

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

COMMISSIONERS: **Lina M. Khan, Chair**
 Rebecca Kelly Slaughter
 Christine S. Wilson
 Alvaro M. Bedoya

**ORDER APPROVING THE ANTI-DOPING AND MEDICATION CONTROL RULE
PROPOSED BY THE HORSERACING INTEGRITY AND SAFETY AUTHORITY**

March 27, 2023

I. Decision of the Commission: HISA’s Anti-Doping and Medication Control Rule Is Approved

The Horseracing Integrity and Safety Act of 2020, 15 U.S.C. §§ 3051–3060, charges a self-regulatory nonprofit organization, the Horseracing Integrity and Safety Authority (“Authority”), with developing proposed rules on a variety of subjects. *See, e.g., id.* § 3055(c)(1) (requiring an anti-doping and medication control rule). The Authority’s proposed rules and proposed rule modifications take effect only if approved by the Federal Trade Commission (“Commission”). *See id.* § 3053(b)(2). As required by the Act, the Authority submitted and the Commission published for public comment in the Federal Register¹ the text and explanation (“Notice”) of a rule proposed by the Authority concerning Anti-Doping and Medication Control (“ADMC”). *See id.* §§ 3053(a), 3053(b), 3055(c)(1). “The Commission shall approve a proposed rule if the Commission finds that the proposed rule is consistent with” the Act and the applicable rules approved by the Commission. *Id.* § 3053(c)(2).²

¹ *See* Fed. Trade Comm’n, *Notice of HISA ADMC Proposed Rule* (“Notice”), 88 Fed. Reg. 5070 (Jan. 26, 2023), <https://www.federalregister.gov/documents/2023/01/26/2023-00957/hisa-anti-doping-and-medication-control-rule>.

² 15 U.S.C. § 3053(c)(2). An amendment made to the Act in December 2022 provides that the Commission may at any time exercise discretionary rulemaking authority to “abrogate, add to, or modify” an Authority rule, if it finds that doing so is “in furtherance of the purposes of the Act.” 15 U.S.C. § 3053(e). But this new power extends only to changing existing Authority rules and does not allow the Commission to modify a proposed rule. Accordingly, here, the Commission’s powers remain limited to approving or disapproving the proposed rule under § 3053(c). Once a

By this Order, for the reasons that follow, the Commission finds that the ADMC proposed rule is consistent with the Act and the Commission’s procedural rule, and therefore approves the proposed rule, which takes effect today.

II. Discussion of Comments and the Commission’s Findings

Under the Act, the Commission must approve a proposed rule if it finds that the proposed rule is consistent with the Act and “applicable rules approved by the Commission.” 15 U.S.C. § 3053(c)(2). Here, the “applicable rules” are the ones issued by Commission that provide the procedures necessary for the Commission’s Office of the Secretary to accept proposed rule or rule modification submissions under the Act. *See* 16 C.F.R. §§ 1.140–1.144 (Commission’s procedural rule). Among other things, the materials submitted by the Authority for Commission review must explain how the proposal is “consistent with the Act” and “how [the Authority] considered the factors in 15 U.S.C. § 3055.” *See* 16 C.F.R. § 1.142(a)(5). As a threshold matter, the Commission finds that the Authority’s proposed ADMC rule is consistent with the procedural rule. This finding formally confirms the previous determination made by the Office of the Secretary of the Commission that the Authority’s submission of its proposal was consistent with the FTC’s procedural rule.³ The remainder of this Order discusses whether the ADMC proposed rule is “consistent with” the Act.

In deciding whether to approve or disapprove the Authority’s proposed rule, the Commission has reviewed the Act’s text, the proposed rule’s text, the Authority’s supporting

rule is approved and goes into effect, the rule can be modified through a rule modification proceeding by the Authority under § 3053(a); by the Commission itself pursuant to § 3053(e) (in a rulemaking proceeding conducted in accordance with 5 U.S.C. § 553), if the Commission concludes that the Authority’s rule does not reflect the policies that the Commission believes would best to protect horseracing integrity or safety; or through a public petition for the amendment of the rule under 16 C.F.R. § 1.31.

³ *See* Notice, 88 Fed. Reg. at 5070 & n.5. The Secretary’s determination that a submission complies with the procedural rule is required before its publication. *See* 16 C.F.R. § 1.143(e) (“The Secretary of the Commission may reject a document for filing that fails to comply with the Commission’s rules for filing . . .”).

documentation and rule explanation referenced in the Notice,⁴ public comments,⁵ and the Authority's response to those comments.⁶ The Commission has considered 130 public comments, which consisted of (i) 20 comments received in response to the October 28, 2022, Federal Register publication of a substantially similar proposed rule (as corrected on November 4, 2022), posted to the FTC-2022-0062 docket at <https://www.regulations.gov/docket/FTC-2022-0062>, and (ii) 110 comments received in response to the Notice, posted to the FTC-2023-0009 docket at <https://www.regulations.gov/docket/FTC-2023-0009>.⁷ The comments come from many

⁴ These materials, which were posted on January 26, 2023, include informal comments that the Authority solicited from stakeholders before submitting a proposed rule to the Commission, and they are available at <https://www.regulations.gov/document/FTC-2023-0009-0002>. The Commission previously published a substantially similar notice of a proposed rule submitted by the Authority. *See* Fed. Trade Comm'n, *Notice of HISA ADMC Proposed Rule*, 87 Fed. Reg. 65292 (Oct. 28, 2022), *as corrected*, 87 Fed. Reg. 66701 (Nov. 4, 2022). The Commission disapproved the proposed rule without prejudice to refile due to a ruling by the United States Court of Appeals for the Fifth Circuit, *Nat'l Horsemen's Benevolent & Protective Ass'n v. Black*, 53 F.4th 869, 884–90 (5th Cir. 2022) (holding that the Act violated the private non-delegation doctrine), which could have undermined the Act's animating principle of national uniformity. *See* Fed. Trade Comm'n, Order Disapproving the ADMC Rule Proposed by HISA (Dec. 12, 2022) ("Disapproval Order"), https://www.ftc.gov/system/files/ftc_gov/pdf/order_re_hisa_anti-doping_disapprove_without_prejudice_0.pdf. Shortly thereafter, Congress addressed the holding of the Fifth Circuit by amending 15 U.S.C. § 3053(e) to provide the Commission with the discretionary authority to "abrogate, add to, or modify the rules of the Authority . . . as the Commission finds necessary or appropriate . . ." *See* Consolidated Appropriations Act, 2023, H.R. 2617, 117th Cong., Division O, Title VII (2022). In its December 12 Order, the Commission stated that, once "the legal uncertainty regarding the Act's constitutionality [is] resolved, the Authority may resubmit the proposed rule or a similar rule, and the Commission [would] consider all comments filed in [the initial] proceeding as well as any updated or new comments and filings." Disapproval Order at 2. The comments to the initial October 2022 notice are available at <https://www.regulations.gov/docket/FTC-2022-0062/comments>.

⁵ Public comments in response to the Notice, which were accepted until February 9, 2023, are available at <https://www.regulations.gov/docket/FTC-2023-0009/comments>.

⁶ The Authority's response, dated February 21, 2023 ("Authority's Response"), which addressed comments filed in response to both the Notice and the October 2022 publication, is available on the Authority's website, <https://hisaus.org/resources/responses-to-public-comments-on-admc-regulations-feb-21-2023>, and permanently at <https://perma.cc/52L6-JDYT>. The Authority's Response was led by its ADMC Committee, a statutorily mandated standing body. *See* 15 U.S.C. § 3052(c)(1). The Commission appreciates the Authority's in-depth treatment of the public comments and finds its responses useful, although not controlling or definitive, in evaluating the public comments and the decisional criteria. Considering the Authority's Response is consistent with the process the Securities and Exchange Commission uses in approving or disapproving proposed rules from self-regulatory organizations under its purview, such as the Financial Industry Regulatory Authority ("FINRA"). HISA's sponsors "closely modeled" the Act after SEC's oversight of FINRA. *See* Fed. Trade Comm'n, *Procedures for Submission of Rules Under the Horseracing Integrity and Safety Act*, 86 Fed. Reg. 54819, 54822 (Oct. 5, 2021).

⁷ The FTC received 915 comments on the Notice. *See* Regulations.gov, HISA ADMC, Dkt. No. FTC-2023-0009, <https://www.regulations.gov/docket/FTC-2023-0009>. Of those 915 submitted comments, 110 comments were posted on the rulemaking docket. *See id.* The other 805 comments were not posted because they were identified as duplicative of or substantially similar to other comments generated through mass-mailing campaigns; for these comments, exemplar comments are posted on regulations.gov and fully considered by the Commission. *See*

corners of the horseracing industry, advocates, and concerned observers. Most of the comments express opposition to the proposed rule, often for reasons unrelated to the two decisional criteria,⁸ while a few reflect broad support for the proposal.⁹ Comments range from those critical of any federal rules in an area traditionally regulated by the states to those recommending changes to particular rule provisions or supporting the proposed rule as protective of horse safety and horseracing integrity.

As explained above and in the Notice, the Commission’s statutory mandate to approve or disapprove a proposed Authority rule is limited to considering only whether the proposed rule “is consistent with” the Act and the Commission’s procedural rule. The Commission stated in the Notice that it would therefore focus on those comments that discuss the statutory decisional criteria: whether the proposed rule was consistent with “the specific requirements, factors,

Regulations.gov, Frequently Asked Questions, <https://www.regulations.gov/faq>. And even of the 110 posted comments, a significant majority are duplicative or nearly identical to other posted comments due in part to templates received through mass-mailing campaigns by two organizations (the National Horsemen and the North American Association of Racetrack Veterinarians (“NAARV”)) advocating against the Commission’s approval of the proposed rule. Two of those comments include the actual solicitation from NAARV or the National Horsemen to their members along with their comment template. *See* Cmt. of K. Myrick (Feb. 6, 2023) (including the National Horsemen’s email solicitation and comment template), <https://www.regulations.gov/comment/FTC-2023-0009-0073>; Cmt. of Bill Yarbrough (Feb. 8, 2023) (including NAARV’s email solicitation and comment template), <https://www.regulations.gov/comment/FTC-2023-0009-0085>.

⁸ Many of these comments were sent by individuals who used templates provided by the National Horsemen or NAARV. *See supra* n.7.

⁹ *See, e.g.*, Cmt. of Nat’l Thoroughbred Racing Ass’n (“NTRA Cmt.”) (Feb. 9, 2023), at 1, <https://www.regulations.gov/comment/FTC-2023-0009-0098> (“We appreciate FTC’s efforts to understand the challenges the horse racing industry faces without this proposed rule” because the “industry has needed change for quite some time . . . Since the passage and implementation of HISA’s Racetrack Safety Program, the industry has made strides that can help preserve horse racing for future generations to enjoy. With the upcoming implementation of the [ADMC] rule, the industry will finally have a minimum standard of fairness . . . This will lead to a safer sport for both our equine and human athletes” and provide confidence “that all those involved in the sport are playing by the same set of rules and regulations.”); Cmt. of Animal Welfare Inst. 1 (Feb. 9, 2023) (“Second AWI Cmt.”), <https://www.regulations.gov/comment/FTC-2023-0009-0097> (appreciating the comprehensive nature of the proposed ADMC rules which represent “a significant undertaking as the first set of uniform and national rules governing the use of medications and performance-enhancing drugs in thoroughbred racing . . . Given the complexity of the subject matter”); Cmt. of Animal Welfare Inst. 1 (Nov. 14, 2022) (“First AWI Cmt.”), <https://www.regulations.gov/comment/FTC-2022-0062-0007> (same).

standards, or considerations in the text of the Act as well as the Commission’s procedural rule.”¹⁰ Nevertheless, the Commission received many comments that are unrelated to whether the proposed rule is consistent with the Act or procedural rule, as well as other comments that offer conclusory assertions regarding the proposed rule’s consistency with the decisional criteria—*i.e.*, provide no analysis in support of the assertions.¹¹ Because those comments do not address the statutory criteria that the Commission must use to determine whether to approve or to disapprove the proposed rule, they have little bearing on the Commission’s determination.¹² In this Order, the Commission canvasses the most weighty substantive comments it received (including many that do not directly address the statutory criteria), as well as some comments with fewer remarks, and the Authority’s responses to these comments, but it does not delve into every issue commenters raise, especially when unrelated to the statutory criteria.

One overarching preliminary issue merits mention at the outset. Some commenters complain that the ADMC rule was not proposed at the same time as other Authority rules, in particular the Racetrack Safety rule. The National Horsemen’s Benevolent and Protective Association (“National Horsemen”) and the Kentucky Horsemen’s Benevolent and Protective Association (“Kentucky Horsemen”) assert that Congress intended the ADMC rule to be submitted at the same time as the Racetrack Safety rule so they could “be evaluated together” and that “piecemeal submission makes it impossible for interested parties to know how these

¹⁰ Notice, 88 Fed. Reg. at 5083–84. The Notice also gave guidance to would-be public commenters whose comments would not address the statutory decisional criteria but instead would more generally “bear on protecting the health and safety of horses and jockeys, the integrity of horseraces and wagering on horseraces, and the administration of the Authority itself.” *Id.* at 5084.

¹¹ *See, e.g.*, II.g, *infra*.

¹² This is not to say that such comments are not helpful or productive in the broader effort to improve the safety and integrity of horseracing. In many instances, comments advance specific suggestions for improving the Authority’s rules, and the Commission expects that, in appropriate cases, the Authority will consider those comments in proposing rule modifications in the future, and the Commission will also consider them in deciding whether to exercise its discretionary authority to modify the Authority’s rules.

rules will be impacted by the additional proposed rules to come.”¹³ Even if Congress had intended the two rules to be enacted simultaneously, the Authority could not have submitted the ADMC proposed rule at the same time as the Racetrack Safety rule because the anti-doping and medication control enforcement agency (“Agency”) had not been selected, and the Act required the input of the Agency (now the Horseracing Integrity & Welfare Unit of Drug-Free Sport International) to develop the ADMC rules as well as the list of prohibited substances. *See* 15 U.S.C. §§ 3054(f)(1)(B), 3055(c)(4)–(5).

Nonetheless, since the Authority’s first submissions of proposed rules, the Commission has regularly heard from commenters that they find it difficult to evaluate a proposed rule, such as Racetrack Safety, in isolation, without also knowing the details of an expected later proposal, such as Assessment Methodology. The ADMC proposed rule is the last of the initial rules required by the Act, and although it is proposed against the backdrop of all of the rules of the Authority that the Commission has already approved, commenters continue to raise concerns about not having been able to evaluate all of the Authority’s initial rule proposals in tandem.

The Commission agrees that there may be some benefit for all of the horseracing rules to be reviewed simultaneously once they have been in effect for enough time to provide all stakeholders with an opportunity to evaluate them. Accordingly, the Commission directs the Authority to review all of its existing rules (Racetrack Safety, Assessment Methodology, Enforcement, Registration, and ADMC) and submit any proposed rule modifications to the Commission by September 27, 2023.¹⁴ In addition to satisfying the requirements of 16 C.F.R.

¹³ Cmt. of Nat’l Horsemen’s Benevolent & Protective Ass’n 1 (“First Nat’l Horsemen Cmt.”) (Nov. 14, 2022), <https://www.regulations.gov/comment/FTC-2022-0062-0019>; Cmt. of Ky. Horsemen’s Protective & Benevolent Ass’n 1 (“Second Ky. Horsemen Cmt.”) (Feb. 8, 2023) & Att. (Hiles Cmt.), <https://www.regulations.gov/comment/FTC-2023-0009-0088>.

¹⁴ This directive supersedes the Commission’s directive to the Authority in its Racetrack Safety Order regarding the simultaneous re-evaluation of only Racetrack Safety and Assessment Methodology. *See* Fed. Trade Comm’n, Order

§§ 1.140–1.144, the Authority’s submissions in support of any proposed rule modification must discuss each of the suggestions made by commenters that the Authority committed to further consider and the reasons that the Authority did or did not adopt the suggestion within the text of the proposed rule modification.¹⁵ In this way, by considering updates to all the rules at once, the Authority, the public, and the Commission will be able to evaluate how the rules interact in practice and to examine both sides of the “cost” and “benefit” ledger at the same time.

a. Rule Series 1000 – General Provisions

The substantive proposed rules are supported by the general rules of interpretation (Proposed Rule 1010) and a list of defined terms (Proposed Rule 1020) to assist with clarity of meaning.

