

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 1280.10

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 prohibited 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.

Pursuant to AB 1388 (Stats 2013, Ch. 116) Food and Agricultural Code section 24011.5 sunsets July 1, 2014, and will be replaced with section 24011.6, at which time the Department must have an approved therapeutic medications and drug list in regulation. The regulation will update the current list in Food and Agricultural Code section 24011.5, as is specified in this proposal under new regulation section 1280.8. The rulemaking changes are 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 permissible list in Food and Agricultural Code section 24011.5 only included NSAIDs. This revision to the list of therapeutic drugs and medicines, as proposed, includes two drugs which are not NSAIDs yet may be prescribed by a veterinarian for therapeutic reasons to treat a veterinarian diagnosed illness or injury.

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 October 31, 2013, the EMMP advisory committee approved the initiation of an emergency rulemaking action to implement regulations for random testing and a list of approved therapeutic medications and maximum detectable plasma and urine levels for equines in public horse shows and sales. The Department was also seeking to implement the new national regulations set by the United States Equestrian Federation (USEF), General Rule (GR) 414 "Prohibited Practices". The USEF is the National Governing Body for Equestrian Sports. The new ruling specifies that no injectable substances may be administered to any horse or pony within 12 hours prior to competing, with exceptions, as specified. The EMMP emergency rulemaking action was approved by the Office of Administrative Law on December 5, 2013 and effective January 1, 2014.

In order to make the emergency regulations permanent in Title 3 of the California Code of Regulations, the Department is proceeding with a regular rulemaking action to adopt sections 1280, 1280.1, 1280.8 and 1280.10, and amend section 1280.7 of Article 1, Chapter 6, Division 2 of Title 3 of the California Code of Regulations to: (1) implement the provisions of AB 1388 (Stats. 2013, Ch. 116); (2) align the EMMP drug testing protocols with the national standards of the USEF; (3) codify existing requirements for the administration of the EMMP including adopting forms and incorporating them by reference pursuant to Government Code sections 11340.5(a) and 11340.9(c), and section 20 of Title 1 of the California Code of Regulations; and (4) adopt a section specifying fines and penalties for a violation of specified sections of the EMMP statutes or regulations.

The Department has evaluated this proposal and believes that it is not inconsistent or incompatible with existing State regulations. 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.

Problem(s) Intended to Address

Effective January 1, 2014, AB 1388 (Stats. 2013, Ch. 116) made various technical changes to the equine drug monitoring and testing laws. It authorizes the Department to establish, by regulation, on or before July 1, 2014, an approved therapeutic medication list and specify the maximum detectable plasma levels in equines in public shows or sales. The Department is also specifying the maximum detectable urine levels in equines to this regulation for clarity purposes under the authority of existing section 24013 of the Food and Agricultural Code,

Effective December 1, 2013, the United States Equestrian Federation (USEF) General Rule (GR) 414, Prohibited Practices, specifies that no injectable substances may be administered to any horse or pony within 12 hours prior to competing, with exceptions, as specified.

In accordance with AB 1388 and GR 414, the Department is proposing to establish, by regulation, an approved therapeutic drugs and medicines list. This proposal would also adopt related provisions of the EMMP, for consistency and clarity purposes, by codifying existing procedures of the EMMP, including incorporating by reference forms used by the EMMP to administer its statutes and regulations in accordance with Chapter 8 (commencing with section 24000) of Division 11 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. Less than 25 percent of California's 1,800 events are registered with USEF. Therefore, a majority of the shows in the state are regulated by the Department's EMMP.

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.

In the past, there have been well-publicized incidents of horses being administered drugs and medications at horse shows which severely affected the health of the horse and placed the

safety of the rider in jeopardy. One report included a pony showing in May 2012 at the Devon Horse Show in Pennsylvania which collapsed and died. Reports indicated that moments before the pony died the trainer administered an injection. Had the child rider been on the pony at the time of collapse and death, the situation could have ended tragically for the child rider. In 2006 a 17 year old girl was killed while riding the cross country course in Temecula, California. The article related to this case indicated that the horse may have had a history of injury and may have been medicated during the ride, however, the horse was not required to be drug tested at the time. *

The USEF investigated the misuse of drugs and medications specifically those instances which the rider safety was of a concern. After a complete evaluation of the industry practices and issues associated with drugs and medications in the performance horse and consultation with American Association of Equine Practitioners, the USEF Drugs and Medication Committee drafted emergency regulations which include prohibited practices related administration of drugs and medications at the show grounds. The USEF board approved the national regulations, effective December 1, 2013, GR 414 "Prohibited Practices".

