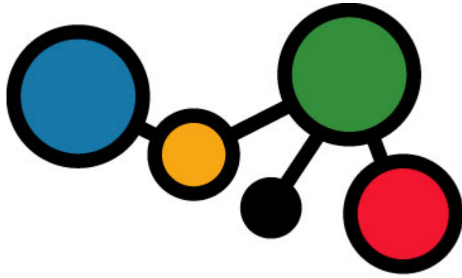

By e-mail to: violet.maziar@wada-ama.org

Regarding: Netherlands reaction to draft 2009 Prohibited List International Standard

Capelle aan den IJssel, June 17th 2008

Dear Mr. Howman,

Thank you for your invitation to review the draft 2009 Prohibited List International Standard. With this letter, I would like to provide you with the comments of the Netherlands, a joint submission of four stakeholders: the Ministry of Health, Welfare, and Sports, the National Olympic Committee NOC*NSF, the NOC*NSF athlete committee, and the official NADO, Anti-Doping Authority the Netherlands.

As always, we have given this review considerable attention as 'the List' is of the utmost importance to our day-to-day work, and also to the credibility of all anti-doping efforts to both the athletes and the general public. In addition to the official organisations mentioned above, we have consulted doctors, pharmacists and other professionals who work in the field.

We would like to offer our assistance if the work of the List Committee can be helped by explaining our proposals in more depth or by providing more data. We would be more than happy to do so.

General comments

We would like to start our comments with stating that many offenders of the anti-doping rules are not premeditated cheats. It is our experience that a large minority, and perhaps even a small majority, tests positive because of clumsiness, forgetfulness or downright stupidity, despite even the best of educational efforts. Notwithstanding this unintentional use, these athletes are at fault and sanctioned, and rightly so. These athletes often accept the consequences of their mistake because they perceive the anti-doping system as both necessary and fair, and justifiably so. But at the same time these cases jeopardise the support that the anti-doping regulations currently possess and we fear that in the long term the credibility of our work could be affected. As an example to underline this opinion, a recent review of all international doping cases in the sport of tennis over the years 2003-2007 revealed that 27 out of 40 cases (68 percent!) were most likely non-intentional violations, as determined by the arbitration panels involved. These facts are the basis of most of our comments in this letter.

A second general comment regards the fact that the doping rules and regulations are increasingly moving towards general medical guidelines, and in our opinion this is a process that inevitably will lead towards problems. Doping and health are two areas that possess a clear overlap, but that also are distinctly different. WADA has no mandate to declare 'general medical practice', yet in introducing the new rule regarding infusions last year the doping rules are placed above regular medical guidelines. In every nation different customs exist regarding infusions, but quite often no alternative medical approach exists. WADA's desire to monitor these costumes lead to an ever increasing workload for ADOs (see also our comment under M2).

As a related issue the first sentence on the Prohibited List ('The use of any drug should be limited to medically justified indication') is rather curious. This sentence is equally true for the misuse of anti-psychotics, narcotics, non-steroidal anti-inflammatory drugs, and of corticosteroids – to name just a few examples. Yet some substances are considered doping and some are not. When compiling the Prohibited List the criteria laid down in article 4.3 of the World Anti-Doping Code are the guidelines that should be followed, and more specifically one should interpret these criteria in an anti-doping context. In this interpretation, it should be acknowledged that competitive sport is built on the principle of athletes pursuing their best possible performances and the anti-doping rules are there to protect the integrity of these performances. We argue that the Prohibited List, with all its major implications as described in the World Anti-Doping Code, should lay specific focus on the aspect of improving athletic ability, while following all rules as set out in that Code.

In this respect it is also interesting to call into memory the debate that was held a couple of years ago about the possible banning of hypoxic chambers. The outcome of the debate showed that the world of sport expects WADA to promote, coordinate and monitor the fight against doping without being too strict on practices that may be peculiar but should not be considered doping. This sort of discussions are of immense value to the strength of all anti-doping regulations, and we hope that our comments add to the debate and thus strengthen the World Anti-Doping Program.

S1

The long texts explaining what happens when values are found outside the 'normal' range are still very difficult to interpret because of the complicated legal language that is used. They also differ from the texts in the Technical Document TD2004EAAS. The List states that three additional tests should be performed when three previous results are not available (after an atypical result), where the Technical Document mentions up to three additional tests, as long as there is a minimum of three results. In our view, the latter option is preferable, but since both documents are legally binding Level 2 documents within the World Anti-Doping Program, these texts should not differ.