1. Rule 1020 – Definitions

The Authority proposes a list of definitions to be applied to the Rule Series 3000, 4000, 5000, 6000, 7000, and the Protocol, many of which restated or were based on the Act’s definitions.¹⁶ Several proposed definitions elicited comments.

The Oklahoma Horse Racing Commission (“Oklahoma Commission”) wonders whether the definition of *Analytical Testing Restriction* would “disincentiviz[e] labs to develop new methodologies for new substances.”¹⁷

Approving Racetrack Safety Rule Proposed by Horseracing Integrity & Safety Auth. 8 & n.26 (Mar. 3, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/order_re_racetrack_safety_2022-3-3_for_publication.pdf.

¹⁵ If the Authority has no changes that it wants to propose to a given rule, it shall so state in a letter to the Secretary of the Commission that explains the reasons why it does not believe any changes are necessary.

¹⁶ 15 U.S.C. § 3051.

¹⁷ Cmt. of Okla. Horse Racing Comm’n 1 (“Okla. Comm’n Cmt.”) (Feb. 7, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0068>. The ADMC proposed rule defines *Analytical Testing Restriction* to mean “a restriction on a Laboratory’s application of specified Analytical Testing Procedure(s) or on the analysis of a particular class(es) of Prohibited Substances or Prohibited Methods to Samples, as determined by the Agency.” Notice, 88 Fed. Reg. at 5085 (Proposed Rule 1020).

The Texas Racing Commission (“Texas Commission”) objects that the definition of *Covered Horse* includes a “loophole” by not including young horses marketed at horse sales that have been the subject of “the rampant use and anabolic effects of beta-agonists, such as albuterol and clenbuterol.”¹⁸

The Kentucky Horse Racing Commission (“Kentucky Commission”) remarks that the definition of *Covered Persons* includes breeders (like other specified persons) only if they are licensed by state boards or commissions, and that therefore no Kentucky breeder will be a *Covered Person* under the Act because the Kentucky Commission does not license breeders.¹⁹

The Oklahoma Commission states that the definition of *Decision Limit* should “be based on objective science of substance testing and findings reported of Laboratories [because] [s]ubjective decision limits will have less uniformity and effect [sic] testing program integrity.”²⁰

The Oklahoma Commission complains about the described sample size in formulating the *Detection Time* because “[u]sing small groups may have higher variability on confidence of data results.”²¹

¹⁸ Cmt. of Tex. Racing Comm’n 1 (“Tex. Comm’n Cmt.”) (Feb. 9, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0099>. *Covered Horse* is defined as “any Thoroughbred horse, or any other horse made subject to the Act by election of the applicable State Racing Commission or the breed governing organization for such horse under section 3054(l), during the period: (A) beginning on the date of the horse’s first Timed and Reported Workout at a Racetrack that participates in Covered Horseraces or at a training facility; and (B) ending on the date on which the horse is deemed retired pursuant to Rule 3050(b).” Notice, 88 Fed. Reg. at 5085 (Proposed Rule 1020).

¹⁹ Cmt. of Ky. Horse Racing Comm’n 1 (“Ky. Comm’n Cmt.”) (Feb. 8, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0089>. *Covered Person* is defined as “all Trainers, Owners, Breeders, Jockeys, Racetracks, Veterinarians, Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such Persons; any other Persons required to be registered with the Authority; and any other horse support personnel who are engaged in the care, treatment, training, or racing of Covered Horses.” Notice, 88 Fed. Reg. at 5085 (Proposed Rule 1020).

²⁰ See Okla. Comm’n Cmt. 1. The proposed rule defines *Decision Limit* to mean “the value of the result for a Threshold Substance in a Sample, above which an Adverse Analytical Finding shall be reported.” Notice, 88 Fed. Reg. at 5086 (Proposed Rule 1020).

²¹ *Id.* at 1. *Detection Time* is defined, in relevant part, as “the interval after a medication is administered during which it is detectable in a specific matrix (serum, plasma, urine, or hair) from any member(s) of a group of test horses. Detection times are determined from analysis of samples collected at specific time points following an administration of a medication to group of, potentially as few as 2, test horses.” Notice, 88 Fed. Reg at 5086 (Proposed Rule 1020).

The Oklahoma Commission remarks that the *Screening Limit* “must be based on objective science and data.”²²

The Authority responds to each of these comments by reference to the statutory definition of the pertinent term or by demonstrating that its definition is proper. Regarding the Texas Commission’s comment about “loopholes” from the definition of *Covered Horse* for young horses drugged with beta-agonists, the Authority cites the statutory definition in 15 U.S.C. § 3051(4) and states that it lacked the power to alter the definition of *Covered Horse*.²³ The Authority defends its definitions of *Decision Limit* and *Screening Limit* (neither of which is defined in the Act) as based on objective scientific grounds. The *Decision Limit* is arrived at by determining the limit from the threshold level for a substance and then adding “the laboratory’s Measurement of Uncertainty, which is the statistically determined maximum range of variation in results when testing for that substance.”²⁴ The Authority’s “Screening Limits for substances having legitimate therapeutic use in the ethical care of race horses” are informed by the limits “developed by the European Horseracing Scientific Liaison Committee, compris[ing] scientists and veterinary specialists, using data from administration studies and applying a statistical method to determine” the amount of a substance.²⁵ Likewise, the *Screening Limit* “for environmental or dietary substances is determined by using extensive and diverse population surveys that take into account agricultural and animal husbandry practices.”²⁶ In the same fashion, the Authority’s *Detection Time* is derived from published studies showing the number of horses participating in a given study. The Responsible Person (*i.e.*, the trainer or, in the absence

²² *Id.* *Screening Limit* is defined, in relevant part, as “a concentration to be used by Laboratories when screening for certain Non-Threshold Substances during the Initial Testing Procedure, below which a Laboratory will not pursue the possible presence of a Prohibited Substance.” Notice, 88 Fed. Reg. at 5090 (Proposed Rule 1020).

²³ Authority’s Response at 30–31.

²⁴ *Id.* at 23.

²⁵ *Id.* at 23–24.

²⁶ *Id.* at 24.

of a trainer, the owner, who is strictly liable for rule infractions) can determine a withdrawal interval greater than the Detection Time and “can consider the size of the study group and adjust their withdrawal interval determination accordingly.”²⁷

The Commission finds that the ADMC proposed rule’s definitions are consistent with the Act, either because the definition at issue is in the Act itself or because those terms not defined in the Act show no apparent inconsistency with any requirement in the Act. Generally, the fact that a definition could be sharper or clearer is unlikely to support a finding that the definition is in conflict with the Act.

If the Commission were presented with information that persuaded it that a rejected alternative was necessary to further the purposes of the Act, it could issue its own rule modification under 15 U.S.C. § 3053(e). No such showing was made to the Commission, but the Commission welcomes any proposed rule modifications that might refine or improve existing definitions as well as any other definitions that experience shows to be inadequate.

Regarding the challenges by the Oklahoma Commission to several definitions that are not statutorily provided, the Commission concludes that the Authority’s definitions are fully consistent with the Authority’s statutory responsibility to (1) develop a horseracing ADMC program providing that “covered horses should compete only when they are free from the influence of medications [and] other foreign substances . . . that affect their performance”²⁸ and (2) issue rules that implement uniform standards for “the administration of medication to covered horses by covered persons” and “laboratory testing accreditation and protocols.”²⁹

²⁷ *Id.* at 25–26.

²⁸ 15 U.S.C. § 3055(b)(1).

²⁹ *Id.* § 3055(c)(1)(A).

As for the Kentucky Commission’s comment about no Kentucky breeder being able to become a *Covered Person* under the Act, that complaint is addressed by the Act itself, which provides that breeders (and other racing professionals) “licensed by a State racing commission” are considered a *Covered Person*. See 15 U.S.C. § 3051(6). Under the Act, Kentucky can cause Kentucky breeders to become *Covered Persons* by requiring breeders to register with the Kentucky Commission.

As for the Texas Commission’s criticism that young horses may be drugged before being sold and becoming protected as a *Covered Horse* under the Act, the Authority correctly notes that its definition is based on the definition in 15 U.S.C. § 3051(4), which provides that a thoroughbred’s protected status begins when the horse has its first timed and reported workout at a participating racetrack. If a young horse were found to have albuterol or clenbuterol in its system when first tested after the sale, it would likely not be able to race. The horse, however, might not be barred from racing if the substances were prescribed as allowed under two exceptions in Proposed Rule 4111. Albuterol may be prescribed by a veterinarian as a bronchodilator under Proposed Rule 4111(a). And clenbuterol may be used “when prescribed by a veterinarian . . . for a duration not to exceed 30 days in a 6-month period,” although a horse that has been so medicated is placed on the Veterinarians’ List and ineligible to participate in any timed workout or covered horserace until urine and blood samples have been found to be free of clenbuterol (or its metabolites or markers).³⁰

³⁰ Notice, 88 Fed. Reg. at 5122 (Proposed Rule 4111(b)).

b. Rule Series 3000 – Equine Anti-Doping and Controlled Medication Protocol

In Rule Series 3000, the Authority proposes to establish an Equine ADMC Protocol as part of the Act’s mandate that the Authority establish a uniform ADMC program to improve the integrity and safety of horseracing in the United States.

1. Rules 3010–3090 – Purpose Scope, and Organization

In Proposed Rule 3010, the Authority proposes the framework for the Protocol, which implements the Act’s anti-doping principles and contains or incorporates by reference rules, standards, and procedures to improve and protect the integrity and safety of horseracing in the United States by deterring and penalizing the improper administration or application of Prohibited Substances and Prohibited Methods to Covered Horses. *See* 15 U.S.C. § 3055(b). The Protocol will be implemented and enforced by the Agency and (where so agreed) by state racing commissions acting under delegated authority. Proposed Rule 3020 implements the Act’s requirements that the Protocol apply to all Covered Horses, Covered Persons, and Covered Horseraces, *id.* § 3055(a)(1), and that Covered Persons must register with the Authority, *id.* § 3054. Other proposed rule provisions govern the liability of Responsible Persons (Proposed Rule 3030), the responsibilities of Covered Persons (Proposed Rule 3040), the retirement of Covered Persons and Covered Horses (Proposed Rule 3050), the procedure for horses that test positive for an ADMC violation following a claiming race in which the horse is claimed (Proposed Rule 3060), procedures for amending and interpreting the Protocol (Proposed Rule 3070), the applicability of the Protocol during the transition to its implementation (Proposed Rule 3080), and limitations periods applicable to rule violations (Proposed Rule 3090).

The Texas Commission challenges Proposed Rule 3010(e)–(f) for permitting certain acts to be conducted by the “Agency,” or “empower[ing] the Agency,” when in the Texas

Commission’s view “the Act only empowers the ‘Authority,’ and allows the Authority to create the Agency, but . . . does not relieve the Authority of its intended responsibilities.”³¹ The Oklahoma Commission asks whether Proposed Rule 3070’s statement about considering the World Anti-Doping Code and related international codes and case law in adjudications should also appear in Proposed Rule 3040(b), which imposes liability on the Responsible Person for violating those codes and standards.³² The Kentucky Commission points out a conflict between the void-claim provisions in Proposed Rule 3060 and existing Rule 2262—a conflict that is said to arise from the fact that there are more conditions imposed in Rule 2262 than in Proposed Rule 3060 for a claimant who wants to keep a claimed horse even if the horse tests positive after a race.³³

The Oklahoma Commission complains that, under Proposed Rule 3040(b)(3), the Responsible Person would become strictly liable for the improper use of medications detrimental to the horse or for the administration of a banned substance or method, that the proposed rule would require additional personnel to ensure due diligence, and that a “significant financial, operational, and logistical burden will be added to daily training costs for the owner.”³⁴ Dr. John Sivick (adopting the template from NAARV) complains about “[t]he regulation’s inclusion of unregistered persons under the jurisdiction of the Authority, simply because they come in contact with Covered Horses” and mentions “colleagues who have been asked to examine and/or treat a horse that is not physically on the racetrack, but nonetheless requires veterinary attention.”³⁵ K. Myrick makes the same complaint, using nearly identical language.³⁶ And Dr. Clara Fenger

³¹ Tex. Comm’n Cmt. at 2.

³² Okla. Comm’n Cmt. at 3.

³³ Ky. Comm’n Cmt. at 1.

³⁴ Okla. Comm’n. Cmt. at 2.

³⁵ Cmt. of Dr. John Sivick (Feb. 7, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0065>.

³⁶ Cmt. of K. Myrick at 2.

repeats the complaint about Proposed Rule 3020(b) as “plac[ing] people who are unwittingly treating and caring for Covered Horses in the position of being subject to HISA regulations and penalties.”³⁷

The Authority responds that it was aware that the void-claim rules differed between Rule 2262 and Proposed Rule 3060, but it states that the solution was already found in its rules.³⁸ More specifically, if the ADMC proposed rule is approved, “Rule 3060 will supersede the parallel provisions in Rule 2262”—a supersession that stems from language in Rule 3070(c) providing that “[i]n the event of any conflict between the Protocol and any other rules , . . . the Protocol shall prevail.”³⁹ The Authority characterizes Dr. Sivick’s complaint (and Dr. Fenger’s similar point) as concerning “unregistered veterinarians who have no direct contact with horse racing and are unfamiliar with the Authority’s rules [becoming] unfairly punished for violations pertaining to the provision of veterinary care to Covered Horses.”⁴⁰ In response, the Authority notes that Proposed Rule 3040(b)(4) obligates the Responsible Person to inform all covered persons, including veterinarians, of their “respective obligations under the Protocol” and “to adequately supervise them.”⁴¹ The Authority does not respond to the Oklahoma Commission’s complaint about Proposed Rule 3040(b)(3) or to the Texas Commission’s complaint about Proposed Rule 3010(e)–(f).

The Commission finds that Proposed Rules 3010–3090, which lay out the purpose, scope, and organization of the Protocol, are consistent with the Act. The provisions of Proposed Rule 3010 closely track the statutory language of 15 U.S.C. § 3055(b). As for the conflict between

³⁷ Cmt. of Dr. Clara Fenger 1 (“Second Fenger Cmt.”) (Feb. 6, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0072>.

³⁸ Authority’s Response at 21–22.

³⁹ *Id.* at 22.

⁴⁰ *Id.* at 3.

⁴¹ *Id.* at 3–4.

Rule 2262 and Proposed Rule 3060 regarding void claims, the Authority provides a cogent explanation for how Proposed Rule 3060 would supersede Rule 2262 through the preemption terms in Proposed Rule 3070(c). Nonetheless, although that reasoning is correct, it is also complex, and the Commission recommends that the Authority consider submitting a proposed modification to Rule 2262 to increase clarity.

The Commission also finds that Proposed Rule 3010(e)–(f) is consistent with the Act. Contrary to the Texas Commission’s contentions, the Act expressly provides the Agency with multiple duties and powers, including to serve as the ADMC “enforcement agency” to “implement[]” the ADMC program on behalf of the Authority, to ensure that covered horses and persons are deterred from violating the ADMC rules, and to implement the anti-doping “testing, compliance, and adjudication program.” 15 U.S.C. § 3054(e)(1)(E). Further, under 15 U.S.C. § 3055(c)(4), the Agency is given additional responsibilities, including participating in developing the ADMC proposed rule; overseeing ADMC results management, the sample collection process, and substance testing; and accrediting testing laboratories. It was the Act (not the Authority) that specified the roles of the Agency, and nothing in those statutory provisions relieves the Authority of its own statutory responsibilities.

The Commission concludes that Proposed Rule 3040 governing Covered Persons is consistent with the Act. The rule requires any Covered Person (including veterinarians) to register with the Authority and imposes affirmative obligations on the person to know, comply with, and be bound by the Protocol and relevant rules at all times. Further, it requires the Responsible Person to ensure that veterinarians (like any Covered Person) are made aware of their responsibilities under the Protocol. Those duties and obligations are consistent with—indeed, mandated by—the Act under 15 U.S.C. § 3054(d).