The EMMP aligns its regulations with USEF, which supports state governments and works closely with other national equine organizations. Consistent with USEF's new national regulation (GR 414), the EMMP advisory committee determined emergency regulations should be promulgated by the Department, which includes enforcing the prohibition of the injection of any medication within 12 hours of competition. Understanding horses may become ill or injured at the event grounds, this rule does permit the emergency administration by a licensed veterinarian of fluids or specified medications.

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 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:

Adopt Section 1280. Definitions.

For clarity purposes, the Department is adopting definitions for terms used or referenced in this proposal 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. "Prohibited substances", as specified, are not allowed if they are administered within 24 hours before competition or 72 hours before a public sale in accordance with section 24011 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.

* Reference the information contained under "Technical, Theoretical, and Empirical Study, Report, or Similar Documents" included in this filing.

Adopt Section 1280.1. Registration.

Subsection (a) is needed for clarity purposes as public equine events and public horse sales that must be registered with the Department as specified in Food and Agricultural Code sections 24001, 24012 and 24015.

Subsection (b) provides a definition of an event manager. This section is needed for clarity purposes so the event manager is aware that they are personally responsible and liable for the collection of all fees due to the Department, including any penalty fees.

Subsection (c) specifies the forms utilized by the EMMP and are required to be submitted to the Department according to the instructions contained on each form. The forms are incorporated by reference in this proposal.

Subsection (c)(1), Application to Register Equine Event/Assessment Report For Registered Event/Event Copy for Managers, Form 76-024A (Rev. 12/13), is required at least 60 days in advance of the event. A fee of \$5.00 per horse entered per public show or sale is assessed in accordance with regulation section 1280.2. The assessment report must be submitted to the Department and fees remitted within 15 days after the final day of the event. Event managers are responsible for notifying the Department of event changes or cancellations. The Department believes the 60-day time frame specified is reasonable and consistent with Food and Agricultural Code section 24015, and provides Departmental staff with sufficient time to record the event and provide time and planning for EMMP staff to be on the premises of the event for sample collection. To ensure all fees and assessments are submitted to the Department in a timely manner, the Department is requiring the event manager submit all fees within 15 days after the final day of the event [e.g., some events are one-day, three days, or longer, depending upon the type of equestrian competition or sale].

Subsection (c)(2), Law Prohibiting the Drugging of Horses/Saleyard Assessment Report, Form 76-025 (Rev. 11/2013), must be filed by the sale manager within 15 days of the end of the month being reported. The assessment fee is \$5.00 for each horse consigned for public sale pursuant to regulation section 1280.2. The Department believes that 15 days after each month of sales is a reasonable time period to allow a saleyard manager to submit the assessment report to the Department. The Department tracks this information for enforcement purposes and to ensure all required fees are submitted to the Department. The form also ensures that saleyard managers are aware that the drugging of horse is prohibited at the sale in accordance with Food and Agricultural Code section 24012, and specifies that late fees may be imposed if assessments are not received by the Department within the required 15 day time period after each month of sales,

Subsection (c)(3), Official Form For Declaration Of Drugs Administered, Form 76-027 (Rev. 11/13), 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.

There is permitted therapeutic usage of certain products that may contain a prohibited substance. Therapeutic use of topical and oral cortisone products (eye, ear and hive preparations) is permissible when administered or prescribed by a licensed veterinarian. Since the potential exists for these products to contain prohibited substances, they are to be used with caution if the ingredients and quantitative analyses of the product are not specifically known.

The time period requirements of three days before a show or five days before a sale is because of the withdrawal time for a substance to be detected in blood or urine of the horse and this requirement is consistent with USEF medication reporting. The prohibited substance withdrawal times for competitions and sales vary from 24 hours to 72 hours; therefore, information for drugs administered three days prior to a competition and five days prior to a public sale is essential for the evaluation of the quantitative drug detected in plasma or urine samples. Additionally, the time it takes for a drug to metabolize is different for a horse competing in a public horse show where the animal is being exercised and ridden in a competition, and the horse stabled at a public horse sale. Therefore, the need for the different time frames as specified.

