

*****TENDERED TO FTC BY HISA FOR CONSIDERATION*****

AGENCY: Federal Trade Commission

ACTION: Proposed Rule

SUMMARY: As directed by the “Horseracing Integrity and Safety Act of 2020”, the Federal Trade Commission (“FTC” or “Commission”) issues a set of proposed rules related to a formula or methodology for determining assessments described in 15 USC § 3052(f).

DATES: The effective date of this proposed rule is January 1, 2023.

The deadline for comments is _____.

ADDRESSES:

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Pursuant to Section 3053(a) of the Horseracing Integrity and Safety Act of 2020¹ (the “Act”) and Rule 1.142 thereunder,² on August 17, 2022, the Horseracing Integrity and Safety Authority (“HISA” or the “Authority”) filed with the Commission the proposed rules described herein, which Items have been prepared by HISA. The Commission has published notice of the proposed rule submitted by HISA and has solicited comments on the proposed rules from interested persons.

¹ Pub. L. 116–260, div. FF, title XII, §1201, Dec. 27, 2020, 134 Stat. 3252, codified at 15 USC Ch. 57A §§3051-3060
² 16 CFR Part 1 Subpart S § 1.142

RULE SERIES 4000

PROHIBITED LIST

TABLE OF CONTENTS

4010. Purpose..... 2

4100. Banned Substances and Banned Methods 2

4110. Banned Substances 2

 Rule 4111. S0 Non-approved substances 2

 Rule 4112. S1 Anabolic agents..... 2

 Rule 4113. S2 Peptide hormones, growth factors, related substances, and mimetics 3

 Rule 4114. S3 Beta-2 agonists..... 3

 Rule 4115. S4 Hormone and metabolic modulators 4

 Rule 4116. S5 Diuretics and masking agents 4

 Rule 4117. S6 Miscellaneous substances 4

4120. Banned Methods 5

 Rule 4121. M1 Manipulation of blood and blood components 5

 Rule 4122. M2 Chemical castration or immunocastration 5

 Rule 4123. M3 Gene and cell doping 5

4200. Controlled Medication Substances and Controlled Medication Methods..... 6

4210. Controlled Medication Substances..... 6

 Rule 4211. S7 Controlled Medication Substances..... 6

 Rule 4212. Exceptions to Rule 4211 6

4220. Controlled Medication Method(s) 7

 Rule 4221. M4 Alkalinization or Use/Administration of an alkalinizing agent 7

 Rule 4222. M5 Intra-articular injections..... 7

 Rule 4223. M6 Nasogastric tube 8

 Rule 4224. M7 Intra-articular injections of polyacrylamide hydrogels..... 8

 Rule 4225. Modification of Race Period 8

4300. Ineligibility periods for Covered Horse 8

4310. Violations involving Prohibited Substances 8

4320. Violations involving Prohibited Methods 9

4330. Other violations leading to a period of Ineligibility for the Covered Horse 9

4000. PROHIBITED LIST

4010. PURPOSE

In accordance with Rule 3111, the Prohibited List identifies substances and methods that are prohibited at all times (**Banned Substances** and **Banned Methods**) and those that are prohibited for Use or Administration in relation to a Covered Horse during the Race Period and prohibited to be present in a Post-Race Sample or Post-Work Sample, except as otherwise specified in the Prohibited List (**Controlled Medication Substances** and **Controlled Medication Methods**). In accordance with the definition of ‘Race Period’ (see Rule 1020), the Prohibited List may specify that, for certain specified Controlled Medication Substances and Controlled Medication Methods, the Race Period shall be shorter or longer in duration.

Prohibited Substances and Prohibited Methods may be included in the Prohibited List by general category (e.g., anabolic steroids) or by specific reference to a particular substance or method. The Prohibited List is supplemented by the ‘Technical Document – Prohibited Substances’, which provides guidance on the Prohibited Substances that fall into the general categories listed in the Prohibited List and on the Screening Limits, Thresholds, and/or Detection Times for those Prohibited Substances (as applicable), and also designates certain Prohibited Substances as **Specified Substances**, which are those that pose a higher risk of being the result of contamination and, therefore, are subject to more flexible sanctions. Certain Prohibited Substances might also first be reported as Atypical Findings requiring further investigation before being declared as Adverse Analytical Findings, in accordance with the Atypical Findings Policy set out as Appendix 1 to the Protocol.