In addition to the previous remark, we would like to suggest that most of the texts explaining the courses of action after an atypical result should be moved to a technical document. The Prohibited List should list the prohibited substances and methods; the way in which evidence is gathered in order to determine whether a violation has occurred or not is more technical and distracts the attention from the List's true focus.

Moving epitestosterone to this category is understandable. With the same reason in mind, it would have been logical in our view to move the group of plasma expanders towards category M2 (see also our comment under S5).

S3

The term 'abbreviated TUE' is used here (and also in S9), but in the new TUE Standard (effective January 1st 2009) this term is not used anymore. These texts should be in line with the new standard.

S5
The addition of the word 'intravenous' explains that the three plasma expanders that follow are only prohibited when administered intravenously. All intravenous injections are already prohibited in category M2, however, so there is an unnecessary and possibly confusing overlap between these two groups (see also our comment regarding epitestosterone and plasma expanders under S1).

The remark 'A Therapeutic Use Exemption is not valid if an Athlete's urine contains a diuretic in association with threshold or sub-threshold levels of a Prohibited Substance(s)' remains to be puzzling. We assume that the reference to thresholds includes the thresholds that are mentioned in the Technical Document TD2004MRPL, but it is perfectly natural to have traces of 19-norandrosterone in one's urine below the threshold of 2 ng/ml. Yet this would mean that an officially granted TUE for a diuretic would not be valid. A better text would be 'A Therapeutic Use Exemption for diuretics is not valid if an Athlete's urine contains a diuretic in association with threshold or sub-threshold levels of (an) exogenous Prohibited Substance(s)'.

M2
The explanatory note announces extra explanations on the issue of intravenous infusion, and this is much needed. The total ban on all intravenous infusions caught us by surprise last year because it was introduced after the stakeholder consultation round had finished. It is very difficult to explain to medical personnel, and it requires our TUE committee to handle a lot of extra applications, primarily from regular surgeries that are in no way doping related and that are often performed out of season. In our personal correspondence with WADA on this issue, we were told that alteration of sample quality is primarily what WADA is concerned about from the anti-doping perspective, and it would be very practical to have an official document that makes such a statement.

M3
We are of course not native speakers of English, but we fear that the combination of words 'to modulating' is not entirely correct and should be changed into either 'to modulate' or '…with regard to modulating the…'.

S6
According to the explanatory note, the division of the group of stimulants into a specified part and a non-specified part is based on at least eleven different criteria, ranging from medical, physiological, historical to economical. It is important to judge each substance on its merits, but given the long list of relevant criteria the end result is arbitrary at best. The distinction specified / non-specified is made in order to allow for appropriate sanctions when mitigating circumstances are present. But what happens with benzylpiperazine-positives that are based on contaminated supplements? Cocaine-positives because of analgesics used in nose or ear surgery? Bromantan positives because of legitimate medical use? We foresee problems in this area and given the current version of the explanatory note we will not be able to explain such cases to the athletes and to the media. We would like to ask the List Committee to state clearly what arguments have been weighed more heavily than others (history of use, pharmacological potential or other).

On the issue of pseudoephedrine we would like to make the following statements:

- The graph presented in the appendix states that these are the data of all monitoring labs (n=17). It is interesting to know what labs were used, since the availability of pseudoephedrine is very different in various parts of the world. The number of athletes who are using it depends, among other things, on the availability of of pseudoephedrine as an over-the-counter cold medicine. The fact that 0.92% of the samples contained this substance in 2007 could very well mean that 0.92% of the tested athletes had a cold – it does not necessarily mean that they were abusing the substance.