Subsection (c)(3)(A), the owner/exhibitor/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. 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. The one-hour requirement is a reasonable reporting time period because the Department recognizes that a veterinary medical emergency may exist at the event, which may require the immediate administration of drugs or medicines, some which may be considered prohibited substances, yet necessary to treat the animal. 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.

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.

Amend Section 1280.7. Random Testing.

Subsection (a) is amended to replace the word "Director" with "Department" because the "director" is no longer referenced and is replaced with "Department" for consistency and clarity with the regulations under Title 3 of the California Code of Regulations.

Subsections (b)(1), (2), (3) and (4) are added to specify the procedures for the owner, trainer, or any person designated to maintain control of a horse that is randomly selected for examination by Department personnel at a public horse competition or sale. The examination of the horse may include physical, urine, and blood tests. It is important when a horse is selected for testing, that the owner or handler does not interfere with sample collection, such as, trying to delay the test so that the drug effects may diminish or the level of the drug detected may be reduced below the maximum permissible detectable level [e.g., walking the horse for a long period of time; bandaging the horses legs, which may be interpreted as interfering with sample collection; etc.). Any or all horses at the event or sale may be selected for examination by the Department. The Department believes the procedures as specified in this subsection are clear and

understandable to persons participating in equine competitions and sales. The procedures are necessary for the safe handling of equines that are tested for the presence of prohibited substances, as specified in this proposal, and serves to ensure the safety of the handler of the horse and Departmental personnel conducting the sample collection.

The Department is also amending 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.

Adopt Section 1280.8. Therapeutic Drugs and Medicines.

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 AB 1388 and the authority as specified in 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. Section 1280.8 would also restrict medications to those of therapeutic purposes for a veterinary-diagnosed illness or injury. It would further restrict the number of non-steroidal anti-inflammatory drugs and the amount of corticosteroids or muscle relaxers permitted to be administered prior to competition. The most significant part of the requirements of this section is the restriction of any injections within 12 hours of competition. The requirements of this section are consistent with the new USEF general rule (GR 414 Prohibited Practices), and the white paper “Clinical Guidelines for Veterinarians Treating the Non-Racing Performance Horse”, published by the American Association of Equine Practitioners, dated July 2011.*

Subsections (a) and (b), the Department is clarifying that therapeutic drugs or medicines administered for purposes other than under veterinary prescription for a diagnosed illness or injury are considered prohibited substances, and their use is a violation of this section. Horses administered therapeutic drugs or medicines for purposes other than under veterinary prescription for a diagnosed illness or injury shall not compete or be available for sale until the prohibited substance is no longer detectable in the urine or blood sample. The Department believes these subsections are necessary to ensure persons participating in public horse shows or sales are aware of the requirements for the use of drugs or medicines. The Department prohibits the use of certain drugs or drug combinations, yet accommodates specific legitimate therapeutic use of medications within specified parameters for the treatment of a veterinary diagnosed illness or injury. A licensed veterinarian must administer or prescribe the administration of prohibited substances and nonsteroidal anti-inflammatory drugs (NSAIDs) to horses entered in a public event or sale.

Subsection (c) is needed to specify the permitted usage of therapeutic drugs or medicines. Therapeutic drugs or medicines¹ are properly used to alleviate pain and to allow or promote healing. However, powerful painkilling drugs may be used on a daily basis, often in combination with several other potent drugs, to enable injured horses to train and compete before their injuries are fully healed. When this happens, the logical result is that additional injury can occur, rapidly accelerating the need for ever more powerful drugs to keep a horse in competition. The widespread use of pharmaceuticals may place the horse at greater risk of crippling injuries and

* Reference the information contained under “Technical, Theoretical, and Empirical Study, Report, or Similar Documents” included in this filing.

death. The rider of the horse is exposed to far greater risk, as medicated horses are much more likely to suffer catastrophic breakdowns during a competition sending the horse and rider tumbling which could lead to serious injuries or death.