The Prohibited List also sets out the periods of Ineligibility applicable to Covered Horses for Anti-Doping Rule Violations and Controlled Medication Rule Violations (see Rule 4300).

4100. BANNED SUBSTANCES AND BANNED METHODS

4110. Banned Substances

Rule 4111. S0 Non-approved substances

Any pharmacological substance that (i) is not addressed by Rules 4112 through 4117, (ii) has no current approval by any governmental regulatory health authority for veterinary or human use, and (iii) is not universally recognized by veterinary regulatory authorities as a valid veterinary use, is prohibited at all times.

For the avoidance of doubt, compounded products compliant with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Guidance for Industry (GFI) #256 (aka Compounding Animal Drugs from Bulk Drug Substances) are not prohibited under this section S0.

Rule 4112. S1 Anabolic agents

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times:

- (a) anabolic androgenic steroids when administered exogenously;
- (b) other anabolic agents, including, but not limited to:

- (1) Selective Androgen Receptor Modulators (SARMs);
- (2) Zeranol;
- (3) Zilpaterol; and
- (4) Ractopamine.

Rule 4113. S2 Peptide hormones, growth factors, related substances, and mimetics

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times:

(a) Erythropoietins (EPO) and agents affecting erythropoiesis, including, but not limited to:

- (1) erythropoietin-receptor agonists;
- (2) Hypoxia-Inducible Factor (HIF) activating agents;
- (3) GATA (Erythroid Transcription Factor) inhibitors;
- (4) Transforming Growth Factor-beta (TGF- β) signaling inhibitors; and
- (5) innate repair receptor agonists.

(b) Peptide Hormones and their releasing factors, including, but not limited to:

- (1) Chorionic Gonadotrophin (CG) and Luteinizing Hormone (LH) and their releasing factors in stallions, ridglings, and geldings;
- (2) corticotrophins and their releasing factors (excluding ACTH if administered outside the Race Period);
- (3) Growth Hormone (GH) and its analogues and fragments; and
- (4) Growth Hormone (GH) releasing factors.

(c) Growth factors and growth factor modulators affecting muscle, tendon, or ligament protein synthesis/degradation, vascularization, energy utilization, regenerative capacity, or fiber type switching.

Rule 4114. S3 Beta-2 agonists

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times: all selective and non-selective beta-2 agonists, including all optical isomers.

Notwithstanding the above, the following are not prohibited under this section S3: (a) inhaled beta-2 agonists (e.g., albuterol, salbutamol) when prescribed by a Veterinarian (in the context of a valid veterinarian-patient-client relationship) as a bronchodilator; and (b) clenbuterol when prescribed by a Veterinarian (in the context of a valid veterinarian-patient-client relationship) for a duration not to exceed thirty (30) days in a six (6) month period and provided that, following administration of clenbuterol, the Covered Horse shall be placed on the Veterinarians' List and shall not be eligible to participate in any Timed and Reported Workout or Covered Horserace until a urine and a blood Sample have been collected

from it by or on behalf of the Agency, and analysis by a Laboratory of those Samples does not detect the presence of clenbuterol or its Metabolites or Markers.

Rule 4115. S4 Hormone and metabolic modulators

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times:

- (a) aromatase inhibitors;
- (b) anti-estrogenic substances, anti-estrogens, and selective estrogen receptor modulators (SERMS);
- (c) agents preventing activin receptor IIB activation, including, but not limited to, myostatin inhibitors;
- (d) metabolic modulators, including, but not limited to:
 - (1) insulins and insulin-mimetics;
 - (2) meldonium; and
 - (3) trimetazidine; and
- (e) thyroid hormone and thyroid hormone modulators.

Rule 4116. S5 Diuretics and masking agents

(a) Diuretics and masking agents, and other substances with a similar chemical structure or similar biological effect(s), are prohibited at all times.

- (b) Notwithstanding the above, the following are not prohibited under this section S5:
 - (1) drospirenone, pamabrom, and topical ophthalmic administration of carbonic anhydrase inhibitors (e.g., dorzolamide, brinzolamide);
 - (2) trichlormethiazide for treatment of edema;
 - (3) plasma expanders for life-saving procedures; and
 - (4) furosemide (aka Lasix/Salix), subject to the limitations set out in Rule 4212(d).