As for the Kentucky Commission's complaints about Proposed Rule 3040(b)(3), it does appear that, because there is no knowledge requirement, the provision imposes strict liability on the Responsible Person to ensure that no improper medications or methods (including banned substances or methods) are administered. These obligations are consistent with Proposed Rule 3030(a), which imposes personal liability on the Responsible Person for his or her Covered Horse regardless of knowledge or intent. Most important, the Kentucky Commission does not point to any inconsistency between Proposed Rule 3040(b)(3) and the Act. Indeed, strict liability for certain infractions under Proposed Rule 3040(b)(3) is consistent with the strict liability sanctions imposed on trainers under 15 U.S.C. § 3057(a)(2)(A) for, among other things, the presence of a prohibited substance in a horse.

Finally, as for the Oklahoma Commission's point about adding into Proposed Rule 3040(b) that adjudicators can consider the World Anti-Doping Code Program, the Commission does not believe that there is a need to do so because Proposed Rule 3070(d) already states that the Code Program may be considered when adjudicating cases.

The Commission welcomes future proposed rule modifications that the Authority decides to submit in response to the useful comment from the Kentucky Commission about the void-claims rule conflict and any other useful comments received.

2. Rules 3110–3140 – Prohibited List, Rules of Proof, and Testing and Investigations

Proposed Rule 3111 describes the Prohibited List, which identifies Prohibited Substances and Prohibited Methods that include both (a) Banned Substances and Banned Methods that are always prohibited as well as (b) Controlled Substances and Controlled Medication Methods that are prohibited only during the Race Period. The Prohibited List is supplemented by the “Technical Document—Prohibited Substances,” which provides further guidance on the

Prohibited Substances. Proposed Rules 3121–3122 place the burden on the Agency to prove a violation of the Protocol “to the comfortable satisfaction of the hearing panel” based on facts “established by any reliable means.”⁴² Proposed Rules 3132–3137 give the Agency broad authority to test Covered Horses, both in and out of competition, mainly to detect the presence of Prohibited Substances. Third parties may request that the Agency conduct enhanced or additional testing, which the Agency may accept or decline in its discretion. Proposed Rule 3140 permits clearance testing (*i.e.*, a request to determine if controlled medication substances have cleared the horse’s system) by a laboratory if, before such testing, (1) the Agency approves such request and (2) the Covered Person pays the costs for sample collection and analysis. Further, the Agency may pursue any violation of the Protocol based on the results of such testing.

The Kentucky Horsemen argue that “the burdens of proof and presumptions in proposed Rules 3121 and 3122(a), (b), and (c) create a significant (if not insurmountable) hurdle for an accused violator of the [ADMC] rules who seeks to defend him or herself” and that “adequate due process” requires that the “accused *must be afforded an unconditional* opportunity to proffer oral and written evidence and other submissions in a full-on arbitral hearing.”⁴³ Along similar lines, the Oklahoma Commission contends that the presumptions in Proposed Rule 3132(a) will “relieve a party from having to actually prove the truth of the fact being presumed [and] may negatively affect integrity of [the Horseracing Integrity & Welfare Unit] testing program.”⁴⁴ The National Horsemen ask whether, in providing that decisions arising from Proposed Rule 3113 (“Validity of the Prohibited List and Related Technical Documents”) “shall not be subject to any challenge,” that proposed rule “implies that no mitigating circumstances [will] be allowed.”⁴⁵

⁴² Notice, 88 Fed. Reg. at 5054 (Proposed Rules 3121–3122).

⁴³ Second Ky. Horsemen Cmt. at 14 (emphasis in original).

⁴⁴ Okla. Comm’n Cmt. at 3.

⁴⁵ First and Second Nat’l Horsemen Cmts. at 40.

The National Horsemen further argue that “[n]ot allowing any challenges to analytical methods, screening limits, decision limits and assuming [that those] are scientifically valid is simply wrong” because “[i]f these methods and limits are scientifically valid, they will stand up to legal challenges” and “if they are scientifically flawed then a horseman should not be held responsible for meeting them and they should be allowed to be challenged and subsequently changed.”⁴⁶ Dr. Fenger likewise complains that “[t]he Prohibited List includes many substances with appropriate use during the out-of-competition period,” which the covered person cannot challenge under Proposed Rule 3113.⁴⁷

As to Proposed Rule 3132(e), which states that “[a]ny sample collected following a Vets’ List workout constitutes a post-race sample, and, as a result is subject to all of the same requirements that apply to [a] sample collection at covered horseraces,” the Kentucky Commission asks whether this provision requires that “post-workout samples will be tested for furosemide (Lasix).”⁴⁸ It also contends that post-workout samples should not be considered post-race samples because “[r]etaining the horse on the Vets’ List following a post-workout positive is sufficient incentive for trainers and vets to avoid administering inappropriate medications to horses during that period.”⁴⁹

On the other hand, the Animal Welfare Institute (“AWI”) emphasizes its “strong[] support [for] a robust out-of-competition testing program” under Proposed Rule 3132 “in order to better identify bad actors and create an effective deterrent against committing violations.”⁵⁰ The United States, according to AWI, presently has a dismal record for “out-of-competition

⁴⁶ *Id.*

⁴⁷ Second Fenger Cmt. at 1.

⁴⁸ Ky. Comm’n Cmt. at 1.

⁴⁹ *Id.*

testing rates among countries with thoroughbred racing.”⁵⁰

Regarding Proposed Rule 3140, one commenter urges the removal of Clearance Testing from the ADMC proposed rule, positing that this provision would allow a trainer to be punished for simply trying to comply with the rules. For example, a horse may come to a trainer from another source with whom the horse “may have accidentally [sic] been exposed to a controlled medication” and the trainer is trying in good faith “to verify that [the substance] is no longer showing in the horse’s system.”⁵¹ The Kentucky Commission states that it was given assurances in earlier negotiations with the Authority that, under Proposed Rule 3140, the *Agency* would pay for post-race sample testing of claimed horses, but the proposed rule instead lays the costs on the Covered Person.⁵²

The Authority states that Proposed Rule 3122 “adopts the same approach” with respect to presumptions “as set out under the World Anti-Doping Code,” and that “[p]resumptions are common in federal and state law and may be rebutted.”⁵³ Regarding Proposed Rule 3140, the Authority states that the purpose of clearance testing is to afford a trainer the ability to verify in advance, through drug testing, that a horse that has been following a course of prescribed medication can be entered into a race.⁵⁴ The Authority responds to the Kentucky Commission’s question regarding whether Proposed Rule 3132(e) requires post-workout samples to be tested for Lasix by noting that Proposed Rule 4212(d) allows the use of Lasix “during Timed and Reported Workouts and Vet’s List Workouts.”⁵⁵

The Commission finds that Proposed Rules 3110–3140 are consistent with the Act.

⁵⁰ *Id.*

⁵¹ Cmt. of Jim Roberts (Jan. 31, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0020>.

⁵² Ky. Comm’n Cmt. at 1.

⁵³ Authority’s Response at 24.

⁵⁴ *Id.* at 19.

⁵⁵ *Id.* at 19–20.

Although the Kentucky Horsemen complain about the burden of proof and presumptions in Proposed Rules 3121 and 3122, the Agency retains the initial burden of establishing that a violation occurred and for that must satisfy a heightened standard of proof: “comfortable satisfaction of the hearing panel,” which is higher than the “preponderance of the evidence” standard.⁵⁶ By contrast, the opposing party’s showing on rebuttal is subject to the lower preponderance standard.⁵⁷ The Oklahoma Commission’s assertion that presumptions “relieve the party from having to actually prove the truth of the fact being presumed” ignores that the same approach is applied under the World Anti-Doping Code, which the Act (15 U.S.C. § 3055(g)(2)(A)(ii)) requires to be considered. Further, the accused person can rebut the presumption by showing “that a departure from the Laboratory Standards occurred that could reasonably have caused the Adverse Analytical Finding.”⁵⁸

The Commission also finds that Proposed Rule 3140 governing Clearance Testing is consistent with the Act. In particular, in developing the ADMC program, the Authority must consider that “[c]overed horses should compete only when they are free from the influence of medications [and] other foreign substances, . . . that affect their performance.” 15 U.S.C. § 3055(b)(1). Clearance testing is one way to ensure compliance with § 3055(b)(1) and allows trainers to use a process to confirm that no banned substances are present in the horse so that it is safe for the horse to participate in races again.

Likewise, the Commission finds that Proposed Rule 3132 (“Authority to Test”) is consistent with the Act. The Commission agrees with the comment from the AWI about the long-overdue need for “out-of-competition testing” that Proposed Rule 3132 would provide.

⁵⁶ Notice, 88 Fed. Reg. at 5097 (Proposed Rule 3121(a)).

⁵⁷ *Id.* (Proposed Rule 3121(b)).

⁵⁸ *Id.* (Proposed Rule 3122(c)).

With respect to the Kentucky Commission’s inquiry about whether Proposed Rule 3132(e) requires testing for Lasix in a post–Vets’ List workout sample, the Authority reasonably observes that Proposed Rule 4212(d) allows such use. Regarding the Kentucky Commission’s suggestion that post–Vets’ List workout samples not be considered post-race samples, it appears that the sampling conducted under Proposed Rule 3132(e) is done at the affirmative request of the Responsible Person to release a horse from the Vets’ List so that the horse may enter races again.⁵⁹ Thus, the Commission believes that it is entirely appropriate to require a sample collection to be tested like a post-race sample to ensure that the horse enters the race period free of any banned or controlled substances. Furthermore, the Commission notes that Proposed Rule 3132(e) states only that the horse “*may* be required to submit to [a] sample collection,” and thus does not require sampling in every instance. As for the Kentucky Commission’s question about imposing costs on the owner for Clearance Testing, it seems entirely reasonable to impose such costs on the party asking for the test’s benefit—in this instance, the trainer, who is asking for Clearance Testing as a means to reenter her horse in races.

3. Rules 3210–3260 – Equine Anti-Doping Rules

In Proposed Rules 3211–3231, the Authority proposes a list of civil sanctions for Anti-Doping rule violations. Proposed Rules 3212–3214 impose violations for the use, attempted use, possession, trafficking, or administration of Banned Substances or Banned Methods to a Covered Horse, and they impose strict liability on the Responsible Person when a Banned Substance is found in a Covered Horse. Proposed Rules 3215–3216 impose sanctions for refusing or failing to submit a Covered Horse to a sample collection, tampering with doping control, complicity in

⁵⁹ Proposed Rule 3132h(e) states in relevant part that “a Covered Horse may be required to submit to Sample collection (at the Owner’s cost) following a Vets’ List Workout in order to be released from the Veterinarians’ List.” Notice, 88 Fed. Reg. at 5098.

another person's violation, associating with a person who is banned, and witness intimidation and retaliation against whistleblowers. Proposed Rule 3221 requires the automatic disqualification of a Covered Horse's results if the violation arises from a post-race sample or occurs during the race period and may also disqualify subsequent results. Proposed Rules 3222 and 3229 mandate that, in presence or use cases, the Covered Horse will be ineligible to race for a period designated in the Prohibited List for the particular Banned Substance detected but will remain subject to testing. Proposed Rules 3223–3229 impose sanctions on Covered Persons that include periods of ineligibility and fines based on the nature of the violation but that allow for a downward adjustment of the sanction when no fault or negligence has been shown, when the Covered Person provides assistance to the investigating body, or when the Covered Person admits to the violation early. Conversely, a sanction can be increased when aggravating circumstances are present or a repeat offense is involved. Proposed Rules 3241–3246 involve analysis and notification of test results when there is evidence of an Anti-Doping rule violation. Proposed Rule 3248 allows a Covered Person to respond to a letter charging a rule violation, and Proposed Rules 3261 and 3264 entitle the Covered Person to have the charge determined by impartial arbitrators, whose final decision is subject to review pursuant to 15 U.S.C. § 3058.

With respect to Proposed Rule 3221(b), the National Horsemen contend that results from subsequent races should not be automatically disqualified when a Covered Horse is claimed from the race in which the Anti-Doping violation occurred, ownership changes, and the horse subsequently races for the new owner.⁶⁰ The National Horsemen also ask why a Covered Person who unintentionally fails to submit a sample should be subject to an automatic 2-year period of ineligibility.⁶¹ Finally, they take the position that the requirement in Proposed Rule 3224 that a

⁶⁰ First Nat'l Horsemen Cmt. at 47 (margin notes).

⁶¹ *Id.*

Covered Person establish how the prohibited substance entered the Covered Horse’s system is too stringent.⁶² Dr. Fenger similarly criticizes Proposed Rule 3224 for requiring the “Horse person to identify the source of the Specified Substance” in order to be found free of fault because, “by the time that a positive is called”—potentially “years after the race,” according to Dr. Fenger—there is no hay, feed, or supplement left to test, and employees may have moved on.⁶³

The Authority provided no response to these comments.

The Commission finds that Proposed Rules 3321–3324 are consistent with the Act. The severe sanction of automatic disqualification for the presence of a banned substance is mandated by the Act, which imposes strict liability on covered trainers for the presence of a prohibited substance in a covered horse. *See* 15 U.S.C. § 3057(a)(2)(A). Thus, Banned Substances are prohibited *at all times* irrespective of the reason why the Banned Substance was present and regardless of any degree of fault on the part of the Covered Person.⁶⁴ As for the National Horsemen’s comment that there should not be a continuing disqualification for racing results when the horse changes ownership and races for the new owners, Proposed Rule 3221(b)(2) provides just that relief.⁶⁵ Regarding the National Horsemen’s question about why a Covered Person who unintentionally failed to submit a sample should be subject to an automatic 2-year period of ineligibility, the rules permit any ineligibility period to be reduced or eliminated when the trainer can show that he or she bears no fault or negligence.⁶⁶ The applicable Authority rules are modeled on those of the World Anti-Doping Code, which is one of the sources of the

⁶² *Id.*

⁶³ First Fenger Cmt. at 2.

⁶⁴ *See* Notice, 88 Fed. Reg. at 5100–01 (Proposed Rule 3221(a)).

⁶⁵ The provision states that if “the Anti-Doping Rule Violation occurs in relation to a Claiming Race in which the Covered Horse is claimed,” Proposed Rule 3221(b)(1) (disqualifying further results from the covered horse) “shall not apply to any results obtained by the Covered Horse under the new ownership.” Notice, 88 Fed. Reg. at 5101.

⁶⁶ *See* Notice, 88 Fed. Reg. at 5075 (Proposed Rules 3223(b), 3224, 3225).

baseline ADMC rules identified in the Act. *See* 15 U.S.C. § 3055(g)(2)(A)(ii).

4. Rules 3310–3360 – Equine Controlled Medication Rules

In Proposed Rules 3312–3316, the Authority proposes a list of sanctionable violations of the Equine Controlled Medication Rules for conduct involving medication substances and methods. Proposed Rules 3313 and 3315 prohibit the use, attempted use, possession, or administration of Controlled Medication Substances or Controlled Medication Methods to a Covered Horse during the Race Period. Proposed Rules 3315–3316 bar a Covered Person from being complicit in another person’s violation or from tampering with medication control. Other violations include the presence of a Controlled Medication Substance in a sample collected from a Covered Horse (Proposed Rule 3312) or the use of a Controlled Medication Substance unjustified by the horse’s medical condition or other criteria (Proposed Rule 3314). Strict liability is imposed in Proposed Rules 3312–3314 for presence and use violations. Proposed Rule 3321 automatically disqualifies racing results (but not subsequent results) when the violation is based on a post-race sample or occurs during the Race Period, and irrespective of the reason why the substance was detected or of any degree of fault. Proposed Rule 3322 states that if a violation is based on a Controlled Medication Substance, horses will be race eligible, but if there is a Controlled Medication Method violation, the horse may be ineligible to race. Proposed Rules 3323–3328 and 3331 impose sanctions (*i.e.*, periods of ineligibility, disqualification of results, fines, legal costs, and public disclosure of violation information) on Covered Persons for a rule violation. Those proposed rules allow for the elimination or reduction of the ineligibility period when there is no or little fault or negligence or if the Covered Person has provided investigative assistance—and, conversely, provide for an increase in the ineligibility period where a repeat offense or aggravating circumstances are involved. Proposed Rule 3328 imposes a penalty point

system for repeat offenders that may result in additional periods of ineligibility.