Subsection (c)(1) specifies that a prohibited substance is permitted if it is administered more than 24 hours before competition or more than 72 hours before a public sale for consistency with section 24011 of the Food and Agricultural Code. This requirement is needed because of the withdrawal time for a substance to be detected in blood or urine of the horse. Twenty-four hours is the minimum length of time after the administration of the medication required for the metabolism and elimination of the medication. After this time the medication is no longer present or is detectable at an insufficient concentration to produce a pharmacological effect in the competition horse. After 72 hours, the drug should no longer be present or detectable in blood or urine as no drugs or medicines are permitted for horses at public sales. The difference is how the drug metabolizes in a competition horse, that is exercised or ridden in a competition and a horse that is stabled at a public horse sale. The extended period of withdrawal time for therapeutic medications in a sale horse is to ensure the drug and drug metabolites are removed from the horse at the time of sale.

Subsection (c)(2) specifies that the therapeutic drug or medicine, or metabolite of the therapeutic drug or medicine, is permitted if it does not interfere with the quantification of any permitted substance or detection of any prohibited substances as defined by Food and Agricultural Code section 24001(h). 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. Restricted substances can be used for therapeutic reasons, that is, to treat a veterinary diagnoses illness or injury but they are subject to strict limits on the amount of the drug or its metabolites (breakdown products) that can be in blood or urine at the time of competition. They include the muscle relaxant methocarbamol, the corticosteroid dexamethasone and seven nonsteroidal anti-inflammatory drugs: phenylbutazone, flunixin meglumine, ketoprofen, meclufenamic acid, naproxen, diclofenac, and firocoxib.

Subsection (c)(3) permits only one nonsteroidal anti-inflammatory drug (NSAID) to be given at one time; when two NSAIDs are in a therapeutic regime, one must be discontinued at least 72 hours before competition. Only one nonsteroidal anti-inflammatory drug is permitted to end the potentially harmful practice of “stacking” these drugs. If the horse has been getting two NSAIDs, one of them needs to be stopped at least 72 hours before competing to ensure blood and urine levels are within permissible regulatory limits.

Subsection (c)(3)(A) permits the emergency treatment of colic or an ophthalmic emergency administration of flunixin by a licensed veterinarian. In this emergency situation, the detection of an additional NSAID may be acceptable in the plasma or urine sample of a horse provided: (i) The licensed veterinarian who administered the substances properly signs and files a drug declaration form with the event manager or designee within one hour after administration of the substances or one hour after the event manager or designee returns to duty if the administration occurs at a time outside competition hours; and (ii) The horse is withdrawn from competition for 24 hours or from public sale for 72 hours.

Although only one NSAID is allowed, there is a provision for therapeutic use of flunixin meglumine for colic or eye problems, conditions for which this drug is particularly helpful. For example, if a horse was given phenylbutazone before a competition and stopped the drug within the recommended withdrawal time, then at the show, the horse displays colic signs, a

veterinarian can administer an emergency dose of flunixin, [Banamine®], and the veterinarian completes a drug declaration for the emergency administration of a second NSAID. However, the horse would be withdrawn from competition for 24 hours or withdrawn from the sale for 72 hours post administration of the emergency NSAID administration to ensure the drug has minimal pharmacologic effect. The variation in withdrawal time for competition horse and sale horse is influenced by the potential variation in drug metabolism and drug pharmacokinetics between an exercising horse and the non-exercised sale horse.

Subsection (c)(4) specifies the detected level in the sample is allowable if it does not exceed the established maximum detectable plasma levels for the following drug or medicine:

(A) 15.0 micrograms per milliliter of phenylbutazone.

In veterinary medicine, this NSAID can be used for horses to reduce fever; 15.0 micrograms is the established maximum detectable plasma level when a horse is selected for random drug testing by the Department. This is because the drug is needed to treat a veterinarian diagnosed illness or injury, and may not be intended to enhance the performance of the horse or change its disposition, which could cause harm to the horse and rider.

(B) 1.0 micrograms per milliliter of flunixin.

In veterinary medicine, this drug can be used for horses to control inflammation and pain from injury; 1.0 micrograms per milliliter is the established maximum detectable plasma level when a horse is selected for random drug testing by the Department. This is because the drug is needed to treat a veterinarian diagnosed injury, and may not be intended to enhance the performance of the horse or change its disposition, which could cause harm to the horse and rider.