Rule 4117. S6 Miscellaneous substances

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times:

- (a) bisphosphonates (except that bisphosphonates may be administered for the purpose of diagnostic imaging, i.e., gamma scintigraphy);
- (b) toxins (e.g., botulinum toxin, botox);
- (c) venoms of any species, their synthetic analogs, or derivatives thereof;

- (d) altrenogest in stallions, ridglings, or geldings; and
- (e) pitcher plant extract (Sarapin).

4120. Banned Methods

Rule 4121. M1 Manipulation of blood and blood components

The following are prohibited at all times:

- (a) The Administration or reintroduction of any quantity of autologous, allogenic (homologous), or heterologous blood or red blood cell products of any origin into the circulatory system.
- (b) Artificially enhancing the uptake, transport, or delivery of oxygen, including, but not limited to: perfluorochemicals; efaproxiral (RSR13); and modified haemoglobin products, e.g., haemoglobin-based blood substitutes and microencapsulated haemoglobin products; excluding supplemental oxygen by inhalation.
- (c) Any form of intravascular manipulation of the blood or blood components by physical or chemical means.
- (d) Withdrawal of blood for any purpose other than for diagnostic/Laboratory Testing procedures.
- (e) Notwithstanding the above, manipulation of blood or blood components is not prohibited under this section M1:
 - (1) procedures performed for life-saving purposes; and
 - (2) use of veterinary regenerative therapies (i.e., autologous conditioned serum or platelet-rich plasma) for the treatment of musculoskeletal injury or disease.

Rule 4122. M2 Chemical castration or immunocastration

In case of chemical castration or immunocastration, the Covered Horse shall remain designated as an intact male. Designating a Covered Horse that has had chemical castration or immunocastration as a gelding constitutes Use of a Prohibited Method.

Rule 4123. M3 Gene and cell doping

The following, which have the potential to enhance performance or modify the heritable genome, are prohibited at all times:

- (a) the use of nucleic acids or nucleic acid analogues that might alter genome sequences and/or alter gene expression by any mechanism. This includes, but is not limited to, gene editing, gene silencing, and gene transfer technologies;
- (b) the use of normal or genetically modified cells; and
- (c) modification of the heritable genome.

4200. CONTROLLED MEDICATION SUBSTANCES AND CONTROLLED MEDICATION METHODS

4210. Controlled Medication Substances

Rule 4211. S7 Controlled Medication Substances

(a) Subject to Rule 4212, only feed, hay, and water are permitted during the Race Period. Accordingly, subject to Rule 4212, any substance administered during the Race Period or present in a Post-Race Sample (including any metabolite(s), artifact(s), and isomer(s) of such substance(s)) that does not otherwise qualify as a Banned Substance shall constitute a prohibited Controlled Medication Substance.

(b) The following Controlled Medication Substances are prohibited from presence in a Post-Work Sample:

- (1) analgesics;
- (2) Nonsteroidal Anti-Inflammatory Drugs (NSAIDs);
- (3) local anesthetics; and
- (4) corticosteroids.

(c) S7 Controlled Medication Substances exclude those substances that fall under section S0, which are Banned Substances.

Rule 4212. Exceptions to Rule 4211

(a) Medications administered or authorized by a Regulatory Veterinarian or Test Barn Veterinarian to provide medical care to a Covered Horse as a result of an injury sustained, or other adverse health event, during the Race Period are not prohibited.

(b) The following may be administered up to twenty-four (24) hours prior to Post-Time:

- (1) orally administered vitamins;
- (2) licensed vaccines against infectious agents;
- (3) anti-ulcer medications (e.g., Cimetidine, Omeprazole, and Ranitidine);
- (4) unsupplemented isotonic electrolyte solutions by oral or intravenous administration;
- (5) altrenogest in female horses;
- (6) antimicrobials (antibiotics) and other anti-infective agents, excluding procaine penicillin or other antimicrobial/anti-infective agents containing or metabolizing to Prohibited Substances; and
- (7) antiparasitic/anthelmintics approved and registered for use in horses, excluding levamisole or other antiparasitic/anthelmintics metabolizing to and/or containing other Prohibited Substances.

(c) Unsupplemented isotonic electrolyte solutions may be consumed by the horse's free choice at any time (but may not be administered except as provided in paragraph (b) above).

(d) Furosemide (aka Lasix or Salix):

(1) is permitted during Timed and Reported Workouts and Vets' List Workouts; and

(2) may be administered during the Race Period in accordance with specific provisions of the Act and any guidance or exceptions approved by the Authority, but shall not be administered within four (4) hours prior to Post-Time.

