WORLD ANTI-DOPING AGENCY
play true

Stakeholder Notice regarding potential meat contamination cases[1]

This Stakeholder Notice explains how a *Results Management* Authority should manage potential meat contamination cases involving clenbuterol, ractopamine, zeranol, or zilpaterol.

A. New reporting requirements for clenbuterol, ractopamine, zeranol, and zilpaterol

Anabolic agents are prohibited for *Athletes* at all times and at any concentration. However, certain anabolic agents may be used in certain countries as a livestock growth promoter. Depending on the circumstances, the consumption of meat containing residues of such anabolic agents may lead to very low concentrations of those anabolic agents and/or their *Metabolites(s)* in an *Athlete's* urine. Laboratory instrument sensitivity now allows detection of anabolic agents and their *Metabolites* in urine *Samples* at low nanogram per mL (ng/mL) levels and, in some instances, much lower. However, it is not currently possible for anti-doping laboratories to distinguish between (a) low concentrations that reflect the tail-end of excretion of a steroid used for doping purposes; and (b) low concentrations that are due to the consumption of contaminated meat.

The World Anti-Doping Agency (*WADA*) has taken various steps to address this issue, and the potential unfairness to innocent *Athletes* that may result. In particular:

- On 16 May 2019, the *WADA* Foundation Board approved the amendment of Article 7.4 of the 2015 World Anti-Doping Code to allow *WADA*-accredited laboratories to report the presence of *Prohibited Substances* identified by *WADA* at or below 5 ng/mL as an *Atypical Finding*, triggering an investigation to determine whether that presence may be due to ingestion of contaminated meat. The first *Prohibited Substance* treated in this way was clenbuterol, due to its prevalent use as a growth promoter in certain countries.[2]

- *WADA* subsequently convened a working group of scientific and legal experts (the 'Contaminants Working Group') to conduct a thorough assessment of the risk of *Athletes* returning *Adverse Analytical Findings* for prohibited anabolic agents as a result of eating the meat products of livestock that had been administered such anabolic agents to promote their growth prior to slaughter. Contamination of meat is generally below levels that are relevant to human health. However, the potential exists for *Adverse Analytical Findings* to result, depending on the specific growth promoter used, the administration regime and withdrawal period observed, and the timing of collection of the *Sample* from the *Athlete* who consumed the meat products.

- The Contaminants Working Group determined that clenbuterol is used in China, Mexico, and Guatemala as a growth promoter for cattle, lamb, poultry, and swine; that ractopamine is used in certain countries

[1] Unless otherwise indicated, words or phrases in italics and/or underlined have the meaning given to them in the World Anti-Doping Code and/or the International Standards.

[2] See *WADA* Stakeholder Notice regarding meat contamination dated 30 May 2019 (2019-05-30-meat_contamination_notice_final.pdf), which is replaced by this Notice.

as a growth promoter for cattle, swine, and large breed turkeys; that zeranol is used in many countries as a growth promoter for cattle; and that zilpaterol is used in certain countries as a growth promoter for cattle. The group assessed the likely residual levels of such substances in the carcass following slaughter if the guidelines on dosage and withdrawal periods were followed, but also if they were not (given that there appears to be significant variability in best practices and agricultural product monitoring and enforcement in certain countries).

- The Contaminants Working Group also considered the concentrations of such substances likely to be found in the urine of *Athletes* who consumed the meat products of such livestock. It determined that the scientific evidence indicates that it is highly unlikely that consumption of edible tissue from livestock fed on clenbuterol or ractopamine or zeranol or zilpaterol would lead to a urinary concentration of that *Prohibited Substance* (or, in the case of zeranol, of zeranol or its *Metabolite*(s)) of more than (>) 5 ng/mL. Instead any urinary concentrations caused by consumption of contaminated meat would likely be below (<) 5 ng/mL.

- Therefore, on the recommendation of the Contaminants Working Group, on 21 May 2021 the *WADA* Executive Committee approved the introduction of the following new requirements, with effect from 1 June 2021:[3]

  - Laboratories shall report the presence in a *Sample* at a concentration of more than (>) 5 ng/mL of clenbuterol or ractopamine or zilpaterol, or of zeranol or its *Metabolite(s)*, as an *Adverse Analytical* Finding, and the normal *Results Management* process shall apply.

  - Laboratories shall report the presence in a *Sample* at a concentration at or below (≤) 5 ng/mL of clenbuterol or ractopamine or zilpaterol, or of zeranol or its *Metabolite(s)*, as an *Atypical Finding*, and the *Results Management* Authority shall conduct an investigation, in accordance with Article 5.2 of the *International Standard* for *Results Management*, to determine whether that finding may be due to ingestion of contaminated meat.

