WADA WORKING GROUP ON CONTAMINANTS

The Working Group recommends as follows:[1]

A. RECOMMENDED MINIMUM REPORTING LEVEL FOR CERTAIN DIURETICS THAT ARE KNOWN CONTAMINANTS OF PHARMACEUTICAL PRODUCTS

1. Subject to paragraph 3, below, a *Minimum Reporting Level* (*MRL*) of 20 ng/mL shall be established for hydrochlorothiazide, acetazolamide, furosemide, torsemide, triamterene, and bumetanide. The presence of one or more of these diuretics or their metabolites in an *Athlete's* urine *Sample* at an estimated concentration at or below (≤) 20 ng/mL shall not be reported either as an *Adverse Analytical Finding* (*AAF*) or as an *Atypical Finding* (*ATF*).

   Rationale: Diuretics may be abused to mask the presence in urine of other *Prohibited Substances*. However, trace quantities of the six diuretics named above have been found as contaminants in oral pharmaceutical products, including both products available by prescription and products available over the counter. While these products are still compliant with purity levels required by good manufacturing practices, the trace quantities are sufficient to cause an *AAF*, due to the improved sensitivity of the testing methods used by *WADA*-accredited laboratories. At estimated urinary concentrations of 20 ng/mL or less, a diuretic would not be effective to mask the presence of any other *Prohibited Substances* that may be present in the *Sample*. Therefore, the new *MRL* for the six diuretics named above will minimize the risk of sanctioning *Athletes* who test positive due to use of contaminated medications, without undermining the fight for clean sport.

2. As a consequence, notes (e) and (g) of TD2019MRPL, relating to the detection of threshold substances (salbutamol, formoterol, cathine, ephedrine, methylephedrine and pseudoephedrine) shall be amended as follows (new text indicated by underlining, deleted text indicated by striking through):

   e. Salbutamol and Formoterol are considered Threshold Substances; therefore, their determination and reporting are covered in the Technical Document on Decision Limits (TD DL). When detected in a sample in conjunction with a prohibited diuretic (at an estimated concentration higher than the *MRL* applicable to that diuretic, if any), or in the presence of any other diuretic or a masking agent (at any concentration), these substances shall be reported as an *Adverse Analytical Finding* at any concentration.

   g. Cathine, Ephedrine, Methylephedrine and Pseudoephedrine are considered Threshold Substances; therefore, their determination and reporting are covered in the Technical Document on Decision Limits (TD DL). When detected in conjunction with a prohibited diuretic (at an estimated concentration higher than the *MRL* applicable to that diuretic, if any), or in the presence of any other diuretic or a masking agent (at any concentration), these substances shall be reported as an *Adverse Analytical Finding* only if present above the *MRL* ~~reporting level~~ established for stimulants (*i.e.* 50 ng/mL) ~~refer to section 4.0 of this Technical Document) should be applied~~.

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

A similar correction will be needed in Articles 2.1 and 2.2, respectively, of the recently approved TD2021DL, which has an effective date of 1 April 2021.

3. As the sole exception to this new *MRL* for hydrochlorothiazide, acetazolamide, furosemide, torsemide, triamterene, and bumetanide, where a *Sample* is collected from an *Athlete* participating in a sport or discipline that uses weight classes, laboratories shall report the presence of one or more of these six named diuretics or their metabolites at an estimated concentration equal to or below (≤) the *MRL* of 20 ng/mL as an *ATF*, triggering a mandatory investigation by the Results Management Authority (*RMA*) to determine whether an anti-doping rule violation (*ADRV*) should be asserted.[2]

   Rationale: Diuretics may be abused to induce weight loss in sports/disciplines where *Athletes* need to meet weight criteria. This risk exists both *In-Competition* and *Out-Of-Competition*. Therefore, when a laboratory reports the presence of one or more of the six diuretics identified above (or their metabolites) at an estimated concentration of 20 ng/mL or less in the *Sample* of an *Athlete* competing in such a sport or discipline, the *RMA* shall conduct an investigation to determine whether it is appropriate in all the circumstances to bring proceedings asserting commission of an *ADRV*. *WADA* will supply laboratories with a list of the sports/disciplines that use weight classes and therefore where this exception applies.