(C) 2.5 micrograms per milliliter of meclufenamic acid.

In veterinary medicine, this NSAID can be used in horses to treat acute and chronic inflammation of the musculoskeletal system, including soft tissue injury, bone and joint pathology and laminitis; 2.5 micrograms per milliliter is the established maximum detectable plasma level when a horse is selected for random drug testing by the Department. This is because the drug is needed to treat a veterinarian diagnosed injury, and may not be intended to enhance the performance of the horse or change its disposition, which could cause harm to the horse and rider.

(D) 40 micrograms per milliliter of naproxen.

In veterinary medicine, this NSAID can be used for horses to control inflammation and pain from injury; 40 micrograms per milliliter is the established maximum detectable plasma level when a horse is selected for random drug testing by the Department. This is because the drug is needed to treat a veterinarian diagnosed injury, and may not be intended to enhance the performance of the horse or change its disposition, which could cause harm to the horse and rider.

(E) 0.240 micrograms per milliliter of firocoxib.

In veterinary medicine, this NSAID may be used in horses to control pain and inflammation associated with osteoarthritis in horses. Osteoarthritis is a painful condition caused by progressive "wear and tear" of cartilage and other parts of the joint; 0.240 micrograms per milliliter is the established maximum detectable plasma level when a horse is selected for random drug testing by the Department. This is because the drug is needed to treat a veterinarian diagnosed injury, and may not be intended to enhance the performance of the horse or change its disposition, which could cause harm to the horse and rider.

(F) 0.005 micrograms per milliliter of diclofenac.

In veterinary medicine, this NSAID may be used in horses to treat arthritis; 0.005 micrograms per milliliter is the established maximum detectable plasma level when a horse is selected for random drug testing by the Department. This is because the drug is needed to treat a veterinarian diagnosed illness or injury, and may not be intended to enhance the performance of the horse or change its disposition, which could cause harm to the horse and rider.

(G) 0.250 micrograms per milliliter of ketoprofen.

In veterinary medicine, this NSAID can be used for horses to reduce fever and is a nonsteroidal anti-inflammatory drug; 0.250 micrograms per milliliter is the established maximum detectable plasma level when a horse is selected for random drug testing by the Department. This is because the drug is needed to treat a veterinarian diagnosed illness or injury, and may not be intended to enhance the performance of the horse or change its disposition, which could cause harm to the horse and rider.

(H) 0.0005 micrograms per milliliter of dexamethasone.

In veterinary medicine, this drug can be used for horses as an inflammation reducer for intense swelling or a severe allergic reaction; 0.0005 micrograms per milliliter is the established maximum detectable plasma level when a horse is selected for random drug testing by the Department. This is because the drug is needed to treat an illness or injury, and may not be intended to enhance the performance of the horse or change its disposition, which could cause harm to the horse and rider.

(I) 0.5 micrograms per milliliter of methocarbamol.

In veterinary medicine, this drug can be used in horses as a muscle-relaxant and can be used to treat muscle spasms associated with back problems and exercise-related muscle problems; 0.5 micrograms per milliliter is the established maximum detectable plasma level when a horse is selected for random drug testing by the Department. This is because the drug is needed to treat a veterinarian diagnosed illness or injury, and may not be intended to enhance the performance of the horse or change its disposition, which could cause harm to the horse and rider.

Subsection (c)(5) specifies that the detected level in the sample is allowable if it does not exceed the established maximum detectable urine levels for the drug or medicine as specified in subsections (c)(5)(A) and (B). The reason why there are urine levels for only two of the nine permissible drugs is the NSAIDs cannot be accurately quantified in urine because urine pH and

metabolism affects the amount of the drug detected in the urine. For the two medications listed below, with permissible urine levels, the urine pH does not affect levels detected.¹

(A) 0.09 micrograms per milliliter of dexamethasone.

In veterinary medicine, this drug can be used in horses as an inflammation reducer for intense swelling or a severe allergic reaction; 0.0005 micrograms per milliliter is the established maximum detectable urine level when a horse is selected for random drug testing by the Department. This is because the drug is needed to treat a veterinarian diagnosed illness or injury, and may not be intended to enhance the performance of the horse or change its disposition, which could cause harm to the horse and rider.