Proposed Rules 3341–3346 provide for the analysis of test results when there is evidence of a rule violation and require that the Covered Person be notified of a possible violation and be allowed to provide an explanation, to take an action that might reduce any sanction, or to resolve the matter without a hearing. Proposed Rule 3348 sets forth information that must be provided in a charge letter and allows the Covered Person to respond to the charges. Proposed Rules 3361–3364 entitle the Covered Person to have charges determined by a panel of impartial arbitrators, with or without a hearing, whose final decision is subject to review pursuant to 15 U.S.C. § 3058.

The Oklahoma Commission comments that, although Proposed Rule 3322(a) states “[t]here shall be no period of Ineligibility for Covered Horses implicated in violations involving only Controlled Medication Substances,” the “[r]egulatory veterinarian should have discretion to place [the] horse on [the] veterinarians’ list” anyway because “NSAIDs and corticosteroids may impact [the] welfare status of the racehorse.”⁶⁷ The Oklahoma Commission makes the same point about Provisional Suspensions under Proposed Rule 3347(a).⁶⁸

The Authority responds that “[h]orses will not be suspended” automatically due to “the detection of a Controlled Medication Substance” but that the Regulatory Veterinarian may place the horse “on the Vets’ List to verify its fitness to race if warranted” in the Regulatory Veterinarian’s opinion.⁶⁹

The Commission finds that Proposed Rules 3310–3360 are consistent with the Act, which requires the Authority, in developing the ADMC program, to consider that horses that are injured or unsound should not train or participate in races.⁷⁰ Section 3054(a) requires the Commission,

⁶⁷ Okla. Comm’n Cmt. at 3.

⁶⁸ *Id.* at 4.

⁶⁹ Authority’s Response at 26.

⁷⁰ *See* 15 U.S.C. § 3055(b)(1).

the Authority, and the Agency to exercise authority over “the safety, welfare and integrity of covered horses.”⁷¹ Regarding Proposed Rules 3332 and 3347, the Act requires the ADMC rules to provide “adequate due process . . . commensurate with the seriousness of the alleged . . . [ADMC] rule violation and the possible civil sanctions for such violation.” 15 U.S.C. § 3057(c)(3). The Act therefore allows for more lenient sanctions for controlled-medication rule violations than for banned-substance violations, thereby excusing the horse found in violation of only a controlled-medication rule from an imposed period of ineligibility. But, at the same time, a Regulatory Veterinarian may place the horse on the Vets’ List if, in her medical judgment, doing so would be beneficial to the horse’s health and wellbeing.

5. Rules 3500–3800 – Other Violations and General Procedure/Administration

Proposed Rule 3510 sets forth additional disciplinary offenses that fall outside the ADMC Rules, such as engaging in disruptive or offensive conduct toward anti-doping or medication-control personnel, refusing or failing to cooperate with the Authority or the Agency, or failing to provide information necessary to locate a Covered Horse for testing (a “Whereabouts Failure”). In Proposed Rule 3520, the Authority proposes sanctions (periods of ineligibility and fines) for those violations. Proposed Rules 3610–3630 provide guidelines for confidentiality and public reporting of decisions. In Proposed Rule 3710, the Authority proposes to provide for the recognition of final decisions issued pursuant to the Equine ADMC Protocol and for the decisions issued by recognized, official third parties (for example, national horseracing authorities in other countries applying substantially similar rules). Proposed Rule 3810 requires the Agency to institute educational programs regarding responsible medication use and doping-free horseracing.

⁷¹ See *id.* § 3054(a)(2)(A).

No comments address these provisions. The Authority accordingly provides no response.

The Commission finds that it is consistent with the Act and will further the Act's purposes to impose additional disciplinary measures for offenses that adversely affect the activities of the Agency or the Authority. The same is true of the proposed rule provisions concerning confidentiality, recognition of final decisions, and the initiation of educational programs that teach responsible medication treatment of horses: All of those proposed rules are consistent with the Act.

c. Rule Series 4000 – Prohibited List

As described in Proposed Rule 4010, Rule Series 4000 contains provisions governing the Prohibited List, through which the Authority proposes to identify prohibited substances and methods, including substances and methods that are prohibited at all times (“Banned Substances and Banned Methods”) and those that are generally prohibited for a more limited time during the race period and in a post-race or post-work sample (“Controlled Medication Substances and Controlled Medication Methods”). The Prohibited List is supplemented by the “Technical Document—Prohibited Substances,” which provides guidance on substances falling into general categories on the list. The Technical Document also designates “as Specified Substances,” certain “Prohibited Substances . . . that pose a higher risk of being the result of contamination and, therefore, are subject to more flexible sanctions.”⁷² Proposed Rule 4010 further explains how “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.”⁷³

Notwithstanding the definition of Specified Substances described above (and elsewhere

⁷² Notice, 88 Fed. Reg. at 5121.

⁷³ See *id.* at 5121–22 (Protocol, Appendix 1).

in the rules),⁷⁴ the National Horsemen maintain that there is no definition for the term and “strongly recommend” that the Authority adopt the definition used by the Fédération Équestre Internationale: “substances which are more likely to have been ingested by Horses for a purpose other than the enhancement of sport performance, for example, through a contaminated food substance.” The National Horsemen express concerns that the source of a positive result—*e.g.*, hay or feed—might not become known until weeks after the substance is consumed, thereby diminishing the mitigating impact that might otherwise arise from identification of such a source.⁷⁵ They also recommend that the Authority remove all endogenous substances from the S0 “Non-Approved Substances” substances category, “since these would be expected to be present at some level in all animals,” and that the Authority “adopt science-based screening limits for endogenous substances in order to prevent inappropriate penalties.”⁷⁶ With regard to dietary substances, which are those that can be detected in the animal’s blood or urine from their natural presence in hay or feed, the National Horsemen observe that not all such substances are associated with screening limits. The National Horsemen urge the Authority “to adopt screening limits for all dietary substances” and note that “[s]ome provisional screening limits can be readily adopted from existing sources.”⁷⁷

The National Horsemen also assert that, in view of increased drug-testing sensitivity, a group of substances with similar characteristics (*i.e.*, mostly eliminated in urine, stable in the

⁷⁴ Proposed Rule 1020 (definitions) states that *Specified Substance* has the meaning given to it in Proposed Rule 3111(c), which states that “Specified Substances . . . are those that pose a higher risk of being the result of contamination and, therefore, are subject to more flexible sanctions.” *Id.* at 5074. *See also id.* at 5077 (Proposed Rule 4010) (providing same definition).

⁷⁵ First Nat’l Horsemen Cmt. at 14 (first page of “Review of Endogenous and Dietary Substances” section).

⁷⁶ *Id.* S0 is defined in Proposed Rule 4111 as “[a]ny 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.”

⁷⁷ *Id.*

environment, and readily absorbed by the horse), which it names “Environmental Substances,” should be considered Specified Substances and, like others in that category, should be recognized by the ADMC Committee as involving inadvertent environmental transfers that can result in positive tests. They therefore contend that “if such inadvertent environmental transfer—rather than intentional administration—to a horse results in an adverse analytical finding, the trainer and the horse should be eligible only for ‘a minimal penalty.’ ”⁷⁸ Because “the source of inadvertent environmental exposure often cannot be identified,” the National Horsemen contend that Authority investigations of adverse analytical findings involving such substances should involve standard investigative procedures, including providing potentially exculpatory evidence, and must be directed to fact finding.⁷⁹ The National Horsemen also recommend screening limits consistent with environmental contamination, similar to the limits they recommend for dietary substances.⁸⁰

Dr. John Sivick (following NAARV’s template) likewise contends that “the majority of violations will result from [innocent] transfer of random substances from the environment.”⁸¹ Dr. Fenger’s comment agrees.⁸²

Regarding the limits of detection for substances on the Prohibited List, one commenter complains about “appropriate classifications for substances [and] establishing reasonable thresholds which correlate with the ability to affect performance or endanger the welfare of the horse.” Of particular concern to this commenter are findings based on limits of detection that

⁷⁸ *Id.*; Second Nat’l Horsemen Cmt. at 20.

⁷⁹ *Id.* at 20–26.

⁸⁰ *Id.*

⁸¹ Sivick Cmt. at 1.

⁸² Second Fenger Cmt. at 2.

(with evolving technology) become an arbitrary “moving target” so that “withdrawal times can change without warning,” leading to arbitrary enforcement.⁸³

Zach Badura argues that the ADMC proposed rule “would situationally negatively impact the welfare of the racehorse” and recommends continuing the application of state rules, most of which utilize policies from the Association of Racing Commissioners International (“ARCI”).⁸⁴

The Authority observes that the Act requires the adoption of International Federation of Horseracing Authorities (“IFHA”) medication controls,⁸⁵ and IFHA publishes thresholds only for endogenous substances and does not provide withdrawal guidelines.⁸⁶ The Authority addresses limits of detection in responding to Dr. Andy Roberts⁸⁷ and other commenters, noting that requiring laboratories to detect banned substances at the limit of detection is consistent with the approach endorsed by ARCI’s Model Rules, which published a limited number of thresholds and provided for other substances to be regulated by the laboratory’s limits of detection. Further, as the Authority notes, laboratories do not publish their limits of detection, which helps to prevent manipulation of the system.⁸⁸

With respect to cases involving possible environmental contamination, the Authority refers to its “Atypical Findings Policy,”⁸⁹ in which Specified Substances, endogenous substances, and two specific medications can be “investigated first as Atypical Findings before being pursued as Adverse Analytical Findings.” The Authority explains that “[i]f it is determined that the presence of the substance in the Covered Horse’s system was the result of environmental

⁸³ Cmt. of MaryAnn O’Connell, Exec. Director, Wash. Horsemen Benevolent & Protective Ass’n, at 1 (Feb. 14, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0090>.

⁸⁴ Cmt. of Zach Badura (Feb. 14, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0109>.

⁸⁵ See 15 U.S.C. § 3055(g)(2)(A)(i).

⁸⁶ Authority’s Response at 8.

⁸⁷ See Cmt. of Dr. Andy Roberts at 1.

⁸⁸ Authority’s Response at 21, 23.

⁸⁹ See Notice, 88 Fed. Reg. at 5120 (Appendix 1 to the Rule 3000 Series).

contamination, the matter will not be pursued as an Adverse Analytical Finding, and the Atypical Finding will not be publicly disclosed.”⁹⁰

The Commission commends the Authority for developing and implementing its Atypical Findings Policy; among other things, the policy takes into account the possibility that a preliminary adverse analytical result may have been caused by innocent environmental contamination, in which case sanctions will not result.⁹¹ The Commission finds that provisions that implement the Atypical Findings Policy are consistent with the Act, particularly the Act’s sections governing investigations, testing, and results management.⁹²

Regarding the National Horsemen’s point about screening limits for endogenous and dietary substances, the Authority states that “[t]hresholds are established in the Technical Document . . . for endogenous substances” and “screening limits are established for dietary substances.”⁹³ As for “Environmental Substances,” the Authority notes that the Technical Document characterizes Specified Substances and lists screening limits for environmental substances that are consistent with IFHA Article 6.⁹⁴

The Commission finds that Proposed Rule 4010 is consistent with the Act. The statute requires the Authority to issue “a list of permitted and prohibited medications, substances, and methods.”⁹⁵ Refinements to the rule suggested by the National Horsemen and other commenters might be considered for future proposed rule modifications, but for purposes of the Commission’s current review these constitute mere policy disagreements with the Authority and

⁹⁰ Authority’s Response at 11–12.

⁹¹ See Notice, 88 Fed. Reg. at 5096, 5106, 5115, 5120 (Proposed Rules 3111(d), 3243(c), 3343(c), 3620(b)(5)); see generally *id.* at 5120–21.

⁹² See, e.g., 15 U.S.C. §§ 3055(c)(4) (results management and investigations), 3055(c)(1)(A)(ii) (uniform standards for laboratory testing protocols).

⁹³ Authority’s Response at 12.

⁹⁴ *Id.*

⁹⁵ 15 U.S.C. § 3055(c)(1)(B).

not any inconsistency with the Act. The Commission also finds that adopting limits of detection and omitting withdrawal times are proper methods to ensure the integrity of testing and are consistent with the Act.⁹⁶ Finally, the Commission concurs with the Authority that, with respect to drawing medication policies from the states that use policies of ARCI and the Racing Medication and Testing Consortium (“RMTC”), the Act requires instead the adoption of IFHA medication controls.⁹⁷

1. Rule Series 4100 – Banned Substances and Banned Methods

In Proposed Rule Series 4100, the Authority identifies from the Prohibited List those substances and methods that are prohibited at all times (“Banned Substances” and “Banned Methods”). Proposed Rules 4111–4117 list six categories of Banned Substances, and Proposed Rules 4121–4123 list three categories of Banned Methods.

The National Horsemen lodge a series of complaints about Rule 4111.⁹⁸ They claim that the rule ignores the statutory standards in 15 U.S.C. § 3055(b)(1) in favor of the Authority’s own requirement that medications must be FDA-approved before they are taken off the S0 banned-substances list. Put simply, they contend that “no substances with a valid therapeutic use should ever be in the S0 category”⁹⁹ and that there is no justification to bar therapeutic medications that are legal but lack FDA approval.¹⁰⁰ Dr. Fenger makes the similar point that “[t]he Prohibited List

⁹⁶ See *id.* §§ 3053(a)(3) (laboratory standards for accreditation and protocol), 3055(c)(1)(A)(ii) (Authority obligated to issue rules concerning “uniform standards for . . . laboratory testing accreditation and protocols”), 3057(b)(1)(C) (Authority responsible for issuing by rule “the standards and protocols for testing such samples”).

⁹⁷ See *id.* § 3055(b)(4), (g)(2)(A).

⁹⁸ Proposed Rule 4111 (“S0 Non-approved Substances”) states: “Any pharmacological substance that (i) is not addressed by Rules 4112 through 4117 [other categories of banned substances], (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 (also known as Compounding Animal Drugs from Bulk Drug Substances) are not prohibited under this section S0.” Notice, 88 Fed. Reg. at 5122.

⁹⁹ Nat’l Horsemen Cmt. at 6.

¹⁰⁰ The National Horsemen list these substances in Tables 1a and 1b of their comment.

includes many substances with appropriate use during the out-of-competition period” and asserts that “[t]he regulations far exceed their mandate, by regulating therapeutic medications beyond the in-competition period, interfering with the ability of veterinarians to appropriately treat their patients.”¹⁰¹

The National Horsemen observe that there were several primary metabolites of S7 substances that are included in the S0 list and contend that, if “the S7 substance does not warrant an S0 penalty, then there is no place for its primary metabolites on the S0 list.”¹⁰² The National Horsemen also raise concerns about the banning of standard medications required for breeding fillies, as well as anesthesia induction, reversal agents, and long-term tranquilizers used in the post-operation period for horses requiring stall rest.¹⁰³ Finally, the National Horsemen complain about imposing a 14-month ineligibility period for using any ADMC medication without a sufficient scientific basis and that doing so could “adversely impact the health and welfare of the horse” by preventing appropriate therapy or by preventing the horse from training because it was “inadvertently administered such a substance.”¹⁰⁴ The National Horsemen urge the ADMC committee (1) to consider moving FDA-approved medications or their metabolites from the S0 to the S7 category and (2) to “further reconsider the 14-month ineligibility period” because “it is inappropriate to include in this S0 category, therapeutic substances whose use is Standard of Veterinary Practice.”¹⁰⁵ The National Horsemen provide no scientific support for their assertions.

The Oklahoma Commission recommends adding ammonium sulfate as an S6 miscellaneous substance (from its current S0 classification), because when “[w]hen fed orally” it

¹⁰¹ Second Fenger Cmt. at 1, 2.

¹⁰² Nat’l Horsemen Cmt. at 6.

¹⁰³ *Id.* at 2, 6.

¹⁰⁴ *Id.* at 7.

