multiple registration classes. This has been added to make explicit that one site cannot have multiple registered classes. The section includes an example: A single cultivation site cannot be registered as both a grower and breeder cultivation site. It also states that a single cultivation site cannot be registered multiple times if more than one of the registrations are effective (not denied, revoked, or suspended). A cultivation site cannot be registered to two different cultivators in separate registrations that are effective at the same time. This has been added as the simpler langue this replaces could lead to some confusion. The requirements for each registration class have distinctly different site requirements which preclude having two registrations class on one site. The public was not clear as to this requirement, so this change make this explicit.

CCR 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. This section now incorporates by reference 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) so any laboratories can have access to these standard method performance requirements. These standards have been chosen as they aligns with the federal lab guidelines, which the Department is required to follow.

Amended CCR Section 4943(b)(7) to add "a copy of the laboratory sample test report in accordance with CCR Section 4944(b)." which requires the laboratory to provide a copy of the laboratory sample test report to the Department in order to verify compliance with CCR Section 4944(b). This section requires lot identification numbers as provided by U.S. Department of Agriculture Farm Service Agency to comply with federal law which requires the template sample test report to be on file for each approved laboratory.

CCR Section 4943(d) is new text. Uncertified laboratories are still listed as being in process, but if the laboratory does not receive certification the growers crop will need to be abated. Laboratories that do not complete their applications have 30 days to provide the requested information to the Department, thus allowing the laboratory time to gain certification and the growers to continue sampling at a different lab that has completed its certification.

The revocation happens on the date of notification. The approval needs to be revoked as soon as the Department is aware of the operating procedure deficiency to ensure that no growers utilize the lab and will be required to destroy their crops. Because the testing results are ineffective any testing results they provide are inaccurate and their results are inactive by law, this is the reason the Department requires a new application after the approval is denied.

CCR Section 4943 (e) is new text. The Department will revoke approvals if the laboratory doesn't meet approval. This is so the lab does not test when they do not meet federal requirements, if they do not meet federal requirements any tests they run will not be valid and the growers crops will be destroyed. 30 calendar days is the timeframe as the THC increases with maturity, federal law requires this timeframe.

The amended CCR Section 4946(b) further specifies that hemp crops that do not receive a passing laboratory report cannot be further handled, except in accordance with CCR Section 4950. This clarifies that handling of crops with a failed laboratory test report pertains to destruction only, and no other actions to protect the public from potentially harmful product.

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. CCR 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, as opposed to another party. This clarifies who can issue such a notice, the commissioner. The Departments needed to clarify the commissioner has the authority and responsibility to notify the registrant, the public needs to know where the notification will come from.

4951. Corrective Action Plan.

This proposed CCR Section,4951(a) has been created to remedy negligence issues without revoking licenses. This provides the registrant opportunities to move back into compliances. This is for those with non-reckless violations, not intentional issues. The Department offers examples of what would be considered negligence violations for the public to illustrate the negligent behavior that could have a corrective action plan.

In CCR Section 4951(b) the Department describes what the violation notices include. This is the violation change, the right to a hearing, and that the agricultural commissioner will created the corrective actions plan. The Department outlines here that if given a violation notice the cultivator will know what the violations are, and they have the right to a hearing so they know the process they can go through to contest the violation. The cultivator also will know what the corrective action plan is so they can ensure its followed for the public safety. Administrative hold, described further in CCR Section 4951(d), lets the registrant know if there's a hold on their crop or portion thereof.

In CCR Section 4951(c) the Department outlines that will be used to send notices of violation. Certified mail is used. Certified mail is used so the Department can track the mailing and confirmed that it reached its destination. Anticipating potential refusal or nonacceptance or false representation of address using Certified mail will prevent a loophole that would delay the administrative hold or more egregious illegal activity.

In CCR Section 4951(d) the Department describes what the administrative hold entails and then explains what will be part of the administrative hold.

CCR Section 4951(d)(1) This is so the hold is limited to the non-compliant crop or portion thereof.

CCR Section 4951(d)(2) within 24 hours the non-<u>compliant</u> hemp must be segregated. This is so the registrant knows the timeframe and actions that need to be taken. The area under hold must be visibly segregated within 24 hours so that there is no accidental harvest.

CCR Section 4951(d)(3) This hemp has been potentially identified as being harmful to the public and needs to be kept out of the public.

CCR Section 4951(d)(4) A grower still has the right to grow the hemp until it's proven it need to destroyed. The hemp has to be segregated to keep potentially harmful products from being harvested and potentially distributed to the public.

