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CCES DISCUSSION PAPER

SUPPLEMENTS AND SPORT

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Date: September 2003

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SUPPLEMENTS AND SPORT

Can supplements be safely consumed by elite athletes without the risk of committing a doping infraction? This is the fundamental question this discussion paper addresses. This paper reviews the issues posed by supplement use by athletes and suggests possible responses.

INTRODUCTION

The Canadian Centre for Ethics in Sport (CCES) is aware that nutraceutical products and dietary supplements (“supplements”) are widely available to and used by athletes and the general public. Athletes have told the CCES that gaining credible and reliable information on supplements is a priority for them. The CCES is committed to providing athletes with reliable information and appropriate guidance so that they play fairly, do not inadvertently harm themselves or their competitors and do not test positive for prohibited substances.

Many Canadians, including a substantial number of Canadian athletes, use supplements because they believe it necessary to augment their regular nutrition practices. They believe supplement use may make them healthier, may alter body composition, may provide them with additional energy and may enhance their athletic performance. Inherent in these beliefs is the erroneous assumption that supplements are effective and safe for all people under all circumstances.

However, supplements can, and often do, contain prohibited substances. Regulation of supplements in Canada and elsewhere is limited. For example, it does not guarantee the content and accurate labeling of supplements. The contents of particular products may change from batch to batch. Labels do not always indicate all of the ingredients; or do they always do so in a way that identifies prohibited substances. Therefore, it is not currently possible for the CCES or any other organization to guarantee that all the ingredients have been listed on the packaging and/or whether the composition may vary during production from batch to batch, without notice. Athletes use supplements at their own risk of testing positive for a prohibitive substance and committing a doping infraction.¹

The CCES believes that the issues surrounding the use of supplements by athletes must be closely examined. This examination will lead to a better understanding of the underlying risks of their use. It will also lead to concrete actions to minimise those risks to athletes. While the CCES’ primary concern is the doping risk associated with the use of supplements, often health and safety risks cannot be disentangled from the use of supplements.

ISSUES

What are “supplements”?

Supplements can be viewed as being in two categories:

1. **Dietary supplements.** The products in this category are taken to meet the dietary needs of high performance athletes whose training and travel schedules may pose unique needs and challenges.
2. **Ergogenic Aids** - The products in this category are used to enhance performance.

For the purposes of this paper, “supplements” include non-pharmaceutical products such as herbal preparations, nutritional products and other supplements which may fall into either of the categories above. These would include “natural health products” subject to proposed new *Natural Health*

¹ See Annex 1, below, for a listing of recent domestic and international arbitration decisions on doping infractions involving nandrolone, just one of the prohibited substances often associated with use of dietary supplements.

Products Regulations, such as vitamins, homeopathic preparations, traditional medicines, amino acids, botanicals and extracts, essential fatty acids, probiotics and minerals or synthetic duplicates of any of these products.

The consumption of supplements, herbal preparations and homeopathic remedies among the Canadian population has increased markedly in the past few years. Consumer spending on supplements has become an extremely lucrative business in North America as well as throughout the world. Manufacturers are continuously developing new products claiming to meet the needs of all segments of the population – from children to seniors. It should therefore come as no surprise that elite athletes are one of the segments targeted by manufacturers of supplements.

Athletes' Views

Although elite athletes represent a small niche of the overall supplement market, manufacturers have become very aware of the athlete's desire to gain a training and performance edge over their competitors, and have therefore incorporated this into their marketing strategies. Athletes have access to products that claim to improve various aspects of sport performance from increased muscle size, weight gain, fat loss, increased energy or endurance, all the way to improvements in recovery from injury or heavy training. There are literally thousands of products available and, with the advent of the internet, athletes can obtain any type of supplement from anywhere in the world. By catering to athletes, manufacturers appear to be aiming for the wider market of active, health conscious Canadians.