¹⁰⁵ *Id.*

acts as a “urinary acidifier in horses” and, in compounded injectable form, “may be used as a regional or local anesthetic on horses for race day purposes.”¹⁰⁶

The Authority responds to criticisms regarding its FDA-approval requirement by stating that, if a substance is not legally required to have FDA approval, “then lack of FDA approval does not disqualify it from use.”¹⁰⁷ On the other hand, “if a substance meets the FDA criteria for a ‘Drug’ and it does not have FDA approval, it is a Banned Substance.”¹⁰⁸ The Authority further notes that “there are FDA approved medications that have no legitimate use in the horse; therefore, they are designated as Banned Substances,” a conclusion it supports.¹⁰⁹ The Authority further notes that the S0 designation can be revised based on a substance’s evolving use as recognized by international regulators and veterinary colleges.¹¹⁰ As for the primary metabolites of S7 substances being on the S0 list, the Authority replies that “the Technical Document provides for penalty mitigation when an S0 substance is determined to be present in a sample as a consequence of a documented administration of an S7 substance.”¹¹¹ Regarding the National Horsemen’s complaint about prohibiting the use of standard medications necessary for breeding fillies, the Authority notes the National Horsemen’s failure to identify any such medications and states further that medications conventionally used for pregnancy purposes are all classified as S7 substances and therefore permitted for use in fillies and mares under specified conditions. As for the use of anesthesia induction agents, the Authority says that conventional agents have been classified as S7 substances based on advice from veterinary specialists.¹¹² Regarding the asserted bar on long-term tranquilizers, the Authority replies that several long-term tranquilizers are S7

¹⁰⁶ Okla. Comm’n Cmt. at 4.

¹⁰⁷ Authority’s Response at 10.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.* at 11.

substances, so veterinarians are able to use those to control horse activity in the peri-operative period.¹¹³ Finally, the Authority disagrees with the National Horsemen’s comment about the 14-month ineligibility period, asserting that there simply “is no period of ineligibility” for a horse that was given an S7 controlled substance.¹¹⁴ As for S0 violations, the Authority agrees that there is an ineligibility period for “up to 14 months” but notes that the prohibited list will be reviewed annually based on science and evolving use.

The Commission finds that Proposed Rule 4111 is consistent with the Act. Proposed Rule 4111’s ban on S0 substances that have “no current approval by any governmental regulatory health authority for veterinary or human use” or are “not universally recognized by veterinary regulatory authorities as a valid veterinary use” is certainly consistent with the Act’s requirement that the medication must “represent[] an appropriate component of treatment.” 15 U.S.C. § 3055(b)(5). As the Authority states, the designation of a banned substance on the S0 category was based on a robust scientific record that included research findings and input from veterinary specialists and research findings, and these sources informed the Authority’s decision to designate a substance in the S0 category due to the health risk it poses to horses.

By contrast, as the Authority points out, the National Horsemen fail to back up many of their claims with scientific evidence. The National Horsemen rely heavily on a provision in the Act that bars medication that “affect[s] [the horse’s] performance.” 15 U.S.C. § 3055(b)(1). But that phrase is susceptible to different interpretations, and the Authority’s determination of banned substances falls comfortably within the scope of § 3055(b)(1). As the Authority points out, the designation of a substance as Banned or Controlled cannot be based solely on individual practitioners’ preferences or beliefs that particular therapeutic substances should not be banned

¹¹³ *Id.*

¹¹⁴ *Id.*

or restricted—particularly in the absence of supporting scientific literature.¹¹⁵ Commenters are incorrect when they assert that the Authority requires FDA approval for a substance to be used. As the Authority replies, if a substance is not legally required to have FDA approval, “then lack of FDA approval does not disqualify it from use.”¹¹⁶ Conversely, “there are FDA approved medications that have no legitimate use in the horse; therefore, they are designated as Banned Substances.”¹¹⁷ Such a reading is entirely consistent with the Act.

As for the Oklahoma Commission’s suggestion to add ammonium sulfate as an S6 miscellaneous substance, the Authority states that, like other ammonium salts, “[a]mmonium sulfate would fall under category S0 of the Prohibited List” as not approved for any veterinary use and thus banned at all times.¹¹⁸ The substance “can be added to the Technical Document when it undergoes annual review,” says the Authority, but until then remains banned.¹¹⁹ The Oklahoma Commission’s suggestion to reclassify ammonium sulfate as a S6 miscellaneous substance under Proposed Rule 4117 and the Authority’s reasoned response that it remains for now an S0 “non-approved substance” under Proposed Rule 4111 might reflect different approaches, but they do not reveal any inconsistency with the Act. The Authority has the power to determine, with the approval of the Commission, what are permitted and prohibited substances and medications.¹²⁰ The Authority’s current determination to keep ammonium sulfate as an S0 substance falls clearly within its power under the Act.

Finally, the Commission notes the Authority’s statement that the Prohibited List is reviewed annually and can be revised based on “new science, evolving trends in medication use,

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 10.

¹¹⁷ *Id.*

¹¹⁸ *See* Notice, 88 Fed. Reg. at 5127 (Proposed Rule 4111 (“S0 Non-Approved Substances”).

¹¹⁹ Authority’s Response at 26.

¹²⁰ *See* 15 U.S.C. §§ 3055(c)(1)(B), 3055(c)(5).

changes to FDA approvals, and input provided by stakeholders and veterinary experts.”¹²¹ The Commission encourages the Authority to submit a proposed rule modification as necessary if any of the above developments support changing the classification of a listed drug.

2. Rule Series 4200 – Controlled Medication Substances and Controlled Medication Methods and Exceptions

In Proposed Rule Series 4200, the Authority identifies a less restricted group of “controlled medication substances and methods” that are prohibited only for use or administration during the “race period” and prohibited to be present in a post-race or post-work sample. Proposed Rule 4211 governs S7 controlled medication substances and prohibits their use during the race period (essentially 48 hours before a race to one hour after the race). Proposed Rule 4212 provides exceptions to those prohibitions for medical necessity. S7 substances are not otherwise banned outside the race period. As specified in Proposed Rule 4211(a), only feed, hay, and water are permitted during the Race Period. Under Proposed Rule 4212(d), Lasix (also known as furosemide or Salix), a diuretic, (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 Act provisions and any guidance or exceptions approved by the Authority), but (3) cannot be administered within four hours of a race.¹²² This exception thus justifies the Prohibited List’s exclusion for the use of furosemide in training exercises.¹²³

The AWI comments on Proposed Rule 4212’s exceptions to Proposed Rule 4211, particularly with respect to the use of Lasix, noting that the “the negative effects associated with this potent diuretic are well understood . . . as is its use as a performance-enhancing

¹²¹ Authority’s Response at 10–11.

¹²² The exemption does not apply to 2-year-olds and stakes races. *See* 15 U.S.C. § 3055(f)(2).

¹²³ *See* Notice, 88 Fed. Reg. at 5140.

substance.”¹²⁴ The AWI notes that the United States was the only major racing jurisdiction in the world to permit the race-day use of Lasix and, while appreciating the Authority’s work, hopes for an eventual prohibition on the race-day use of Lasix in the United States.¹²⁵ Although recognizing the therapeutic role Lasix can play to treat exercise-induced pulmonary hemorrhage, the AWI notes that such treatment “affects only a small percentage of horses,” whereas the overreliance on Lasix in the lead-up to a race has long been a serious concern; indeed, it cites research that approximately 95% of starters in the United States receive Lasix. As a powerful diuretic, Lasix can cause horses to lose 20 to 30 pounds of fluid, enabling them to run faster but also causing severe dehydration, which in turn can be linked to electrolyte imbalance, muscle fatigue, and overall exhaustion. AWI recognizes that resistance to barring or even limiting the use of Lasix exists in the United States. AWI characterizes as important first steps the Agency’s position that Lasix should be categorized as a controlled medication category and its four-hour race day prohibition, but nevertheless notes that “workouts pose just as much risk for horses as racing.” Other commenters express opposition to any restrictions on the use of furosemide.¹²⁶

The Texas Commission states that “[s]ince feed is undefined in the HISA regulations, the provision [Proposed Rule 4211] may or may not make complete feed illegal in the last 24 to 48 hours.”¹²⁷ It also suggests changing Proposed Rule 4211(b) to the language used in Texas rules that prohibit the use of substances for 24 hours before post time, which allows “treatments that are necessary for horse welfare” without any ill effects “on the safety or integrity of the sport.”¹²⁸

¹²⁴ Second AWI Cmt. at 3.

¹²⁵ *Id.*; see also First AWI Cmt. at 2–3.

¹²⁶ Cmt. of Joseph Bahadoor (Jan. 29, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0008>; Cmt. of Gerald Bergsma Cmt. (Jan. 30, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0015>; Cmt. of Cindy Murphy Cmt. (Feb. 8, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0092>.

¹²⁷ First Tex. Comm’n Cmt. at 4.

¹²⁸ Second Tex. Comm’n Cmt. at 2–3.

The Authority takes issue with the Texas Commission’s comment to change Proposed Rule 4211(a), suggesting that such a change would allow the use of banned substances and would allow more than only feed, hay, and water to be given to the horse during the last 48 hours before race time. In response to AWI’s Rule 4212 proposal, the Authority notes that the 4-hour window is solidly grounded in science and based on the period of time required for furosemide’s dilution effect on the urine to resolve.¹²⁹ The Authority explains that the risk of a masking effect from the use of diuretics is based on the production of dilute urine below the laboratory’s sensitivity to detect that substance.

The Authority also discusses its obligations under 15 U.S.C. § 3055(e)–(f) to convene an advisory committee to study the use of furosemide on horses during the 48-hour period before post time, and that the committee’s findings must be submitted within three years of the program’s effective date. During the three-year period, state racing commissions are permitted to request an exemption for furosemide from the prohibition in 15 U.S.C. § 3055(d) (an exemption that may not be requested for two-year-old Covered Horses or Covered Horses competing in stakes races). In the meantime, as the Authority observes, there is a sound scientific basis for the provisions proposed by the Authority concerning furosemide; moreover, “much of the international racing community conducts racing without the use of race-day furosemide and has done so for decades,” which shows that “horses can race safely and successfully without furosemide administration.”¹³⁰

The Authority disagrees with the Texas Commission’s assertion that Proposed Rule 4211 might make feed illegal up to 48 hours before race time. It states that “[f]eed is clearly permitted

¹²⁹ Authority’s Response at 4.

¹³⁰ *Id.* at 4–5.

in Rule 4211.”¹³¹ The Authority also takes issue with the Texas Commission’s comment to change Proposed Rule 4211(a) because it believes that Texas’s suggested changes would allow the use of banned substances and would allow many more substances to be given to the horse in the 48 hours prior to post time beyond only feed, hay, and water during the 48-hour race period.

The Commission finds that Rule Series 4200 is consistent with the Act. As for furosemide (Lasix), the Commission finds that the limited (and temporarily three-year-excepted) use of Lasix under Proposed Rule 4212(d) is consistent with the Act.¹³² Regarding whether feed is barred during the race period, Proposed Rule 4211(a) expressly states that “feed, hay, and water are permitted during the Race Period.”¹³³ Although the Texas Commission is not exactly clear on what changes it seeks to Proposed Rule 4211(a), the Commission believes that the proposed provision (along with the exceptions in Proposed Rule 4212) strikes an appropriate balance by prohibiting all banned substances at any time and restricting the abuse of any controlled medical substances in the two days before race time, after which only feed, hay, and water can be given to the horse; Proposed Rule 4211(a) is consistent with the Act’s requirements to protect the health and wellbeing of racehorses.

3. Rule Series 4300 – Ineligibility Periods for Covered Horses

In Rule Series 4300, the Authority proposes ineligibility periods for anti-doping and controlled medication methods rule violations. Proposed Rules 4310–4330 impose ineligibility periods for violations involving prohibited substances and methods as well as for violations of Proposed Rule 3215. Proposed Rule 4310 contains a table detailing the period of ineligibility

¹³¹ *Id.* at 15–16.

¹³² *See* 15 U.S.C. § 3055(d) (generally prohibiting the use of controlled medication substances during the “Race Period”), (e) (three-year advisory committee study and report on Lasix), (f) (allowing states to seek exemptions for Lasix during the three-year period). *See generally* Notice, 88 Fed. Reg. at 5077.

¹³³ Notice, 88 Fed. Reg. at 5078.

resulting from a violation involving a prohibited substance; it states that there is no period of ineligibility resulting from a violation involving an S7 controlled medication substance, but that the covered horse “may be placed on the Veterinarian’s List, and, if so, then a subsequent Vets’ List Workout must be scheduled [and] [a] post-Vets’ List Workout Sample may be required.”¹³⁴

The Oklahoma Commission suggests that the rule specify that the Regulatory Veterinarian possesses discretion to place a horse on the Vets’ List after an S7 substance violation even if the horse were eligible to compete, out of concern for “NSAIDs & corticosteroids (among other substances) possibly masking lameness & welfare issues.”¹³⁵ The Authority agrees, with the desirability of such discretion, stating that “[t]he horse may be placed on the Vets’ List to verify its fitness to race if warranted in the opinion of the Regulatory Veterinarian.”¹³⁶

The Commission agrees with both the comment and the Authority that, even when a horse could return to racing after a finding of an S7 controlled-medication violation, the Regulatory Veterinarian has the discretion to postpone such return and place the horse on the Vets’ List until the horse’s condition improves. Proposed Rule 4310 as applied is consistent with—indeed, mandated by—the Act.¹³⁷

4. Rule Series 4000 Appendix: Technical Document—Prohibited Substances

The Proposed Rule Series 4000 Appendix lists those prohibited substances falling within the general categories in the Prohibited List and sets forth their detection times, screening limits, and thresholds.

¹³⁴ See *id.* at 5124.

¹³⁵ Okla. Comm’n Cmt. at 4.

¹³⁶ Authority’s Response at 26–27.

¹³⁷ See 15 U.S.C. § 3055(b)(2) (requiring the Authority to consider, in developing its ADMC program, that “covered horses that are . . . unsound should not . . . participate in covered races, and that “the use of medications [and] other foreign substances . . . that mask or deaden pain in order to allow . . . unsound horses to . . . race should be prohibited”).

The Authority’s Prohibited Substances—Technical Document elicited many comments. The National Horsemen and Kentucky Horsemen (using identical language) argue that the Technical Document “completely reorganizes the existing [ARCI] Uniform Classification Guidelines” for “no good reason”; they describe the Guidelines as having “been developed and refined over many years,” and as based on peer-reviewed, veterinary science–based research concerning “the potential for a substance to affect racing performance or endanger the welfare of the horse.”¹³⁸ The National Horsemen and Kentucky Horsemen also raise concerns about blank spots in the Prohibited Substance list that would default to the limit of detection without regard for a substance’s ability to be transferred from the environment or to have a very long terminal half-life.¹³⁹ They claim that 12% of substances on the list are at risk of environmental transfer either from common, legal use as an oral medication or from stability in the environment. Further, they express the concern that veterinarians will need to be careful about using therapeutics with extremely long terminal half-lives.¹⁴⁰

The National Horsemen also complain about the Authority’s handling in the Prohibited Substances—Technical Document of S7 therapeutic medications,¹⁴¹ which they deem a clear departure from the original ARCI goal of establishing scientifically based withdrawal times and thresholds for therapeutic medications. The National Horsemen claim (as does a nearly identical comment from K. Myrick) that the Authority has determined the regulation of most therapeutic medications to be at limit of detection, which they claim restricts the use of many therapeutic

¹³⁸ Second Nat’l Horsemen Cmt. at 3; First Nat’l Horsemen Cmt. at 1, 3; Second Ky. Horsemen Cmt. at 1 & Att. (Hiles Cmt.).

¹³⁹ Second Nat’l Horsemen Cmt. at 3; First Nat’l Horsemen Cmt. at 1, 3; Second Ky. Horsemen Cmt. at 1 & Att. (Hiles Cmt.).

¹⁴⁰ Second Nat’l Horsemen Cmt. at 1, 3; Second Ky. Horsemen Cmt. Attach. (Hiles Cmt.) at 2; First Nat’l Horsemen Cmt. at 1, 3.