B. RECOMMENDED MINIMUM REPORTING LEVEL FOR CERTAIN SUBSTANCES KNOWN TO BE POTENTIAL MEAT CONTAMINANTS

1. The presence in urine of clenbuterol or zilpaterol or ractopamine, or of zeranol or its metabolite, at an estimated concentration of more than (>) 5 ng/mL shall be reported as an *AAF*.

   Rationale: Clenbuterol is used (unlawfully) in China, Mexico, and (according to laboratory testing statistics) Guatemala as a growth promoter for cattle, lamb, poultry, and swine. Zilpaterol is used in certain countries as a growth promoter for cattle. Ractopamine is used in certain countries as a growth promoter for cattle, swine, and large breed turkeys. Zeranol is used in many countries as a growth promoter for cattle. However, all of the scientific evidence indicates that it is highly unlikely that consumption of edible tissue from livestock fed on clenbuterol or zilpaterol or ractopamine or zeranol would lead to a urinary concentration of the *Prohibited Substance* (or, in the case of zeranol, of the parent compound or its *Metabolite*) of more than (>) 5 ng/mL. Therefore, such a finding should be reported as an *AAF* and the standard results management process should be applied. Where an *ADRV* is asserted, the *Athlete* may still seek to prove meat contamination, as the basis for a plea in mitigation of the *Consequences* to be imposed for the *ADRV*, but the *Athlete* will have to satisfy the hearing panel that meat consumption is more likely than not to be the cause of the *AAF*, notwithstanding that the level of the substance found in their sample is significantly greater than what would generally be expected from meat contamination.

2. The presence in urine of clenbuterol or zilpaterol or ractopamine, or of zeranol or its *Metabolite*, at an estimated concentration at or below (≤) of 5 ng/mL shall be reported as

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[2] A Stakeholder Notice will be published, detailing the mandatory investigative process.

an *ATF*, triggering a mandatory investigation by the *RMA* to determine whether evidence exists that establishes that meat contamination is more likely than not the explanation for the *ATF*. If there is sufficient evidence to accept meat contamination as the explanation, an ADRV shall not be asserted. If there is insufficient evidence to support meat contamination as the explanation, an *ADRV* shall be asserted. In such circumstances, the *Athlete* may still seek to prove meat contamination, as the basis for a plea in mitigation of the *Consequences* to be imposed for the *ADRV*.

Rationale: Depending on the circumstances, the consumption of meat containing clenbuterol or zilpaterol or ractopamine or zeranol may lead to (respectively) very low urinary concentrations of clenbuterol or zilpaterol or ractopamine, or of zeranol or its *Metabolite*. Therefore, the presence in urine of clenbuterol or zilpaterol or ractopamine, or of zeranol or its *Metabolite*, at a concentration of 5 ng/mL or less shall be reported as an *ATF*, even though the likelihood of meat contamination as the cause decreases materially the closer the urinary concentration gets to that limit. Upon receipt of the *ATF*, the *RMA* shall conduct a mandatory investigation to determine whether or not there is sufficient evidence to support meat contamination as the explanation.[3] If so, no *ADRV* shall be asserted against the *Athlete*. The investigation shall take into account all of the relevant facts and circumstances. For example, where properly corroborated, consumption shortly before sample provision of meat from a country where contamination with clenbuterol is a recognized issue, such as China, Guatemala or Mexico, may be accepted as an explanation for a clenbuterol *AAF*.

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3. In each case mentioned in A and B above, when the specific gravity (SG) of the urine sample in question (as measured in the laboratory) is greater than (>) 1.018, the concentration of the substance estimated in the urine shall be adjusted prior to reporting according to the following equation:

(Eq. 2) $$\mathrm{Conc_{adj}} = \frac{(1.020 - 1)}{(\mathrm{SG_{Sample\_Max}} - 1)} \cdot \mathrm{Conc_{measured}}$$

Refer to the effective TD DL for instructions on calculating SG_{Sample_Max}].

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[3] This process has been in place for clenbuterol since 2019 and working well. See WADA Stakeholder Notice regarding meat contamination dated 30 May 2019 (2019-05-30-meat_contamination_notice_final.pdf), which will be updated following acceptance of this recommendation to reflect the additional substances recognized as potential meat contaminants (zilpaterol, ractopamine, and zeranol).