(B) 350 micrograms per milliliter of methocarbamol.

In veterinary medicine, this drug can be used in horses as a muscle-relaxant and can be used to treat muscle spasms associated with back problems and exercise-related muscle problems; 0.5 micrograms per milliliter is the established maximum detectable urine level when a horse is selected for random drug testing by the Department. This is because the drug is needed to treat a veterinarian diagnosed illness or injury, and may not be intended to enhance the performance of the horse or change its disposition, which could cause harm to the horse and rider.

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 exceptions:

(1) A minimum of 10 liters of polyionic fluids 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. The intent of this regulation is to permit the rehydration of a horse between 6–12 hours of competition. This regulation is to address the severely dehydrated horse thus the requirement of a minimum of 10 liters of polyionic fluid. The amount would prohibit 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 time frame for permissible administration of fluids is between 6–12 hours.

¹ pH is an abbreviation for "power of hydrogen" where "p" is short for the German word for power, *potenz* and H is the element symbol for hydrogen. The H is capitalized because it is standard to capitalize element symbols. The pH scale is a logarithmic scale that usually runs from 1 to 14. Each whole pH value below 7 (the pH of pure water) is ten times more acidic than the higher value and each whole pH value above 7 is ten times less acidic than the one below it.

(2) Antibiotics, except procaine penicillin G, administered by a licensed veterinarian between 6-12 hours of competition.

This section is needed because the treatment of competition horses with injectable antibiotics may be required for the treatment of a veterinarian diagnosed illness or injury. Due to the prohibited anesthetic characteristics of procaine, the injectable procaine penicillin would not be permitted for the emergency use by a veterinarian. An example of emergency use of intravenous antibiotics is a horse with a veterinarian diagnosed resistant skin infection which would require injectable antibiotics by a licensed veterinarian between 6–12 hours of competition. Administration of this emergency therapeutic medication at this time would not have a performance enhancing effect.

(3) Dexamethasone, not to exceed 0.5 milligram per 100 pounds, administered by a licensed veterinarian between 6-12 hours of competition exclusively for the treatment of acute urticaria (hives). The total dose of dexamethasone administered within 24 hours shall not exceed 1.0 mg per 100lbs.

Horses during competition frequently have allergic type skin reactions due to new environments and exposures. Veterinarians examining these horses commonly diagnose acute urticaria, also known as hives. Dexamethasone is the most effective injectable medication for the treatment of hives. The veterinarian administration of injectable dexamethasone is restricted to between 6-12 hours of competition to reduce the amount of drug or metabolite in the system at the time of competition. After this time the medication or metabolite is detected at an insufficient concentration to produce a pharmacological effect in the competition horse.

(4) The licensed veterinarian who administered the injectable substances in subsection (d)(1) through (3) shall sign and file a drug declaration [Form 76-027(Rev. 11/13)] with the event manager or designee within one hour after the administration of the injectable substance or one hour after the event manager or designee returns to duty if the administration occurs at a time outside competition hours.

The one-hour requirement is a reasonable reporting time period because the Department recognizes that a veterinary medical emergency may exist at the event, which may require the immediate administration of drugs or medicines, some which may be considered prohibited substances, yet necessary to treat the animal. For example, the intravenous injection of dexamethasone is necessary for the therapeutic emergency treatment of hives (acute urticaria).

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.

Section 1280.10. Violations.

For clarity purposes, the Department is providing information of fines and penalties. Should individuals willfully or 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 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.