¹⁴¹ Second Nat’l Horsemen Cmt. at 2–4, 28.

medications to the detriment of the horses' health and welfare.¹⁴² Further, they contend, limit-of-detection regulations for therapeutic medications are subject to change whenever technology advances, resulting in a lack of consistency.¹⁴³ The National Horsemen lament that “the ARCI thresholds for substances for which no IFHA Screening Limit exists are ignored in the . . . Technical Document” and that “there was no reason for the Authority to abandon the in-place ARCI thresholds for substances not included in the IFHA screening limits.”¹⁴⁴ While acknowledging drawbacks to ARCI's methodology, the National Horsemen claim that the methodology is “significantly more scientifically rigorous than virtually all of the HISA/IFHA therapeutic medication guidelines.”¹⁴⁵ The National Horsemen recommend that the Authority “establish a transition period between the existing therapeutic medication regulations and the new IFHA based regulations” to avoid an “upheaval in horse racing.”¹⁴⁶

Dr. Richard Braithwait calls for the removal of Methyl Sulphonyl Methane (“MSM”) from the S7 controlled substance list and notes its omission from an ARCI classification list. He also cites research showing that supplementation with MSM reduced horses' oxidative and proinflammatory “marker levels significantly.”¹⁴⁷ Zach Badura recommends the declassification of dimethyl sulfoxide (“DMSO”) as an NSAID (nonsteroidal anti-inflammatory drug), citing “evidence that DMSO is a naturally occurring substance in the environment” and that it “is a safe and effective medication utilized . . . in treating various conditions.”¹⁴⁸

Regarding the National Horsemen's critique of the Authority's use of limits of detection,

¹⁴² *Id.*; Myrick Cmt. at 1 (same).

¹⁴³ Myrick Cmt. at 1.

¹⁴⁴ Second Nat'l Horsemen Cmt. at 28.

¹⁴⁵ According to the National Horsemen, ARCI has regulated controlled therapeutic medications “by establishing a withdrawal period that represents a balance between appropriate care of the equine athlete” and “preventing an effect of the medication on the outcome of the race.” *Id.* at 28.

¹⁴⁶ *Id.* at 29.

¹⁴⁷ Cmt. of Dr. Richard Braithwait (Jan. 30, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0010>.

¹⁴⁸ Cmt. of Zach Badura.

the Authority responds that “the Act requires adoption of IFHA medication controls.”¹⁴⁹ The Authority points out that “[t]he IFHA does not provide withdrawal guidance,” which the Authority in any event contends “would not be more reliable because it would be based on generalized data” and not take “account of inter-individual variability.”¹⁵⁰ The Authority also responds to the National Horsemen’s identification of items in the Technical Document that the National Horsemen claim are errors requiring clarification and correction. The Authority acknowledges and seeks to correct some errors while indicating that other of the challenged items are correct.¹⁵¹ Finally, regarding the National Horsemen’s request for a transition period, the Authority responds that, although “[t]he Act does not provide for a grace period,” the Agency “is undertaking an extensive educational program to minimize errors in medication control.”¹⁵²

As for Dr. Braithwait’s request that the Authority remove MSM from the S7 list, the Authority declines to do so, stating that, as reflected in the Prohibited List, IFHA recognizes MSM as a dietary substance and has established a screening limit for it; the Authority further explains the use and prohibitions on using MSM as a S7 substance.¹⁵³ The Authority also denies Mr. Badura’s request to declassify DMSO as an NSAID but adds that IFHA’s screening limit considers that DMSO is a dietary or environmental substance.¹⁵⁴

The Commission finds that the Authority’s inclusion of MSM as an S7 controlled substance and DMSO as a dietary or environmental substance classified as an NSAID in the Technical Document is consistent with the Act. Specifically, the Act provides for the baseline

¹⁴⁹ Authority’s Response at 8.

¹⁵⁰ *Id.* at 12.

¹⁵¹ *Id.* at 12–13.

¹⁵² *Id.* at 14.

¹⁵³ *Id.* at 21.

¹⁵⁴ *Id.* at 22.

ADMC rules to include the lists of prohibited substances in effect for the IFHA, which is exactly what the Authority did in these provisions.¹⁵⁵

Several scrivener's errors, typos, and other minor mistakes found in the Technical Document have been brought to the Commission's attention by commenters or by the Authority. Those that the Commission has found to be very minor errors are noted in the footnote will be deemed corrected in the final rule.¹⁵⁶

d. Rule Series 5000 – Equine Standards for Testing and Investigation

1. Rules 5100–5500 and 5800 – Testing

Proposed Rules 5110–5150 require the Agency to plan and implement effective testing by using risk assessments, prioritizing among categories of horses and types of testing, and directing sample analysis and retention. Proposed Rules 5210 and 5200 require that samples be collected for testing without advance notice if possible, pursuant to procedures and notification requirements based on when the sample is collected. Sample collections will be conducted by suitably qualified personnel (Proposed Rule 5450), using suitable equipment (Proposed Rule 5320), in a suitable “test barn” environment (Proposed Rule 5310). Proposed Rule 5410 dictates general collection procedures necessary to ensure the integrity of samples, and Proposed Rules

¹⁵⁵ See 15 U.S.C. § 3055(g)(2)(A)(i); Notice, 88 Fed. Reg. at 5073 (stating that the baseline standards include the lists of prohibited substances in effect for the IFHA).

¹⁵⁶ The corrections in the final rule will be: (1) capitalizing terms in the heading so the proposed term “Specific substances” will be “Specific Substances,” the term “Detection time” will be “Detection Time,” the word “Screening limit” will be “Screening Limit”; (2) for Desoximethasone, the word “Topicor” will be “Topicort”; (3) for Donepezil, the name “Aricep” will be “Aricept”; (4) for Dorzolamide, the name “Casp” will be “Cocopt”; (5) for Estranediol, the name “Estroge” will be “Estrogen”; (6) for Gonadorelin, the name “Gonabree” should be “Gonabreed”; (7) for Hydralazine, the name “Bidi” will be “Bidil”; (8) for Hydrochlorth (Lopessor), the word “other” will be “others”; (9) for Isomethadone, the words “DEA Schedule I” will be “DEA Schedule II”; (10) for Levorphanol, the words “DEA Schedule I” will be “DEA Schedule II”; (11) for Mehtyltrienolone, the stray word “F89” will be deleted; (12) for Methysergide, the word “availabl” will be “available”; (13) for Nalorphine, the stray word “F94” will be deleted; (14) for Oripavine, the words “DEA Schedule I” will be “DEA Schedule II”; (15) for Phendimetrazide, the words “DEA Schedule II” will be “DEA Schedule III”; (16) for Psilocin, the words “DEA Schedule” will be “DEA Schedule I”; (17) for Tetrahydrogestrinone, the word “approva” will be “approval”; and (18) for Thioridazine, the word “Generc” will be “Generic.”

5320(c)–(e) and 5420–5440 set forth additional requirements concerning the collection of urine, blood, and hair samples. Proposed Rules 5510 and 5520 specify procedures governing the storage and transportation of samples to laboratories to protect the samples’ integrity.

According to the Kentucky Commission’s comment on the sample collection equipment requirements in Proposed Rule 5320, while “[n]othing states that each item must be packaged individually . . . , it is the KHRC’s understanding that HIWU interprets this regulation to require individual packaging.”¹⁵⁷ Doing so, the Kentucky Commission claims, is “not only inefficient and unnecessary, but also bad for the environment and expensive”; the Kentucky Commission therefore recommends that the rule “clarify that sample collection equipment must be clean and sealed prior to use, but need not require individual packaging of each blood or urine container.”¹⁵⁸ The Kentucky Horsemen challenge the sample collection process in Proposed Rule 5410 as failing to provide “adequate due process” to the accused in several respects.¹⁵⁹ First, they argue that, at an adjudication of any alleged errors occurring during sample collection process, they would be limited to presenting their concerns and a supporting an affirmation, and they would not be able to present photographs, videos, or any other evidence.

The Kentucky Horsemen also question whether the Covered Person at the collection site would know what the proper collection procedures are, whether they were followed properly, or how to reflect accurately the sample collection session on the documentation forms.¹⁶⁰ The Kentucky Horsemen complain about Proposed Rule 5410(m)’s prohibition on photographing or video/audio recording the sample collection session, claiming that such documentation would

¹⁵⁷ Ky. Comm’n Cmt. 2.

¹⁵⁸ *Id.*

¹⁵⁹ Cmt. of Ky. Horsemen’s Benevolent & Protective Ass’n 5 (Nov. 11, 2022) (“First Ky. Horsemen Cmt.”), <https://www.regulations.gov/comment/FTC-2022-0062-0005>.

¹⁶⁰ *Id.* at 15.

provide “the most conclusive evidence there is” of what happened there.¹⁶¹ They assert that these provisions hamstring their ability to contest “the Agency’s ECM rule violation charge [as] incorrect due to non-compliance with a key sample collection, handling, or testing protocol.”¹⁶² The Oklahoma Commission expresses the same concern regarding the prohibition on photography/videography of the sample collection session, stating that the provision “decreases testing integrity and transparency” and that—especially given the Responsible Person’s potential liability—“recording of [a] sampling session should be a reserved right.”¹⁶³

The Oklahoma Commission further complains that under Proposed Rule 5520(d),¹⁶⁴ the transported samples and documentation “will more than double [the storage space required] for testing Laboratories,” and that “[t]he extra space needed will prevent additional testing equipment from being added efficiently and possibly negatively impacting HIWU testing program.”¹⁶⁵ The Kentucky Horsemen also claim that the accused is “denied the ability to call witnesses [at the adjudication] who can offer oral testimony as to what transpired in the sample collection and handling process.”¹⁶⁶ Due to that bar, the Kentucky Horsemen contend, the accused will be unable to show that everything was regular and in accordance with applicable standards; according to the Kentucky Horsemen, “whatever gets documented by the Sample Collection Personnel during the Sample Collection Session” under Proposed Rule 5410 becomes conclusive.¹⁶⁷ The Kentucky Horsemen thus contend that, “[i]n an ECM rule case, the accused *must be permitted* to call potentially adverse witnesses to testify” about whether the applicable

¹⁶¹ *Id.*

¹⁶² *Id.* at 14–15.

¹⁶³ Okla. Comm’n Cmt. at 4–5.

¹⁶⁴ Proposed Rule 5520(d) requires that the “A and B Samples (and official and duplicate TCO2 Samples) will be shipped together to the Laboratory conducting the A Sample analysis.” Notice, 88 Fed. Reg. at 5168.

¹⁶⁵ Okla. Comm’n Cmt. at 5.

¹⁶⁶ *Id.* at 15 (citing Proposed Rules 7180 and 7110(b)).

standards “governing investigations or sample collection[s]” were followed properly.¹⁶⁸ The Kentucky Horsemen assert that the accused must be able to supplement the record created in the adjudicatory stage if review of the final decision and sanction is sought from the Commission under § 3058.¹⁶⁹

Dr. Sivick complains that the proposed rule provisions “permit laboratories to call positive tests at their limits of detection, which may vary widely from lab to lab.”¹⁷⁰ “The end result of this regulation,” Dr. Sivick asserts, “is to have completely different rules depending upon which laboratory is testing the samples,” such that “[t]he approval of these regulations will result in differing violations from jurisdiction to jurisdiction depending on the laboratory limits of detection.”¹⁷¹ Finally, the Texas Commission criticizes Proposed Rule 5450(b)(2)(i) as “prohibiting individuals from performing the duties of Sample Collection Personnel if they are involved in the administration of horseracing.” The Texas Commission claims this restriction will essentially “exclude any Association Veterinarian from collecting samples . . . [and] will put the Association in the untenable position of being required to obtain a sample for injured or euthanized horses but unable to do so because of the lack of authorized personnel on site.”¹⁷²

As for Kentucky Commission’s comment about sample collection packaging under Proposed Rule 5320, the Authority notes that “[b]ulk packaging only ensures the first container retrieved from the sealed package is ‘clean and sealed prior to use,’ ” but that, “once opened, bulk packaging allows the remaining collection supplies to be exposed to dust, dirt, and moisture” and therefore fails to ensure that the sample is “clean and sealed prior to use.”¹⁷³

¹⁶⁸ Ky. Horsemen Cmt. at 16.

¹⁶⁹ *Id.* at 16, 19.

¹⁷⁰ Sivick Cmt. at 1.

¹⁷¹ *Id.*; *see also* Myrick Cmt. at 2 (quoting precisely the same language).

¹⁷² Second Texas Comm’n Cmt. at 3.

¹⁷³ Authority’s Response at 31.

Regarding the Oklahoma Commission’s complaint about lack of storage space for samples and related materials, the Authority responds that “[m]any jurisdictions already send A and B samples to their laboratories[,] and that “[t]he Agency has been communicating with all RMTC-accredited laboratories on sample storage requirements . . . and [n]one have expressed concerns about storage requirements constraining laboratory activities.”¹⁷⁴ With respect to the complaints about the bar on photographing or videorecording the collection session, the Authority responds that the approach set out in Proposed Rule 5410 “is consistent with that taken by the international anti-doping community.”¹⁷⁵ Finally, regarding the Texas Commission’s complaint about Association Veterinarians not being able to collect samples simply because they are involved in the administration of horseracing, the Authority notes that Proposed Rule 5450(b)(2)(i) excludes Association Veterinarians unless they meet other criteria that the Agency has designated as constituting a conflict.¹⁷⁶

The Commission finds that Proposed Rules 5100–5500 and 5800 are consistent with the Act. Regarding the Kentucky Commission’s comment about whether individual sample collection packaging is required under Proposed Rule 5320, the Commission agrees with the Authority that this does not reflect an inconsistency with the Act but essentially a policy disagreement with the Authority. The Authority states that bulk packaging will not satisfy Rule 5320(b)(4)’s requirement that the packaging be “clean and sealed prior to use,” which is a fair reading of that rule. But the Commission is also concerned that the requirement of individual packaging is not more explicit in the rule and therefore suggests that the Authority consider providing Guidance or submitting a rule modification proposal to clarify that individual and not

¹⁷⁴ *Id.* at 27.

¹⁷⁵ *Id.* at 24.

¹⁷⁶ *Id.* at 29–30.

bulk packaging meets the requirements of Proposed Rule 5320(b). With respect to the Oklahoma Commission’s complaint about testing laboratories’ purported lack of storage space due to housing samples and related documents, the Authority’s response shows that in fact laboratories have not expressed concerns about limited storage capacity or less space to conduct testing.

Proposed Rule 5410 provides a very comprehensive—and secure—procedure to collect horse urine, blood and hair samples. It ensures equal representation during the sample collection session to both the Agency and the Responsible Person (either the trainer or the owner). And it provides *two* opportunities to the accused (during and after the sample collection session) to record any “concerns” about the sample collection session.¹⁷⁷ The rule also requires a person who is suspected of a violation to acknowledge and describe the processing of sample collection data during the session,¹⁷⁸ as well to record (after the session) “their satisfaction (or otherwise) that the documentation accurately reflects the details of the . . . sample collection session.”¹⁷⁹

As for the Kentucky Horsemen’s concern that the Covered Person may not understand the procedures and standards required at the sampling session or be able to fully record their concerns in the collection documentation, the rules require that the Responsible Person (the trainer or in his absence, the owner, both of whom face strict liability for doping violations) must be present at the sample collection session.¹⁸⁰ Consistent with the Act, Responsible Persons must register with the Authority and are expected to acquire the requisite knowledge, including by availing themselves of the education materials and guidance the Authority makes available on its website.

¹⁷⁷ Notice, 88 Fed. Reg. at 5165 (Proposed Rule 5410(i)(21) (concerns regarding conduct during the session)); *id.* (Proposed Rule 5410(j) (concerns about the manner the session was conducted to be recorded after the session ends)).

¹⁷⁸ *See id.* (Proposed Rule 5410(i)(22)).

¹⁷⁹ *Id.* (Proposed Rule 5410(j)).

¹⁸⁰ *See id.* (Proposed Rule 5410(b)(2)).

Scrivener's errors were found in Proposed Rules 5430(e) and 5510(b)(1). The Commission deems the errors to be corrected in the final rule.¹⁸¹

2. Rules 5600–5700 – Investigations

Proposed Rules 5610–5640 require the Agency to obtain, assess, and process anti-doping and medication control intelligence from all available sources so as to detect and deter doping and medication abuse, develop effective test planning, and conduct investigations. Proposed Rules 5710–5740 require the Agency to conduct efficient and effective investigations into (among other things) atypical findings and other sample abnormalities, and to scrutinize other information or intelligence, in order to determine whether there has been an anti-doping or controlled medication rule violation or other rule violation. The Agency must use all available investigative resources, including obtaining information from law enforcement authorities and other regulators. The investigative powers provided to the Agency by Proposed Rule 5730 include inspection, examination, seizure, production of documents, subpoenas, and interviews. Proposed Rule 5720(f) requires all covered person to cooperate with the Agency's investigations and provides that failure to do so may result in the imposition of sanctions.

