

**DEPARTMENT OF FOOD AND AGRICULTURE**  
Animal Health Branch  
**INITIAL STATEMENT OF REASONS**

**Subject Matter of Proposed Regulation**

Equine Medication Monitoring Program

**Sections Affected**

Sections 1280, 1280.1, 1280.7, 1280.8, and 1280.11

**Specific Purpose of Each Adoption, Amendment, or Repeal**

Existing law, section 407 of the Food and Agricultural Code, provides that the Secretary may adopt such regulations as are reasonably necessary to carry out the provisions of this code which she is directed or authorized to administer or enforce.

Existing law, Chapter 8 (commencing with section 24000) of Division 11 of the Food and Agricultural Code authorizes the Department of Food and Agriculture (Department) to implement the Equine Medication Monitoring Program (EMMP) to prevent the misuse of drugs and medications in equines. The EMMP monitors horses in public shows and sales through random sample collection for chemical analysis.

Existing law section 24001(e) defines a therapeutic substance, which includes non-steroidal anti-inflammatory drugs (NSAIDs), within existing section 24011.5, permitting the use of some NSAIDs as specified.

Existing law, section 24006 of the Food and Agricultural Code states that administration of a prohibited substance is a violation of the chapter.

Existing law, section 24011.5 of the Food and Agriculture Code prohibits use of certain drugs or drug combinations, yet accommodates specific legitimate therapeutic use of medications within specified parameters. Prohibited substances are drugs or medications that affect the performance or disposition of the horse, mask or interfere with laboratory testing for chemicals, or are metabolites or derivatives of a prohibited substance.

Existing law, section 24013 of the Food and Agricultural Code authorizes the Department to adopt regulations necessary to carry out the provisions of the chapter. It also specifies that in making and adopting regulations, the Department is to first consult with the advisory committee appointed pursuant to section 24013.5. On February 2, 2015, the EMMP advisory committee approved the initiation of a rulemaking action to establish a violations matrix in regulations, as well as making other technical changes to update its existing medications list for horses entered into State registered public horse events and sales.

This regulatory proposal will make technical changes to existing regulations and adopt a new violations matrix into regulation to ensure the public is aware of the penalties for violating specified regulations relating to public horse events and sales that are required to be registered with the Department. This proposal is also needed for the purpose of regulating the administration of therapeutic drugs and medicines and to describe the circumstances in which the administration of these substances shall be prohibited.

The Department is the sole State authority over specified public equine events and sales pursuant to Chapter 8 (commencing with section 24000) of Division 11 of the Food and Agricultural Code. The Department has evaluated this proposal and believes that it is not inconsistent or incompatible with its existing State regulations regarding public equine events and sales. There are other State regulations dealing with the proper use of drugs and medications in equines under the California Horse Racing Board (Board) which is separate and distinct from the Department's equine program. The Department has no jurisdiction over horse racing in the state, yet work together with veterinarians of the Board to ensure a consistency of the programs within the State.

### **Problem(s) Intended to Address**

The Department is making technical changes to its existing regulations relating to public horse shows, events, competitions, and sales under the authority of existing section 24013 of the Food and Agricultural Code. The Department is also specifying fines and penalties for any person who is found to be in violation of the regulations relating to exhibiting equines in public horse events and sales including adopting a violations matrix for clarity and consistency with sections 24002, 24003, 24004, 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24011.6, 24012 and 24015 of the Food and Agricultural Code.

### **Statement of Factual Basis and Rationale**

The Animal Health Branch is the State's organized, professional veterinary medical unit that protects livestock populations, consumers, and California's economy from catastrophic animal diseases and other health or agricultural problems. It addresses diseases and other problems that cannot be successfully controlled on an individual animal or herd basis, but require statewide coordinated resources. The Branch is responsible for deterring any activities that have the potential to compromise California's abundant food supply or the safety of public and animal health.