B. The investigation of an *Atypical Finding*

When a *Results Management* Authority receives an *Atypical Finding* from a *WADA*-accredited laboratory for clenbuterol or ractopamine or zilpaterol, or zeranol or its *Metabolite(s)*, at a concentration at or below (≤) 5 ng/mL, it shall take the following investigative steps:

1. Conduct a review in accordance with Article 5.2 of the *International Standard* for *Results Management* to determine (a) whether an applicable *TUE* has been granted or will be granted for the substance in question; or (b) whether there is any apparent departure from the *International Standard* for *Testing* and *Investigations* or the *International Standard* for *Laboratories* that caused the *Atypical Finding*. If so, no further action shall be taken in respect of the *Atypical Finding*. If not, the further investigative

[3] As an interim measure while the TD2021MRPL is under review, these are reflected in a new Technical Letter 23 - *Minimum Reporting Level for Certain Substances Known to be Potential Meat Contaminants* (TL23).

steps set out below shall be followed.

2. As soon as possible, and in any event before notifying the *Athlete* of the *Atypical Finding*, collect another urine *Sample* from the *Athlete* in a *No Advance Notice* test.

3. Review the *Athlete's* steroid *Athlete Biological Passport* as well as the *Athlete's* prior *Testing* history for any potential abnormalities. Consider whether analytical results from the testing of other *Samples* tend to corroborate or rule out either the doping hypothesis or the meat contamination hypothesis.

4. Determine (e.g., from the *Athlete's* recent whereabouts filings) in which country or countries the *Athlete* was located in the days leading up to collection of the *Sample* that returned the *Atypical Finding.*

5. Contact and interview the *Athlete* about the circumstances of the *Atypical Finding*, including finding out: (A) the country or countries where they were located in the days leading up to collection of the *Sample* that returned the *Atypical Finding* (see para 4, above); (B) where they travelled in that country/those countries; and (C) whether they ate any meat products in the 72 hours prior to collection of the *Sample.*

6. Where the *Athlete* says that they ate meat products in the 72 hours prior to the collection of the *Sample*, determine whether there is evidence of use of the substance in question as a livestock growth promoter in the country where the meat was bought (or the country from which the meat was imported, if different). This may resolve the inquiry: for example, if the *Atypical Finding* is for clenbuterol, clenbuterol is not used as a growth promoter outside of China, Mexico, and Guatemala.

7. If step 6 does not resolve the inquiry (i.e., if the *Prohibited Substance* in question is used as a livestock growth promoter in the country where the meat came from), gather as much evidence and information as possible about the source of the meat product, including purchase details and (if available) where the livestock was reared and slaughtered, and what exactly was eaten, including the type and cut of meat (i.e., flesh and/or organs - as these growth promoters are known to accumulate in liver and offal), when and where it was eaten, and the quantity consumed. The *Athlete*'s explanation and any evidence tendered as corroboration (e.g. food diaries, food menus, restaurant or grocery store purchase receipts, credit card statements, dining partners, social media, etc.) should be carefully evaluated.

8. Determine the regulations, guidelines, and/or best practices followed in the administration of the substance to livestock, and the monitoring and enforcement thereof, in the country of origin of the meat consumed. *WADA* may also be able to provide guidance regarding current governmental regulations and/or past case history related to the specific substance in that country.

9. Evaluate whether the estimated urinary concentration of the *Atypical Finding* is consistent with the consumption of meat described by the *Athlete*, by evaluating the timing of ingestion relative to *Sample* collection, and by considering the excretion properties of the substance as described in the scientific literature, always bearing in mind that meat contamination becomes materially less likely to be the

cause of the *Atypical Finding* the closer the urinary concentration gets to the 5 ng/mL limit.[4]

10. The above is not intended to be an exhaustive list of possibly relevant investigative steps. The *Results Management* Authority should pursue all potentially relevant lines of inquiry and take into account all of the relevant facts and circumstances.

Once the investigation is completed, if the *Results Management* Authority is satisfied that the *Atypical Finding* was caused by inadvertent contamination from meat consumed by the *Athlete* prior to *Sample* collection, the *Results Management* Authority shall take no further action against the *Athlete.* However, it shall report that conclusion (with reasons) to all parties with a right of appeal pursuant to Article 13.2.3 of the World Anti-Doping Code, and its decision to take no further action remains subject to appeal by any such party.

On the other hand, where the *Results Management* Authority is not satisfied following investigation that the *Atypical Finding* was caused by inadvertent contamination from meat consumed by the *Athlete* prior to *Sample* collection, the *Results Management* Authority shall pursue the *Atypical Finding* as an *Adverse Analytical Finding* in accordance with Article 5.1 of the *International Standard* for *Results Management.* The *Athlete* may still contend, in support of a plea in mitigation of *Consequences*, that the *Adverse Analytical Finding* was a result of ingestion of contaminated meat, but it will be their burden to establish that on the balance of probabilities.

We trust that the instructions found in this Notice will assist *Results Management* Authorities faced with potential meat contamination cases and will ensure that cases are managed fairly for all *Athletes*. In the event that *WADA* identifies in the future other exogenous *Prohibited Substances* that are known meat contaminants, it will update this Notice accordingly.

[4] Laboratories and/or *WADA* may be able to assist with the most up-to-date human pharmacokinetic and pharmacodynamic data as well as known patterns of *Adverse Analytical Findings* based on geographical region.