No comments were received about these proposed rules and thus the Authority provided no response.

The Commission finds that these rules are consistent with the Act. Investigations of potential ADMC rule violations play a central part in the program and are required to be conducted pursuant to several statutory provisions.¹⁸²

e. Rule Series 6000 – Equine Standards for Laboratories and Accreditation

¹⁸¹ In the final rule, the words “within the kit” will be deemed as stricken from Rule 5430(e). The Notice explained this change, stating that “it was not consistent with collection kits available in the industry.” See 88 Fed. Reg. at 5083. In Rule 5510(b)(1), the word “refrigerator” will be deemed to be corrected as “refrigerator” in the final rule.

¹⁸² See, e.g., 15 U.S.C. §§ 3054(c)(1)(A), 3054(e)(1)(E), 3055(c)(4).

Proposed Rule Series 6000 establishes “Laboratory Standards” to govern the accreditation of laboratories used to test samples obtained from Covered Horses, the process for achieving and maintaining such accreditation, and the standards and protocols for testing the recovered samples. Its “main purpose . . . is to ensure that Laboratories report valid test results based on reliable evidentiary data and to facilitate harmonization in Analytical Testing of Samples by Laboratories.”¹⁸³ Proposed Rule Series 6100 prescribes the standards and procedures under which a laboratory can obtain and maintain HISA Equine Analytical Laboratory (“HEAL”) accreditation. Proposed Rule 6130 deals specifically with a laboratory’s efforts to maintain HEAL accreditation, while Proposed Rule 6140 addresses the Agency’s monitoring of laboratories’ accreditation status. Proposed Rule 6500 sets forth the circumstances that may lead to suspension, revocation, or restriction of a laboratory’s HEAL accreditation. Proposed Rule Series 6200, 6400, and 6600 establish procedures for monitoring the quality of laboratories’ performance. Under Proposed Rule 6210, the Agency will distribute samples used to monitor laboratories’ capabilities and performance. Proposed Rule Series 6400 sets forth the procedures that will be used by the Agency to inform laboratories of deficiencies in their testing operations and results and to monitor the laboratories’ corrective efforts. Proposed Rule Series 6300 includes standards for the analysis of samples as well as criteria to govern the withdrawal of HEAL accreditation if a laboratory falls short of those standards.

The American Association for Laboratory Accreditation (“A2LA”) “commend[s]” the Authority “for developing a robust program concerning Anti-Doping and Medication Control” and “support[s] . . . the laboratory testing requirement”: “specifically[,] the inclusion of the requirement to be ISO 17025 accredited by an accreditation body who is an [International

¹⁸³ Notice, 88 Fed. Reg. at 5171 (Proposed Rule 6010(a)).

Laboratory Accreditation Cooperation (“ILAC”)] full member and a signatory to the ILAC.”¹⁸⁴

With respect to biobanking, however, A2LA recommends a revision to Proposed Rule 6319(e)(3)(ii) to “strengthen[] the requirements when using a specialized secure sample storage facility” to include only ISA 20387.¹⁸⁵ Proposed Rule 6319(e)(3)(ii) now provides that “[i]f [an] external Sample storage facility is not covered by the Laboratory’s ISO/IEC 17025 accreditation, then the subcontracted external storage facility shall be Fit-for-Purpose and have its own ISO accreditation or certification (*e.g.*, 17025, 20387, 9001).” A2LA recommends that the ISO 20387 standard “should be given preference when implementing requirements for external sample storage facilities as it is the ISO standard written specifically for biobanks” and “includes requirements for activities that are distinct to biobanking.” Further, A2LA recommends that “[i]n order to achieve accreditation, a biobank [must] demonstrate[] their technical competency in performing the biobanking tasks to ISO 20387 and the HISA requirements”; as A2LA notes, ISO 20387 was recently included in the ILAC Mutual Recognition Arrangement. By contrast, because ISOs 17025 and 9001 “do not include these specific biobanking activities” and “ISO 9001 is not an accreditation standard” so that “an attestation of technical competency could not be formally declared,” those two standards should be omitted from the rule, according to A2LA.¹⁸⁶

As noted above, Dr. Sivick complains that the proposed rules “permit laboratories to call positive tests at their limits of detection, which may vary widely from lab to lab.”¹⁸⁷ Dr. Fenger likewise complains about “the lack of uniformity that is included in [the Authority’s] laboratory requirements,” asserting that “[t]he actual level at which any substance may be detected and

¹⁸⁴ Cmt. of Am. Ass’n for Lab. Accreditation’s 1 (Nov. 14, 2022) (“A2LA Cmt.”).

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ Sivick Cmt. at 1.

reported may vary widely between laboratories” as long as all of the levels meet the Minimum Required Performance Level for a substance.¹⁸⁸

In response to these concerns regarding testing variability, the Authority notes that “[t]he fact that some laboratories may be better at detecting certain substances than others is not unfair, as these substances must never be used on a horse.”¹⁸⁹

The Commission concludes that Rule Series 6000 is consistent with the Act. The Act requires the Authority to issue rules governing “the standards and protocols for testing” samples from covered horses¹⁹⁰ and “uniform standards for . . . laboratory testing accreditation and protocols,”¹⁹¹ but it does not specify a preference for one standard over any other to govern the preservation of samples in an external storage facility, instead leaving that task to the Authority. Proposed Rule 6319(e)(3)(ii) therefore complies with the Act. A2LA’s concerns regarding the inclusion of ISOs 17025 and 9001, however, appear to have merit, and the Authority’s failure to explain that decision hinders the Commission’s evaluation of Proposed Rule 6319(e)(3)(ii). The Commission therefore recommends that the Authority study this comment and, if appropriate, consider filing a proposed rule modification for Proposed Rule 6319(e)(3)(ii).

As the Commission appreciates, “[t]he Act recognizes that the establishment of a national set of *uniform* standards for racetrack safety and medication control will enhance the safety and integrity of horseracing.”¹⁹² In that vein, the Authority has proposed various rules designed to ensure uniformity in testing among laboratories. For example, Proposed Rule 6210 requires the Agency to regularly distribute External Quality Assessment Scheme samples to Laboratories”;

¹⁸⁸ Second Fenger Cmt. at 3.

¹⁸⁹ Authority’s Response at 21.

¹⁹⁰ 15 U.S.C. § 3057(b)(1)(c).

¹⁹¹ *Id.* § 3055(c)(1)(A)(ii).

¹⁹² 88 Fed. Reg. at 5070 (emphasis added); *see also id.* at 5071 (Protocol and related rules are intended, among other things, to address the need for uniformity in horseracing).

these samples are “designed to continually monitor the capabilities of the Laboratories . . . to evaluate their proficiency, and to improve test result uniformity between Laboratories.” Rule 6610(h)(2) requires a “laboratory director or staff to participate in developing standards for best practices and enhancing uniformity of Analytical Testing in the HEAL-accredited laboratory system.”

These rules are consistent with the Act. In particular, 15 U.S.C. § 3053(a)(3) directs the Authority to develop proposed rules relating to “laboratory standards for accreditation and protocols,” and requires the Authority to issue rules governing “the standards and protocols for testing” samples from covered horses.¹⁹³ And those testing requirements are designed to ensure uniformity of test results among laboratories.¹⁹⁴

f. Rule Series 7000—Arbitration Procedures

Proposed Rule Series 7000 establishes a disciplinary process for hearing and adjudicating violations of the rules and related offenses. Proposed Rules 7020–7040 govern the duties and appointment of members of the bodies adjudicating violations of the Anti-Doping rule (the Arbitral Body) and the Controlled Medication rule (the Internal Adjudication Panel, or IAP). Proposed Rules 7060–7161 set forth procedures for the initiation of proceedings by the Agency. Proposed Rules 7170–7180 govern procedures for hearings before both adjudicative bodies. Proposed Rule 7250 provides the general framework for conducting the hearings, while Proposed Rule 7260 prescribes the submission of evidence. Other rules concern the maintenance of confidentiality (Proposed Rule 7210), the right to be represented by counsel (Proposed Rule 7220), the closing of the hearing (Proposed Rule 7300), and the reopening of a hearing in order

¹⁹³ 15 U.S.C. § 3057(b)(1)(c) (standards, procedures, and protocols regulating medication).

¹⁹⁴ See, e.g., *id.* §§ 3055(c)(1)(A) (rules must ensure “*uniform* standards for . . . laboratory testing accreditation and protocols), 3055(b)(3) (requiring the Authority, in developing the ADMC program, to consider “[r]ules, standards, procedures, and protocols regulating medication and treatment methods for Covered Horses and Covered Horseraces should be *uniform* and *uniformly* administered nationally”) (all emphases added).

“to avoid manifest injustice” (Proposed Rule 7310). Proposed Rule 7340 sets forth the timing for issuing a final decision, and Proposed Rule 7350 authorizes arbitrators and IAP members to “grant any remedy or relief authorized by the Act” or its rules. Under Proposed Rule 7400, final decisions of the Arbitral Body or the IAP are subject to review pursuant to 15 U.S.C. § 3058.

The Kentucky Horsemen challenge multiple rule provisions in Rule Series 7000. They first contend that the Act created a “separation of powers” framework in which the Authority has been given “legislative-like functions” while the Agency has been provided both law enforcement and adjudicative authority.¹⁹⁵ For enforcement duties, they cite to the Act’s directive that the Agency “shall . . . serve as the independent [ADMC] enforcement organization.”¹⁹⁶ They assert that the Agency’s adjudicative functions derive from its statutory mandate to “conduct and oversee [ADMC] results management, including independent investigations, charging, and adjudication of potential [ADMC] rule violations.”¹⁹⁷ This mandate, the Kentucky Horsemen contend, gives the Agency the exclusive right to choose members of the Arbitral Panel and the IAP.¹⁹⁸ According to the Kentucky Horsemen, such an arrangement—embodied in Proposed Rules 7020, 7030, and 7040, which allow the Authority to enter “mutual agreements” with the Agency in the selection and appointment of arbitrators and adjudicators who serve on those panels—violates the Act by improperly (*i.e.*, without statutory authorization) giving “the Authority a role in ‘adjudication.’”¹⁹⁹

The Kentucky Horsemen further contend that “Sections 3054(a), (e)(1) and 3055(c)(4)(B) of the Act *do not permit the Authority* to have any say or input—by ‘mutual agreement’ or

¹⁹⁵ First Ky. Horsemen Cmt. at 2–3.

¹⁹⁶ *Id.* at 1; *see* 15 U.S.C. § 3054(c)(1)(E)(i).

¹⁹⁷ First Ky. Horsemen Cmt. at 2–3 (citing 15 U.S.C. § 3055(c)(4)(B); *see also* 15 U.S.C. § 3054(e)(1)(E) (providing duties of the Agency)).

¹⁹⁸ First Ky. Horsemen Cmt. at 3.

¹⁹⁹ *Id.*

otherwise—in selecting or appointing *independent* arbitrators or adjudicators, or pools of same, to adjudicate ADMC rule violations or sanctions.”²⁰⁰ The Kentucky Horsemen contend that the Act structurally walls off the Authority from exercising any role in the Agency’s “conduct and over[sight of] . . . results management,” including the Agency’s oversight of “independent . . . adjudication.” 15 U.S.C. § 3055(c)(4)(B). The Kentucky Horsemen assert that this structural wall assures “Covered Persons” that the Agency alone exercises the power to select and appoint arbitrators or adjudicators, who are independent of influence or manipulation by the Authority, to hear charges and consider sanctions.²⁰¹ The Kentucky Horsemen argue that each of the contested rules breaches the Act’s exclusive assignment of “results management” functions to the Agency to “conduct and oversee . . . independent . . . adjudication.”²⁰²

The Authority rejects these arguments on the grounds that “[t]he Act does not establish a system of separation of powers within the Authority.”²⁰³

The Commission finds that Proposed Rules 7020, 7030, and 7040 are consistent with the Act. The Kentucky Horsemen fail to show that allowing the members of the Arbitral Body and the IAP to be selected by “mutual agreement of the Authority and the Agency” violates the Act’s provision for the Agency to “conduct and oversee antidoping and medication control results management, including . . . adjudication.”²⁰⁴ Adjudications are the central element in disciplinary proceedings brought under the Act, and the Act empowers both the Agency and the Authority to play a role in that process. Indeed, the Authority is given broad powers to establish the overall ADMC program itself, including specifying the persons and horses to be covered by the ADMC

²⁰⁰ *Id.* at 4.

²⁰¹ *Id.* at 3–8.

²⁰² *Id.* at 7.

²⁰³ Authority’s Response at 2.

²⁰⁴ 15 U.S.C. § 3055(c)(4)(B); *see also id.* § 3054(e)(1)(E)(iii) (power to “implement anti-doping . . . adjudication programs”).

rules,²⁰⁵ the ADMC program’s “disciplinary process,” the “[h]earing procedures” for [ADMC] rule violations,²⁰⁶ and the rules and procedures for access to relevant facilities and the issuance of subpoenas.²⁰⁷ The Authority also may submit for Commission approval numerous rules pertaining to nearly all aspects of the ADMC program, including provisions pertaining to the “process or procedures for disciplinary hearings,”²⁰⁸ provisions describing ADMC rule violations and imposing sanctions for violations,²⁰⁹ and provisions governing ADMC “results management.”²¹⁰

The Agency does not have “exclusive” authority over the adjudicatory process under the Act. Further, contrary to the Kentucky Horsemen’s suggestion, the Agency and the Authority are not cabined in strictly defined roles but are obligated to consult with each other in several important respects. For example, the Agency must “consult” with the Authority’s ADMC standing committee to develop “[ADMC] rules, protocols, policies, and guidelines,” as well as lists of “prohibited medications, methods, and substances” for the Authority’s approval.²¹¹ Along similar lines, the Agency is obligated “to consult” with the Authority’s standing committee and Board “on *all* [ADMC] rules”—including those involving adjudications “of the Authority”²¹² Indeed, the Agency is obligated to “implement[] the [ADMC] program on behalf of the Authority.”²¹³ Clearly, the Act’s framework does not impose the rigid separation claimed by the Kentucky Horsemen but rather reflects a collaborative process between the Agency and the Authority.

²⁰⁵ *Id.* § 3055(a)(1).

²⁰⁶ *Id.* § 3057(c).

²⁰⁷ *Id.* § 3054(c)(1)(A).

²⁰⁸ *Id.* § 3053(a)(10).

²⁰⁹ *Id.* § 3053(a)(8), (a)(9).

²¹⁰ *Id.* § 3057(c)(1)(A).

²¹¹ *Id.* § 3055(c)(4)(A), (c)(5).

²¹² *Id.* § 3054(f) (emphasis added).

²¹³ *Id.* § 3054(e)(1)(E)(i).

Second, the Kentucky Horsemen complain that Proposed Rules 3361, 7060(b), 7110(b), and 7180, which concern the adjudication of alleged controlled medication rule violations, fail to provide the “adequate due process” required under 15 U.S.C. § 3057(c)(3) because they allow the IAP to rely solely on the parties’ written submissions instead of holding an evidentiary hearing where adverse witnesses can be cross-examined. Cross-examination, the Kentucky Horsemen claim, is required under § 3057(c)(2)(B).²¹⁴ The Kentucky Horsemen further assert that an in-person hearing is required at the adjudicative stage because there is no assurance that there will be an evidentiary hearing before an Administrative Law Judge when the final sanction is reviewed by the Commission under 15 U.S.C. § 3058.²¹⁵ The Kentucky Horsemen also contend that proposed Rules 7180(c) and 7180(d) fail to provide due process by presumptively disallowing reply briefs.²¹⁶ Lastly, say the Kentucky Horsemen, the rules impose “disparate subpoena power” by allowing the Agency to seek relevant information during the investigation and again during the adjudicatory proceeding, whereas the accused may seek relevant information only during the adjudicatory proceeding.