In California, equine industry organizations rely on the Animal Health Branch's Equine Medication Monitoring Program (EMMP) for the enforcement of standard drugs and medication rules to ensure the safety of rider and the welfare of all equine including horses, ponies, mules and donkeys at public equine events and sales.

Equine drug testing is a form of drug testing applied to performance horses in regulated competition. Most common in racehorses, drug tests are also performed on horses in shows or exhibitions and in international competition such as the Olympics and the International Federation for Equestrian Sports [referred to as FEI] sanctioned competitions. Many horses in competitions sanctioned by various national organizations, such as the United States Equestrian Federation (USEF) in the United States, are also tested for improper drug use. In California, the EMMP conducts random drug testing of horses in public competitions and sales, [excluding racehorses, which are under the jurisdiction of the California Horse Racing Board].

California hosts approximately 1,800 registered horse events annually, ranging from small backyard schooling shows to internationally recognized endurance events, shows and other types of competition, as well as public horse sales.

The EMMP has four main components: (1) Event registration and assessment of fees; event managers must register their event 60 days before the event; (2) random sample collection from horses entered in registered events; (3) sample chemical analysis at the Kenneth L. Maddy

Equine Analytical Chemistry Laboratory at the University of California – Davis; and (4) investigation of positive samples and application of civil penalties for violations.

The EMMP monitors horses in public shows and sales through random blood or urine sample collection for chemical analysis. The intent is to ensure the integrity of public horse shows and sales through the control of performance and disposition enhancing drugs and permitting limited therapeutic use of drugs at horse shows and competitions. “Therapeutic drugs or medicines” mean drugs or medicines that are used without a prescription from a licensed veterinarian for the treatment of a diagnosed illness or injury. Prohibited substances are drugs or medicines used for non-therapeutic purposes, or any stimulant, depressant, tranquilizer, anesthetic, including local anesthetic, sedative, analgesic, corticosteroid excluding dexamethasone, anabolic steroid, or masking agent administered within 24 hours before competition or 72 hours before public sale. The misuse of drugs and medicines in a performance horse can mask a serious injury, or respiratory problem, or other serious health issue which could place the rider of the horse in jeopardy.

California’s EMMP and USEF continuously work together to prevent the misuse of drugs and medications specifically those which pose a significant risk to the safety of the rider and a risk to the horse’s health. A horse injected with a drug or medicine by a trainer during competition could subsequently stumble, fall or collapse while being ridden which could place the rider’s life in jeopardy. Therefore, there is necessity for the Department to implement and enforce rules governing the administration of permissible drugs and medicines to lessen the risk of serious injury to humans and horses.

The proposal is as follows:

#### Amend Section 1280. Definitions.

For clarity purposes, the Department is amending its definitions for terms used or referenced in the regulations that are specific to the veterinary medical industry and the equine industry. The definitions are consistent and supplemental to the definitions specified in Food and Agricultural Code section 24001. The Department is adding subsection (a)(3)(D) and (E) to regulation section 1280 to prohibit the use of any anabolic steroid administered within 90 days before a competition or sale and fluphenazine or reserpine administered within 45 days before a competition or sale.

Anabolic steroids can affect muscle mass and is sometimes used to enhance performance of the animal in a public competition. Fluphenazine and reserpine can be used to calm excitable or difficult to handle horses, and could be used to enhance the horse’s performance in the show ring or to calm the horse during a public auction or sale and masking the disposition or an underlying health problem of the animal. These prohibited substances and time frames for administration are added for consistency with section 24011(a)(2) of the Food and Agricultural Code. The Department is also amending the reference citation for the section pursuant to Government Code section 11349.1 and section 14 of Title 1 of the California Code of Regulations.