- The graph lists cases where the urinary concentration was above 25 mcg/ml, but the (preliminary) proposal is to establish a threshold of 100 mcg/ml (we assume that the threshold of 100 mcg per *litre* that is mentioned in the Appendix is a typo…). This makes it difficult to interpret the old data in relation to the new proposal.
- The text states that after an initial rise in its use (which is perfectly understandable since its ban had just been lifted) there is a 'plateau'. But looking at the graph a clear drop can be seen since 2005. It is strange to put a substance back on the Prohibited List when its use seems to decline in the last two years.
- Athletes and their support personnel are not helped by confusing decisions on taking substances off the list, and relisting them again. Since pseudoephedrine is a borderline decision chances are that it will be taken off again in a few years time. In addition, the Andreea Raducan case in 2000 is still extremely influential on the image of our work and the world of anti-doping cannot afford to list a substance that is highly likely to render more non-intentional doping cases, which is likely to be the result of putting pseudoephedrine back on the list.
- In our view the facts mentioned above do not necessarily mean that pseudoephedrine should not be listed, but we would like to ask the List Committee to carefully weigh all arguments again, including the ones we made above. In order for ADOs to be able to explain changes of the Prohibited List all of these arguments need to be addressed in the explanatory note.
- Whatever the decision of WADA may be, we are very interested in the data that support the suggested 100 mcg/ml threshold. This is important information, but without background information we are not in a position to comment on this suggestion. We highly value the consultation processes on all of WADA's decisions regarding the Code and its standards and we assume that consultation will also be part of this decision.

S8

For years, we have expressed our views on the presence of cannabinoids on the Prohibited List and on the selective use of the "Spirit of Sport" criterion in this regard. We are still of the opinion that the anti-doping community should refrain itself from banning the use of a substance that is immoral, but that is highly unlikely to improve athletic abilities and that is no more contrary to the spirit of sport than speeding on ones way to a training venue, binge drinking after a victory (or defeat) or money laundering with prize money – all of them acts that are not subject to the sanctions listed in the World Anti-Doping Code.

Last year we and several other stakeholders have proposed an alternative way of dealing with this substance, which in our opinion would cater for all differing views that exist. One year further along the road we still feel that using this approach, based on the rules regarding whereabouts failures and missed tests, offers an opportunity to tackle cannabis use while still keeping it on the Prohibited List. We know that we are not the only stakeholders who would support such an approach (and we would like to stress that our opinion in this matter does not originate from the specific position of cannabis within the Dutch criminal system but is based on firm anti-doping sentiments). We also know that this subject really divides the anti-doping community and we urge WADA to try and find a solution that recognises both positions rather than deciding in a manner which completely rejects the strongly held views of one group.

S9

Regarding corticosteroids we would like to share some very recent scientific data with the List Committee. The Maastricht University in the Netherlands has performed a study to determine the effects of glucocorticosteroids on maximal power output and mood state. A balanced, double blind, placebo-controlled design showed that four weeks of daily inhalation of 800 μg budesonide (twice the standard dose) did not have any effect on

these characteristics in 28 well-trained cyclists and rowers. These findings have been published in the (peer reviewed) British Journal of Sports Medicine.

These findings corroborate previous studies on this issue that performance enhancing properties of corticosteroids are unlikely. In our view, the fact that they are misused in certain sports does not justify listing them on the Prohibited List for all sports, especially because of their disproportionate impact on the TUE systems. Given the current body of scientific evidence, which has increased even more in the past year, we do not feel that these substances should be part of the S- or M-groups of the Prohibited List.

New Code, new list?
The revised WADC, going into force January 1st 2009, will strengthen the world wide anti-doping efforts even further, and we would like to reiterate our appeal from last year that this revision also marks an opportune time to thoroughly restudy the structure and contents of the Prohibited List. The efforts made by the List Committee in 2002/2003 were highly appreciated, and since then the removal of caffeine has served the anti-doping community well. The Prohibited List would benefit from a re-evaluation of the much discussed topics of, among other things, beta-2 agonists, glucocorticosteroids, and cannabinoids.

This could also be a good time to address strange anomalies like the absence of thyroid hormones from the Prohibited List (being performance enhancing in all sports where body weight is a decisive factor, and possessing many side effects) and the ever unclear status of nicotine (which can be considered a substance with a similar biological effect to many stimulants, but is nevertheless not considered to be prohibited in practice). Addressing these issues would increase the strength of the Prohibited List.

We hope that our remarks and ideas can be of service to the WADA List Committee. As stated before, we will be more than happy to provide any help or additional clarification if this is needed.

With sincere greetings and wishing you and your team all the best in compiling the Prohibited List for 2009,

Also on behalf of the Ministry of Health, Welfare, and Sports, the National Olympic Committee NOC*NSF, and the NOC*NSF athlete committee,

Anti-Doping Authority the Netherlands

Herman Ram
CEO