CCR Section 4951(d)(5) The registrant can surrender their industrial hemp, this is the option if maintaining hemp that is subject to an administrative hold is not feasible. The grower cannot destroy their hemp themselves so they have the option to identify the hemp and surrendering it, they still can contest the hold and have a hearing

CCR Section 4951(d)(6) ensures that a grower to gather evidence if needed for a hearing to prove their case

CCR Section 4951(d)(7) specifies that if a Notice of violation is found to be unsubstantiated, that the grower continues to have a right to cultivate the product in question

CCR Section 4951(d)(8) provides a timeframe so that a product does not remain indefinitely on hold or enter commerce until the hearing. This protects both the public and the grower from the consequences of uncertified hemp reaching the market.

CCR Section 4951(d)(9) clarifies that there is no intention in these regulations that this section be used to delay destructions or enforcement. All timeframes need to be enforced to protect the public and the grower in an efficient manner.

CCR Section 4951(d)(10) allows the grower to continue farming once it has been determined that they are back in compliance.

CCR Section 4951(e) limits the number of violations to one violation that can be applied within a year. This it to allow ample opportunity for growers to enter into the program and remains in compliance.

CCR Section 4951(f) allows a process between the cultivator and commissioner to work out a corrective action plan. Timelines are provided to prevent indefinite delays. The corrective action plan must include measures to correct the violation so the public is no longer at risk. There almost must be periodic reporting from the cultivar to the commissioner so the commissioner can confirm the corrective action plan is being followed.

CCR Section 4951(g) clarifies that review and approval of the corrective action plans falls under the authority and responsibility of the agricultural commissioner.

CCR Section 4951(h) informs the public that the commissioner has access to the site to ensure that the activities are being executed in compliance with the corrective action plan.

CCR Section 4951(i) clarifies that repeated refusal to comply with this section will be deemed a threat to the public and destroying the crop may be necessary to protect to the public.

CCR Section 4951(j) is to protect the public from a cultivator that is not trying to remedy the issue in an efficient manner.

CCR Section 4951(k) has added the word "new" before the text "registration application" to make clear that this applies to submitting a registration application after revocation. The 30 calendar days from the revocation allow the grower to clear the field of the previous noncompliance crops, and reapplying allows the grower to better understand the rule and methods required to grow hemp in compliance. Requiring a corrective action plan is a way for the commissioner to ensure the grower understand the requirements of the regulations

CCR Section 4951(I) makes specific Code of Federal Regulations 990.31(c), the Department is reflecting the federal regulations as required.

CCR Section 4951(m) implements FAC 81012(b)(1)(C), the Department is reflecting the agricultural code as required in FAC 81012(b)(1)(C).

CCR Section 4951(n) implements FAC 81012(b)(2), the Department is reflecting the agricultural code as required.

CCR Section 4952. Appeals.

The Department has existing appeal processes in other regulations which were used to model CCR Section 4952, including cannabis regulations, Title 4 CCR Section 17801.1, the Direct Marketing Program Title 3 CCR § 1392.10.1, Fertilizing Materials Inspection Program Title 3 CCR § 1392.10.1, and Division of Measurement Standards appeals, Title 4 CCR § 4800.

CCR Section 4952(a) outline the appeal process. This allows the cultivators an opportunity for standard due process procedures to contest the violation in which the consequences of such violation can result in cessation of business and agricultural activities, such as loss of crops, and remedial costs. The appeals process allows 30 days is because cultivators cannot be in a position where it is indefinitely uncertain whether a respondent will file an appeal. This would stymie efforts to correct violations and protect public safety. Respondents need to know that they can access the appeal process according to information contained in the Notice of Violation.

CCR Section 4952(a)(1) explains that the cultivators cannot be in a position where it is indefinitely uncertain whether a respondent will file an appeal because this would stymie efforts to correct violations and protect public safety.

CCR Section 4952(a)(2) works with due process principles that respondents should be able to point out factual misunderstandings or legal misinterpretations that led to the notice of violation and provides transparency of government evidence used to justify enforcement action.

CCR Section 4952(a)(3) provides a swift conclusion to the appeal which allows respondents to have timely clarity on the implications of enforcement actions, such as impacts on business, investments, and contracts.

CCR Section 4952(b) allows 30 days for appeals to the Secretary because cultivators cannot be in a position where it is indefinitely uncertain whether a respondent will file an appeal. This would stymie efforts to correct violations and protect public safety. Respondents need to know that they can access the appeal process.

CCR Section 4952(b)(1) outlines that the respondents need to know how to appeal or else the appeal procedure is not accessible to the respondents.

CCR Section 4952(b)(1)(A) contents allow for efficient determination of appeals because the Department is made aware of the facts relevant to an appeal ahead of the hearing, allowing for hearing officers to focus the content of the hearing.