#### Amend Section 1280.1. Registration.

Subsection (c)(3) is amended to provide for the option of allowing an exhibitor or consignor to either complete the Department’s Official Form For Declaration Of Drugs Administered, Form 76-027 (Rev. 11/13) or a compatible document of the event-sanctioning organization. Many

organizations routinely hold registered equine events and may use their own drug declaration form. Providing this option is reasonable and cost effective and expedient for the Department and the event participants and exhibitors. The form must be completed by a registered event exhibitor or consignor and filed with the event manager for any horse that has received a prohibited substance for therapeutic reasons within three days before a show/competition or five days before a sale. Prohibited substances are drugs or medications that affect the performance or disposition of the horse, mask or interfere with laboratory testing for chemicals or are metabolites or derivatives of a prohibited substance. Prohibited substances affecting performance or disposition of equines include stimulants, depressants, tranquilizers, anesthetics, local anesthetics, sedative analgesics, anabolic steroids, corticosteroids, and soring agents.

Subsection (c)(3)(A) is amended to provide the option of allowing the owner, exhibitor, or trainer is to submit the completed Form 76-027 (Rev. 11/13) to the event manager within one hour if administration of the product(s) occurs at the event or they may use a compatible document of the event-sanctioning organization. Providing this option of allowing the use of a compatible document is reasonable and cost effective, and expedient for the Department and the event participants, exhibitors, and trainers. If the product administration occurs at a time other than during show or sale hours, the owner or trainer should submit the completed form within one hour after an event manager returns to duty. The disclosure of the administration of a product is necessary because a licensed veterinarian may administer or prescribe the administration of a therapeutic prohibited substance or nonsteroidal anti-inflammatory drugs (NSAIDs) to a horse at a public event. For example, a horse experiencing hives may require dexamethasone treatment by a licensed veterinarian or a horse displaying colic signs may require the therapeutic emergency administration of the non-steroidal anti-inflammatory medication, flunixin.

#### Amend Section 1280.7. Random Testing.

Subsection (a) is amended to replace the word “contracting” veterinarians with “approved California licensed” veterinarians for consistency and to conform the regulation to the existing statute, section 24001(g) of the Food and Agricultural Code. Also, a contract veterinarian possesses a valid contract with the Department to vaccinate animals or perform other veterinary functions, which is not an appropriate term for this regulation. No contract is needed with the Department, as the veterinarian is not providing a personal service to the Department’s program. The Department is also amending the reference citation for the section pursuant to Government Code section 11349.1 and section 14 of Title 1 of the California Code of Regulations.

#### Amend Section 1280.8. Therapeutic Drugs and Medicines.

The EMMP aligns its regulations with USEF, which supports state governments and works closely with national equine organizations. This section provides a detailed list of permissible therapeutic medications and drugs and establishes the maximum detectable plasma and urine levels that are allowable for horses in public shows or sales in accordance with Food and Agricultural Code section 24013. It cites specific time frames for the administration of the drug or medicine, and requires a licensed veterinarian on the event premises to administer any needed emergency drug or medication. Regulation section 1280.8 also restricts medications to those of therapeutic purposes for a veterinary-diagnosed illness or injury. It further restricts the number of non-steroidal anti-inflammatory drugs and the amount of corticosteroids or muscle relaxers permitted to be administered prior to competition.

Subsection (d) specifies that no injectable substance shall be given to a horse within 12 hours of competition. This requirement is intended to prevent the use of any injectable substance that may enhance or change the horse's disposition or affect the health and welfare of the horse. Multiple drugs or medicines can have severe adverse reactions causing the horse to suffer respiratory or other problems, causing the horse and rider injury or death. This requirement is consistent with the new USEF ruling GR 414, which includes the following exception, as amended in this proposal, as follows:

Subsection (d)(1) A minimum of "10" liters is amended to read "1" liter of polyionic fluids "per 100 pounds of body weight" given therapeutically by a licensed veterinarian between 6-12 hours of competition. Therapeutic fluids with concentrated electrolytes, such as magnesium, are prohibited.