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) Form 76-024A (Rev. 12/13) Application to Register Equine Event/Assessment Report for Registered Event/Event Copy for Managers
- 2) Form 76-025 (Rev. 11/2013) Law Prohibiting Drugging of Horses/Saleyard Assessment Report
- 3) Form 76-027 (Rev. 11/13) Official Form for Declaration of Drugs Administered
- 4) Minutes from the October 31, 2013 Equine Medication Monitoring Program Advisory Committee meeting.
- 5) United States Equestrian Federation (USEF), general rule, "GR 414 Prohibited Practices" effective December 1, 2013.
- 6) Clinical Guidelines for Veterinarians Treating the Non-Racing Performance Horse, dated July 2011.
- 7) EMMP Brochure dated January 2013, "Equine Medication Monitoring Program-Drugs and Medication Guidelines".
- 8) EMMP spreadsheet of some of the violations issued as evidence of the drugging of horses in the non-USEF competitions in California. The data indicates the practice of stacking of non-steroidal anti-inflammatory drugs; the Romifidine and Acepromazine sedative detections illustrate the use of sedatives in competition, which can potentially put the horse and rider at risk.
- 9) Economic Impact Assessment
- 10) Article regarding a petition, *Force Change*, "Commending Crackdown on Horse Drugging at Competitions", which pertains to the USEF for taking action to stop horse drugging at competitions by passing a rule that all injections must be administered by a licensed veterinarian, which had not been the case in the past.
- 11) Article from *Political News*, June 24, 2012, "Ann Romney's Horse Lawsuit-Over Drugging a Lame Horse to Sell It". The article reports that according to court papers, the horse was sold under the influence of medications.
- 12) Article published in the *New York Times*, December 27, 2012 "Sudden Death of Show Pony Clouds Elite Pursuit". The article states that a pony at the Devon Horse Show in Pennsylvania that collapsed and died. Reports indicate moments before the pony died the trainer administered an injection. The death of a supposedly fit pony about to carry a young rider over hurdles was worrisome by itself, but the circumstances surrounding the

death made it even more so. Investigations into this pony's death revealed the pony had received numerous drug treatments including multiple anti-inflammatories, corticosteroids, and muscle relaxants three days prior to the event.

- 13) Article published by the *New Jersey, Star-Ledger*, January 20, 2013 "USEF moving to control over-use of medications in show horses", the article stated that a horse died after getting a shot at a hunter/jumper fixture in Ohio, while two ponies collapsed but survived after being injected at last summer's pony finals competition. The article discussed making it a rule that most permitted medications (some of which also could have a calming effect) cannot be injected less than 12 hours before a class. Drug tests can reveal through metabolites whether a permitted substance was administered in under 12 hours.
- 14) Article from the *Arabian News World*, online library, March 2013, "Putting the Horse First", discussed the differences between medication control involving therapeutic substances and doping. Medication control is focused on preventing medication violations that may mask an underlying health problem or affect performance, while at the same time providing appropriate therapeutic treatment to help protect the well-being of the horse in competition (such as the use of NSAIDs). Anti-doping, on the other hand, is focused on preventing the use of prohibited substances to mask an underlying health problem or affect performance.
- 15) Article published by *The Horse*, October 15, 2013, "Badminton, Burghley Winner Produces Positive Drug Test", which reported that a New Zealand eventing champion was suspended after one of his mounts tested positive for a banned substance following the Burghley Horse Trials. The rider could face a 2-year suspension from all international competitions as well as a fine, pending test results and any subsequent hearings.
- 16) <http://www.sfgate.com/bayarea/article/Parents-can-sue-over-equestrian-daughter-s-death-2478604.php>: Article about a 17 year old was killed while riding the cross country course at Galway Downs in Temecula, California, in 2006. According to the article, the horse had a recent documented history of injury and was most likely medicated during this ride; however, the horse was not drug tested at the time and there was no requirement to report the fall.
- 17) <http://tracks.endurance.net/2013/07/distance-rider-dies-in-horse-accident.html>
<http://www.legacy.com/obituaries/omaha/obituary.aspx?pid=166063927>: Articles about an incident at an Endurance Ride through the Sierra-Nevada Mountains near Lake Tahoe, when a horse tripped causing the death of the rider. There was no information on a veterinary examination of the horse, but as there is no current requirement for examination it is likely that no drug testing was done.
- 18) <http://horsetalk.co.nz/news/2009/08/022.shtml>
<http://www.auburnjournal.com/article/waitte-lead-tevis-cup-penyryn-womans-horse-ethanized>: Articles concerning two horse deaths associated with the 100 mile Tevis Cup Endurance Ride in California. No information on the veterinary examination of the horses was available, but as there is no current requirement for examination it is likely that no drug testing was done.

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 serves 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 serves 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 serves 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 serves 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.