CCR Section 4952 (b)(2) allows the commissioner to correct any inaccuracies and respond to arguments in the respondent's submission, allowing the hearing officer to weigh both sides.

CCR Section 4952(b)(3) outlines a process similar to CCR Section 4952(a), except this also affords such opportunity to respondent to appeal. Both parties need to know how to submit these documents in order to be considered.

CCR Section 4952(b)(4) The Department has 45 days to schedule an informal hearing to ensure a swift conclusion and prevent indefinite uncertainty as to when the hearing will be held. The hearing information is necessary so that respondents' have access to the process and the attorney notice is so that respondents are not disadvantaged by confronting complex legal concepts, or, if they are so faced, are aware they need not face such concepts without an attorney.

CCR Section 4952(b)(5) provides notice to the Department of respondent's desire for a formal hearing, which eliminates potentially wasteful and inappropriate use of an informal hearing procedure.

CCR Section 4952(b)(6) notices respondents of identity of hearing officers and provides insulation against conflicts of interest among CDFA staff.

CCR Section 4952(b)(7) explains that substantial evidence is a typical standard for upholding administrative decisions short of those which require denial, revocation, or suspension of a right to do business (license, registration, certification, etc.)

CCR Section 4952(b)(8) recognizes that CDFA staff witnesses, advocates, hearing officer, and respondents may not always be able to meet in person, and comports with trends for more access in light of Covid-19.

CCR Section 4952(b)(9) provides transparency as to decision and memorializes decision and basis.

CCR Section 4952(b)(10) provides respondents timely notice of decisions that will have implications. See explanation of need for timely filing of appeals in CCR Section 4952(a).

CCR Section 4952(b)(11) notices respondents where to look for decision.

CCR Section 4952(b)(12) provides for timely enforcement action that is held to be properly exercised on appeal. This protects public health and safety.

CCR Section 4952(b)(13) provides for review of the decision outside the Department. Writ filing opportunity is given in many appeal processes, and often by statute.

CCR Section 4952(c) generally refers to the formal hearing process in the Government Code because under due process doctrine, suspension, denial, or revocation of a license is a more severe consequence than other violations that might be appealed under CCR

CCR Section 4952(a) and (b) and therefore there are heightened evidentiary and procedural requirements necessary for determining whether the action is legitimate.

CCR Section 4952(c)(1) allows that respondents need to have early notice of the basis for violations in order to effectively appeal, or else they will lack the facts and arguments to file the necessary paperwork.

CCR Section 4952(c)(2) is outlined in the earlier explanation on the need for timely knowledge of cultivators as to whether appeal will be filed in CCR Section 4952(a).

CCR Section 4952(c)(3) refers to the formal hearing process in the Government Code Chapter 5 (commencing with Section 11500), Part 1, Division 3, Title 2.

CCR Section 4952(c)(4) refers to the formal hearing process in the Government Code Chapter 5 (commencing with Section 11500) Part 1, Division 3, Title 2.

CCR Section 4952(c)(5) preponderance of evidence is used rather than substantial evidence because revocation, denial, or suspension of registration is more severe than complying with a corrective action plan, remedy in the informal hearing described in 4952(b), and standard for administrative actions to deny, suspend, revoke licenses, certifications, registrations, or other right to conduct certain business.

Economic Impact Analysis (Government Code 11346.3(b)) Having a well-regulated industrial hemp industry will benefit:

The general public by ensuring that all hemp products entering the stream of commerce are cultivated adhering to both federal and state regulations. By having California industrial hemp meet these standards the public will be protected from products that could be harmful or misleading.

The agricultural industry by ensuring that all hemp cultivators are required to meet the same regulatory requirements which will ensure a fair and equitable marketplace. Having a fair and equitable marketplace assists both new and existing business as the enter the industry and grow.

The State's general fund by implementing an effectively operated regulatory framework for hemp cultivation which decreases the burden on other regulatory programs affiliated with this industry and the relevant stakeholders.

### The Creation or Elimination of Businesses in California

As the proposed modifications of the hemp regulations will allow the continuance of a preexisting program, the Department has determined that this regulatory proposal will not have a significant impact on the creation of new businesses in the State of California. The changes proposed here

do not create a larger burden on hemp businesses, small or large, and do not make the registration, sampling, and testing process more difficult or costly for hemp cultivators.

### The Expansion of Businesses in California

As the proposed modifications of the hemp regulations will allow the continuance of a preexisting program, the Department has determined that this regulatory proposal will not have a significant impact on the expansion of businesses currently doing business in the State of California. The changes proposed here do not create a larger burden on hemp businesses, small or large, and do not make the registration, sampling, and testing process more difficult or costly for hemp cultivators.