This requirement is needed because horses during competition, especially during summer months in California, have an increased risk of dehydration and it permits the rehydration of a horse between 6–12 hours of competition. It addresses the severely dehydrated horse thus the requirement of a minimum of 1 liter per 100 pounds of body weight as specificity was needed as horses and ponies vary in size, height, and weight and the amount of the medication depends upon the weight of the animal. The amount of 1 liter per 100 pounds of body weight prohibits the administration of a lesser amount which could be utilized as a performance enhancing amount. Supplemented fluids such as those with electrolytes or spiked with magnesium would not be permitted. Administration any closer than six hours of competition may be considered performance enhancing, therefore, the existing time frame for permissible administration of fluids is between 6–12 hours.

#### Adopt Section 1280.11. Fines and Penalties.

Subsection (a) provides the authority for the Department to impose fines and penalties should individuals willfully and knowingly violate statutes or regulations relating to the drugging of horses. The Department has the authority to seek prosecution in accordance with sections 24002, 24003, 24004, 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24011.6, 24012, and 24015 of the Food and Agricultural Code. Penalties are assessed on a case by case basis, and may include the loss of awards from a horse show or competition and suspension from participating in future public horse events, which serves as a deterrent to potential violators.

Subsections (b)(1), (2) and (3) are needed to provide the public with an explanation and definition of what the Department considers to be serious, moderate and minor violations of its regulations relating to the EMMP. The Department believes only the most egregious and repeated violations of the equine medication and drugging regulations, or fraudulent business practices relating to public horse events and sales, would warrant serious penalties. As an example, a serious offense is an individual who has repeated progressive offenses or use a prohibited substance such as cocaine to enhance the performance of a horse in competition, which has no therapeutic use. Approved uses of certain medications, drugs, and therapeutic remedies is found in existing regulation section 1280.8

Any person found to be in willful violation of the medication and drug regulations which could result in serious injury or death to the horse and rider should face severe penalties, however, it will be handled on a case by case basis, depending upon the facts and evidence in each instance. The misuse of permitted drugs and medications could also cause the horse to have a serious reaction, such as respiratory or heart failure during a competition or event, and thereby

putting the rider in jeopardy. If the horse collapses over an obstacle during competition, it could be fatal to the rider.

Lesser offenses would be considered moderate and minor depending on the type of violation, such as, failing to report a permitted drug or medication, or failure to register a public equine event with the Department. However, repeated “moderate” or “minor” offenses could escalate and be considered serious offenses when a person appears to be ignoring the statutory and regulatory requirements of the Department after being cited repeatedly by the Department, and the person is made aware of the violation.

Additionally, the Department is clarifying that event managers who permit participation of a suspended individual are subject to a violation and civil penalty in accordance with Food and Agricultural Code sections 24007 and 24015(c). The reason for this is because suspended individuals, as part of the penalty assessment, is not permitted on registered event grounds until or unless the penalty has been remedied by the Department and the person who was found to be in violation of drug medication statutes and/or regulations.

Suspensions may be issued to individuals with a history of multiple violations or a detection of a prohibited non-therapeutic substance that has the potential to cause significant harm to the health or well-being of the horse. A suspended individual is one who has demonstrated the failure to adhere to the drugs and medication rules. Therefore, the individual shall not be permitted to own, train and enter into competition any horse at a registered event. Suspended individuals would be prohibited from entry onto the event grounds for the duration of the suspension period. Event managers are notified by the Department of the suspended individuals and a list of suspended individuals would also be posted on the Department’s EMMP Internet web site. Event managers would review the list of exhibitors to ensure the suspended individual is not on the event grounds.