(e) The Use or Administration of supplements or feed additives during the Race Period shall not be prohibited if the Responsible Person or Covered Person establishes, or the Agency expressly accepts, that such substances are not capable at any time of causing an action or effect, or both an action and effect, within one or more of the following mammalian body systems:

(1) the blood system;

(2) the urinary system;

(3) the cardiovascular system;

(4) the digestive system;

(5) the endocrine system;

(6) the immune system;

(7) the musculoskeletal system;

(8) the nervous system;

(9) the reproductive system; and/or

(10) the respiratory system.

4220. Controlled Medication Method(s)

In addition to any prohibited practices set forth in the Rule 2000 Series (Racetrack Safety Program):

Rule 4221. M4 Alkalinization or Use/Administration of an alkalinizing agent

Alkalinization or Use/Administration of an alkalinizing agent is prohibited on Race Day. A threshold concentration of total carbon dioxide (TCO₂) in the blood in excess of 37 mmol constitutes *prima facie* evidence of alkalinization or Use/Administration of an alkalinizing agent.

Rule 4222. M5 Intra-articular injections

Intra-articular injections are prohibited on Race Day; within fourteen (14) days prior to Post-Time; and within seven (7) days prior to any Timed and Reported Workout.

Rule 4223. M6 Nasogastric tube

The use of a nasogastric tube for any purpose is prohibited within twenty-four (24) hours prior to Post-Time.

Rule 4224. M7 Intra-articular injections of polyacrylamide hydrogels

Intra-articular injections of polyacrylamide hydrogels are prohibited within one hundred and eighty (180) days prior to Post-Time.

Rule 4225. Modification of Race Period

The start of the ‘Race Period’ shall be modified for each of the Controlled Medication Methods above (i.e., each of M4-M7) based on the restricted administration time period specified for such method (e.g., the Race Period for M7 shall start one hundred and eighty (180) days prior to Post-Time).

4300. INELIGIBILITY PERIODS FOR COVERED HORSE

4310. Violations involving Prohibited Substances

The period of Ineligibility of a Covered Horse resulting from a violation involving a Prohibited Substance shall be as set forth in Table 1 below:

TABLE 1

<u>Violation</u>	<u>Ineligibility Period</u>
S0 BANNED Substances-non-approved substances	Up to 14 months
S1 BANNED Substances-anabolic agents	14 months
S2 BANNED Substances-peptide hormones	6 months
S3 BANNED Substances-beta-2 agonists	14 months
S4 BANNED Substances-hormone and metabolic modulators	3 months
S5 BANNED Substances-diuretics and masking agents	0 months
S6 BANNED Substances-miscellaneous substances	—
(1) Bisphosphonates	Life
(2) All other S6 miscellaneous substances	0 months
S7 CONTROLLED Medication Substances	0 months The Covered Horse may be placed on the Veterinarians’ List, and if so, a subsequent Vets’ List Workout must be scheduled. A post-Vets’ List Workout Sample may be required.

4320. Violations involving Prohibited Methods

The period of Ineligibility of a Covered Horse resulting from a violation involving a Prohibited Method shall be as set forth in Table 2 below:

TABLE 2

<u>Violation</u>	<u>Ineligibility Period</u>
M1 Manipulation of blood and blood components	6 months
M2 Chemical castration or immunocastration	0 months
M3 Gene and cell doping	Life
M4 Alkalinization	0 months
M5 Intra-articular injection	1 month
M6 Nasogastric tube	0 months
M7 Intra-articular injection of polyacrylamide hydrogel	12 months

4330. Other violations leading to a period of Ineligibility for the Covered Horse

The period of Ineligibility of a Covered Horse resulting from a violation of Rule 3215 shall be as set forth in Table 3 below:

TABLE 3

<u>Violation</u>	<u>Ineligibility Period</u>
Evading collection of a Sample from a Covered Horse; refusing or failing without compelling justification to submit a Covered Horse to Sample collection; or refusing or failing to comply with all Sample collection procedure requirements (Rule 3215)	<i>Evasion:</i> 18 months <i>Refusal or failure:</i> 18 months, unless it is established by the Responsible Person that fairness requires otherwise, in which case the period of Ineligibility may be reduced, depending on the specific circumstances of the case and considerations of horse welfare.