The Authority responds that its proposed ADMC rules were “fully compliant” with its due-process obligations under 15 U.S.C. § 3057(c)(3) and that a hearing was also available before the Commission under 15 U.S.C. § 3058.²¹⁷

The Commission finds that Proposed Rules 3361, 7060(b), 7110(b), and 7180 confer sufficient due process protections to satisfy the criteria in § 3057(c)(3). The Rules allow the

²¹⁴ First Ky. Horsemen Cmt. at 8–17. Section 3057(c)(2) lists the elements that “shall” be included in the disciplinary process. Section 3057(c)(3) states that the ADMC rule “shall provide for adequate due process, including impartial hearing officers or tribunals commensurate with the seriousness of the alleged . . . [ADMC] rule violation and the possible civil sanctions for such violation.”

²¹⁵ First Ky. Horsemen Cmt. at 8–14.

²¹⁶ *Id.* at 10.

²¹⁷ Authority’s Response at 2.

parties to submit “all supporting documentation” on which they seek to rely²¹⁸ and permit adjudication on written briefs alone *only* if the IAP determines that it will be “sufficiently well-informed to render a decision” without a hearing.²¹⁹ Written submissions could include, for example, documentation from the sample collection session reflecting the results of the collection and the integrity of the procedures employed, relevant materials received from third parties by IAP order,²²⁰ and information or documents obtained from the other party.²²¹

The procedures employed in IAP proceedings to resolve medication control rule charges were deliberately made simpler and less costly “partly in response to requests by commenters to provide for a simplified hearing process for Covered Persons charged with a violation.”²²² “The procedure allows the adjudication process to dispense where appropriate with certain of the more formal and costly aspects of legal proceedings.” *Id.* The submissions also fit comfortably within the Act’s command that “adequate due process” be “commensurate with . . . the possible civil sanctions for such violation.” 15 U.S.C. § 3057(c)(3). Infractions of the Authority’s medication control rules result in fines and do not lead to periods of ineligibility. If the only available sanction in the Authority’s proposed rules were a lifetime ban from the industry, “adequate due process” would likely require more. But with the sliding-scale approach to discipline evidenced in its proposals, the Authority’s medication control rule violation procedures provide “adequate due process” that is “commensurate” with the available sanctions. This process is therefore fully consistent with long-standing Supreme Court precedent recognizing that due process does not

²¹⁸ Notice, 88 Fed. Reg. at 5199 (Proposed Rule 7180(e)).

²¹⁹ *See id.* at 5118, 5197 (Proposed Rules 3361, 7060(b)).

²²⁰ *See id.* at 5199 (Proposed Rule 7260(b)).

²²¹ *See, e.g., id.* at 5165 (Proposed Rule 5410) (providing detailed procedures for sample collection, including presence of horse trainer or owner to ensure the integrity of the sample); *id.* at 5199 (Proposed Rule 7190) (allowing for “the exchange of information between the parties” and authorizing the adjudicator to “resolve any disputes” that might arise from that exchange); *id.* (Proposed Rule 7260(b)) (permitting party to request IAP member(s) to order production of any document which the party believes to be “relevant and material to the dispute”).

²²² *Id.* at 5083.

require administrative evidentiary hearings where adequate procedural safeguards are in place and probative information can be provided through written documentation.²²³

The pertinent procedural safeguards here include a provision for timely notice of an alleged infraction, the right to have charges resolved by an impartial adjudicator,²²⁴ the right for responsible parties to directly observe the same collection process, and the ability of responsible parties to record any concerns on a form that would be provided to the IAP if charges are brought.²²⁵ Moreover, no commenter has credibly alleged that the IAP would be anything but “impartial.” 15 U.S.C. § 3057(c)(3). The Kentucky Horsemen, for example, provide no evidence to support the suggestion that an adjudicator jointly chosen by the Authority might show bias. Nonetheless, part of the Authority’s response is off base. Although the Authority rests on the observation that the accused may always seek an evidentiary hearing in Commission review proceedings under § 3058,²²⁶ § 3057(c)’s due process requirements relate solely to the Authority’s own processes. But as discussed above, the Commission finds that the Authority’s hearing procedure satisfies the requirements for due process stated in § 3057.

As for “international best practices,” § 3055(b)(4) of the Act requires the Authority to “consider[] international anti-doping and medication control standards to the extent consistent with” the Act, which the Authority did by “rely[ing] heavily on international anti-doping standards” in preparing its ADMC rules.²²⁷ Regarding reply briefs, the IAP has the discretion to permit those if it determines that doing so will better inform its decision-making.²²⁸ Finally,

²²³ See *Mathews v. Eldridge*, 424 U.S. 319, 343, 345 (1976); see also 88 Fed. Reg. at 5081, 5118 (the comparatively less serious sanctions imposed for controlled medication rule violations—as compared to anti-doping rule violations—allow for a more flexible and informal adjudicatory process for which written submissions alone may be adequate).

²²⁴ See Notice, 88 Fed. Reg. at 5196 (Proposed Rule 7040(a)).

²²⁵ See *id.* at 5165 (Proposed Rule 5410).

²²⁶ Authority’s Response at 2.

²²⁷ Notice, 88 Fed. Reg. at 5072.

²²⁸ See *id.* at 5199 (Proposed Rule 7180(c), (d)).

differences in the subpoena power of the Agency relative to the accused simply reflect the ordinary manner of public investigations, in which the enforcement body obtains a subpoena to gather enough evidence to determine whether to bring charges.²²⁹ If charged, the accused may seek from the IAP a subpoena (or several) for witnesses, documents, and other evidence to defend herself.²³⁰

Third, the Kentucky Horsemen challenge Proposed Rules 3264, 3364, and 7400, which govern review of final adjudicative decisions, as failing to provide a separate intra-Authority appeals process that they claim is required by 15 U.S.C. § 3057(c)(2)(F).²³¹ The Kentucky Horsemen assert that each of these rule provisions, which provide that a final decision of the IAP will be considered the final decision of the Authority and will be reviewable by the Commission, “completely fail to provide an appeals process before” review to the Commission. According to the Kentucky Horsemen, “the only way to properly reconcile . . . Section 3057(c)(2)(F) and Section 3055(c)(4)(B)” is to conclude that an appellate review process is required before the stage of Commission review.²³² They assert that each of those provisions, which provide that the final decisions of the adjudicator are “subject to [Commission] review in accordance with Section 3058 of the Act,” must be interpreted to require a separate appellate review by the Commission after an internal appeals process within the Authority.²³³

The Authority disagrees but provided little guidance other than the tautology that “the Act does not require an additional level of appeal within the Agency beyond the appeal procedures established by the Act and the ADMC Rule proposal.”²³⁴ As relevant here, 15 U.S.C.

²²⁹ See Notice, 88 Fed. Reg. at 5072.

²³⁰ See *id.* at 5200 (Proposed Rule 7260(f)).

²³¹ First Ky. Horsemen Cmt. (Additional Comment).

²³² *Id.*

²³³ See Notice, 88 Fed. Reg. at 5109, 5118, 5200 (Proposed Rules 3264 (Agency or the Arbitral Body), 3364 (Agency or the IAP), 7400 (Arbitral Body or IAP)).

²³⁴ Authority’s Response at 1–2.

§ 3507(c)(2)(F) requires that the Authority establish procedures for appeals of any sanctions imposed through the "disciplinary process" before the IAP, and § 3055(c)(4)(b) provides that "review" of a "final decision" resulting from an ADMC rule violation proceeding constitutes the "final decision" of the Authority," which may be "reviewe[d] [by the Commission] in accordance with Section 3058." Giving effect to both provisions and reading them together leads to a conclusion that the Commission's "review" under § 3058 of the final decision of the IAP *is* the "appeal" from the disciplinary proceeding before the IAP contemplated by § 3057(c)(2)(F). If Congress had intended a different result, it would have made clearer its intent for two separate review proceedings at each level. Accordingly, no additional review is required at the Commission.

In addition, 15 U.S.C. § 3507(c)(3) requires the rules to provide for adequate due process commensurate with the seriousness of the alleged violation and the possible sanctions for such violation. Because infractions involving medication controls do not lead to a period of ineligibility, the process specified in Proposed Rules 3264, 3364, and 7400 satisfies the statutory standard in 15 U.S.C. § 3047(2).

The Texas Commission criticizes the "creation" of a National Stewards Panel in Proposed Rule 7130(b), asserting that racetrack stewards cannot be expected to assume additional duties given the "enormous responsibilities" already placed on them for their respective racing jurisdictions.²³⁵ In addition, the Texas Commission sought clarification on the applicable methods for exchanging information between parties under Proposed Rule 7190.²³⁶

²³⁵ Second Tex. Comm'n Cmt. at 3.

²³⁶ *Id.*

As to Proposed Rule 7130(b), the Authority responds that the panel will consist of “qualified individuals” who volunteer for a position and that “no steward will be required to serve on the Panel.”²³⁷ The Authority does not respond to the inquiry about Proposed Rule 7190.

The Commission finds that Proposed Rule 7130 is consistent with the Act. Proposed Rule 7130 governs the appointment of administrative hearing panels to adjudicate cases arising from alleged violations of the anti-doping and controlled medication rules. Under Proposed Rule 7020(b), a charge resulting from an alleged controlled medication rule violation is adjudicated by members of an IAP, the new name for the pre-existing National Stewards Panel.²³⁸ Proposed Rule 7040(f) specifically allows stewards to serve “concomitantly” as IAP members (as long as they have no conflict of interest), but the proposed rule provisions do not oblige stewards to perform such service. Indeed, Proposed Rule 7130(b) provides that even a steward who has volunteered to serve as an IAP member may decline to participate in any particular case if doing so would impose a “personal hardship.”

Proposed Rule 7190 addresses “the exchange of information between the parties consistent with the expedited nature of the proceedings.”²³⁹ It also empowers the arbitrator or IAP member to resolve information disputes between the parties.

The Commission finds that Proposed Rule 7190 is consistent with the Act’s goal of an expedited and fair resolution of charges filed for ADMC rule violations. If experience shows that information requests are not being complied with, or that resolution between the parties has been

²³⁷ Authority’s Response at 27.

²³⁸ See Notice, 88 Fed. Reg. at 5083.

²³⁹ Second Tex. Comm’n Cmt. at 3. Proposed Rule 7190 (Exchange of Information) provides that “information shall be exchanged electronically, unless otherwise agreed by the parties. The arbitrator(s) and IAP member(s) are authorized to resolve any disputes concerning the exchange of information between the parties consistent with the expedited nature of the proceedings.”

minimal, the Commission recommends that the Authority submit a proposed rule modification to impose deadlines in these rules to resolve discovery matters.

Scrivener’s errors were found in Proposed Rule 7180(c) and (d) and will be fixed in the final rule.²⁴⁰

g. Comments Unrelated to the Commission Determination

The Commission received many comments that were unrelated to whether the proposed rules are consistent with the Act and the Commission’s procedural rule. Such comments will not be discussed here. For example, at least one commenter takes issue with a rule in a different rule series that the Commission already approved in previous order.²⁴¹ The United States Trotting Association comments about the different medical treatment and training needs for Standardbred horses, but such horses are not now subject to the Act.²⁴² Other comments are unrelated to any particular rule provision; some discuss concerns about other aspects of equine welfare (and its impact on human health),²⁴³ while others criticize the Act more generally. By far the most common example of the latter category consisted of comments that assert that the Act is an unconstitutional violation of the private-nondelegation doctrine; these comments cite to the same Fifth Circuit decision from November 2022²⁴⁴ that commenters claim has resulted in “legal uncertainty” and the lack of national uniformity over horseracing regulation.²⁴⁵ Congress

²⁴⁰ In Rule 7180(c) and (d), the words “Arbitral Body” will be deemed as corrected to “Internal Adjudication Panel” in the final rule.

²⁴¹ See Cmt. of Jim Roberts (Feb. 1, 2023) (discussing Proposed Rule 2143(a)), <https://www.regulations.gov/comment/FTC-2023-0009-0020>.

²⁴² Cmt. of U.S. Trotting Ass’n 1–3 (Feb. 8, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0079>.

²⁴³ See Second AWI Cmt. at 4–5 (discussing NTRA’s estimate that 7,500 thoroughbreds are “transported across the border to be killed for human consumption” and the “distinct public health and food safety risks as these horses are routinely treated with a range of drugs that are expressly prohibited for use in meat products due to their toxicity to humans”); First AWI Cmt. at 4–5 (same).

²⁴⁴ *Nat’l Horsemen’s Benevolent & Protective Ass’n v. Black*, 53 F.4th 869 (5th Cir. 2022).

²⁴⁵ See, e.g., Cmt. of Pacific Legal Foundation (“PLF Cmt.”) 5–7 (Nov. 14, 2022), <https://www.regulations.gov/comment/FTC-2022-0062-0020>; Second Ky. Horsemen Cmt. at 1; Second Nat’l Horsemen Cmt. at 1; Cmt. of Zach Badura (Feb. 14, 2023); Cmt. of Terry J. Westemeir 1 (Feb. 6, 2023); Cmt. of MaryAnn O’Connell at 1.

addressed the private nondelegation concern by amending 15 U.S.C. § 3053(e) to give the Commission the power to “abrogate, add to, and modify the rules of the Authority.”²⁴⁶ Indeed, the Sixth Circuit has addressed and upheld the amended statute as constitutional.²⁴⁷ The many (mostly duplicative) comments maintaining that legal uncertainty remains either fail to provide an explanation or erroneously base it on a second ruling by the Fifth Circuit that remanded the case for further proceedings in light of the statutory amendment.²⁴⁸ Commenters have also claimed, with little support, that the Act violates other constitutional²⁴⁹ and statutory²⁵⁰ provisions.

The Commission discerns no persistence of “legal uncertainty” following the statutory amendment. In any event, these comments do not relate to the statutory decisional criteria and thus are irrelevant to the Commission’s decision whether to approve or disapprove the ADMC proposed rule.

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²⁴⁶ Consolidated Appropriations Act of 2023, Pub. L. No. 117-328, 136 Stat. 4459, 5231–32 (2022).

²⁴⁷ *Oklahoma v. United States*, No. 22-5487, 2023 WL 2336726 (6th Cir. Mar. 3, 2023) (upholding the law against non-delegation and anti-commandeering challenges).

²⁴⁸ See, e.g., Cmt. of U.S. Reps. Lance Gooden and Jake Ellzey (Feb. 9, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0102> (maintaining that the amendment to 15 U.S.C. § 3053(e) did not cure the statute’s constitutional infirmity and recommending that the Commission disapprove the proposed ADMC rules); Cmt. of U.S. Trotting Ass’n (Feb. 8, 2023) (same); Cmt. of K. Myrick (same); Ky. Horsemen Cmt. at 1 (Att. 1) (same); Cmt. of Kim Williams (Feb. 8, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0086> (noting that ARCI has asked the Commission to refrain from approving the ADMC proposed rules until resolution of the Act’s constitutionality was resolved); Cmt. of Jared Easterling, General Counsel, Global Gaming Solutions, LLC (Feb. 9, 2023) (“Global Gaming Cmt.”), <https://www.regulations.gov/comment/FTC-2023-0009-0101> (discussing Fifth Circuit’s decision in January 2023 not to withdraw its original holding); Tex. Comm’n Cmt. at 1 (claiming that “the Authority as private actors remains the initial rule drafters regardless of attempts to fix the facially unconstitutional Act”); Cmt. of Liberty Justice Center (Feb. 8, 2023), <https://www.regulations.gov/comment/FTC-2023-0009-0084> (legal uncertainty of the Act remains and emphasizing the need for national uniformity). The Authority disagrees with those comments. See Authority’s Response at 3 (Fifth Circuit’s decision concerned the prior version of the Act before the Congressional amendment addressed that court’s concern).

²⁴⁹ See PLF Cmt. at 7–10 (claiming the Act violated Articles II and III of the Constitution and the Seventh Amendment).

²⁵⁰ See Global Gaming Cmt. at 1–2 (claiming proposed ADMC rules and any Commission approval of those rules would violate the Regulatory Flexibility Act, the Small Business Regulatory Enforcement Fairness Act, the Unfunded Mandates Reform Act, and the Paperwork Reduction Act).

For the preceding reasons, the Commission finds that the Horseracing Integrity and Safety Authority's ADMC proposed rule is consistent with the Horseracing Integrity and Safety Act of 2020 (as amended) and the Commission's procedural rule governing submissions by the Authority. Accordingly, the Anti-Doping and Medication Control rule is APPROVED.