Subsection (c), the Department is adopting a violations matrix, Table A, Equine Medication Monitoring Program Violations Matrix, into Title 3 of the California Code of Regulations. Each violation cited on the table is from existing sections of the regulations relating to the EMMP, and the matrix provides a list of each penalty associated with each violation. There are no new penalty provisions being adopted into the table. The information is consistent with the regulations cited and placed in a matrix format. There will be no change to how fines have been assessed in the past by the Department. After determination and a review of the facts and evidence presented in the matter, on a case by case basis, a penalty will be assessed to alleged violators according to the matrix. The violations matrix will provide the public with clear information on how the Department cites and fines persons, and what it considers to be serious, moderate and minor violations for persons found to be in violation of the regulations implementing the statutes relating to the EMMP under Chapter 8 (commencing with section 24000) of Division 11 of the Food and Agricultural Code.

The Department is also adopting the authority and reference citations for the section pursuant to Government Code section 11349.1 and section 14 of Title 1 of the California Code of Regulations.

### **Technical, Theoretical, and Empirical Study, Report, or Similar Documents**

1. Equine Medication Monitoring Program Advisory Committee, February 2, 2015, Meeting Minutes.
2. 2015 Guidelines for Drugs and Medications, United States Equestrian Federation (USEF), [excerpt] General Rule, "GR 414 Prohibited Practices".
3. Brochure dated January 2014, "Equine Medication Monitoring Program, Drugs and Medication Guidelines".
4. Brochure dated January 2014, "Equine Medication Monitoring Program, Event Registration Instructions and Guidelines".
5. Brochure dated January 2014, "Equine Medication Monitoring Program, Information for Exhibitors and Consignors".
6. Economic Impact Assessment

### **Specific Technologies or Equipment**

This regulation does not mandate the use of specific technologies or equipment.

### **Consideration of Reasonable Alternatives**

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Department would either be more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. This proposal is necessary to make technical amendments to existing regulations and adopt a violations matrix to serve to ensure the Department fulfills its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with Food and Agricultural Code sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

### **Reasonable Alternatives The Department Has Identified That Would Lessen Any Adverse Impact On Small Businesses**

The Department has not identified any reasonable alternatives to the proposed action and no adverse impacts to small businesses are expected as a result of this proposed action. This proposal is necessary to make technical amendments to existing regulations and to adopt a violations matrix to serve to ensure the Department fulfills its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with Food and Agricultural Code sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

### **Benefits of This Regulatory Action**

The California horse industry produces goods and services valued at approximately \$4.1 billion and approximately 698,000 horses in California, over 70 percent of which are involved in showing, sales, and recreation. This proposal benefits the equine industry by promoting the

safety of the horse and rider in competition and horses at public sales to prevent any potential misuse of drugs or medications that could fraudulently mask a disease, condition, or injury of the horse which could place its rider in jeopardy. This proposal is necessary to make technical amendments to existing regulations and to adopt a violations matrix to serve to ensure the Department fulfills its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with Food and Agricultural Code sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

### **Facts, Evidence, Documents, Testimony, or Other Evidence of No Significant Adverse Impact on Business**

No facts, evidence, documents, testimony, or other evidence of any significant adverse economic impact on business have been identified.

### **Results of Economic Impact Assessment**

The Department has made an initial determination that the proposed regulatory action will have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states by making it more costly to produce goods or services, and that it will not create or eliminate jobs or occupations. The proposal does not affect the creation of new businesses or the elimination of existing businesses within the State of California, and does not affect the expansion of businesses currently doing business within the State of California. This proposal does not impact multiple industries. This proposal benefits the equine industry by promoting the safety of the horse and rider in competition and horses at public sales to prevent any potential misuse of drugs or medications that could fraudulently mask a disease, condition, or injury of the horse which could place its rider in jeopardy. This proposal is necessary to make technical amendments to existing regulations and adopt a violations matrix, to serve to ensure the Department fulfills its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with Food and Agricultural Code sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

### **Duplication or Conflicts with Federal Regulation**

This proposal does not duplicate or conflict with federal regulations because there are no federal regulations governing public equine events or sales. The Department of Food and Agriculture is the sole State authority over specified public equine events and sales pursuant to Chapter 8 (commencing with section 24000) of Division 11 of the Food and Agricultural Code.