Recent athlete discussion sessions conducted by CCES have indicated that many Canadian athletes are involved in a supplement use regime. Athletes indicate they are constantly struggling to meet the demands of their athletic careers.² For example, most athletes feel they do not receive enough government funding and are therefore required to find part-time jobs to support the high costs of participation in their sport. Others are trying to balance school with part-time jobs while they train to achieve national and international status in their sport. This balancing act poses a challenge for athletes as they strive to maintain a healthy diet and obtain an adequate amount of rest to recover from strenuous workouts.

Some athletes report they are tired, have difficulties maintaining an adequate and healthy diet, and argue they require supplementation to balance the scale. However, there is another segment of the athlete population that take supplements for the performance enhancement they feel they receive from taking such substances. Other reasons for supplement use by athletes may include following questionable advice from trainers and coaches, through to replicating the winning methods of those athletes seen to be at the top of their field.

Sections of the sport community, including some sporting organizations, college sporting programs, elite coaches and trainers, openly support the use of supplements. This may not only be for the supposed performance enhancing benefits associated with their use. The value of a partnership with large multinational companies, and the input of resources into program sponsorships, may also influence the decision of coaches and school programs pushing for the use of certain supplement products by their athletes.

² See Annex 2, below, for a summary of athlete, coach, sport doctor and sport administrator views on dietary supplement and sports issues.

Education

Recent claims from athletes that their positive test results were caused by contaminated supplement products has resulted in some athletes exercising increasing caution when choosing to use a product.³ Others have stopped using supplements altogether stating that the risks far outweigh any known benefit.

Despite a recent trend for elite athletes to show some caution, there remains a fairly significant segment of the athlete population that is completely unaware of the risks associated with supplements. This segment comprises high school and club level athletes who begin supplement use at an early age and bring this practice with them as they progress to higher levels in their athletic careers.

Educational initiatives directed at Canadians in respect to the health and safety risks associated with supplements have been minimal. Elite athletes are likely the most educated segment of the athlete population through CCES initiatives, which include the CCES website, Athlete Handbook, Drug Classification Booklet and a series of supplement advisory notes. Included in these initiatives are aspects of an informed decision making model developed by the 'Centre for Substance Use in Sport and Health' (SUSH). The model is designed to assist athletes in deciding whether it is worthwhile using a supplement.

The risks athletes face with respect to testing positive and the consequent sanctions from their sport, have motivated some to become more educated on the topic. Unfortunately, the athlete segment which includes high school and club level athletes is largely unaware of the doping and health risks associated with supplements. The unfortunate and alarming result is that this uneducated group uses these products on a regular basis and form their purchasing decisions on recommendations from their friends, team mates and coaches.

Roles and Responsibilities

The CCES is the lead organization with responsibility for administering all aspects of Canada's Doping Control Program. This includes policy development, detection, deterrence, education and research. Because of the association (in Canada and elsewhere) between supplements and positive doping tests, the CCES has an obligation to address the issues related to supplements.

Supplement information coming from manufacturers in the form of marketing and sponsorship campaigns is largely unreliable. Advice on supplement use from trainers and others in positions of influence with athletes is often ill-informed. This has resulted in confusion among athletes and a tension within the sport community. A perceived need by athletes for the use of supplement products is in direct contrast to the CCES' current position of discouraging their use both on scientific and ethical grounds.

The CCES has therefore taken on the task of developing an action plan that will enable the CCES to assist athletes and their support staff on how to make informed decisions regarding their use of supplements. It is the CCES' endeavour to provide a solution framework that will enable us to provide more practical supplement information to athletes.

³ The position taken by the CCES in its most recent Advisory Note on the matter is that while it is still preferable to avoid the risk posed by dietary supplements by not using them, athletes who choose to take these products should do so in a deliberate and considered way by reviewing a series of questions or topics (such as product effectiveness, health side effects, risk of positive tests, affordability, etc.). For a copy of this Advisory Note, go to: http://www.cces.ca/forms/index.cfm?DSP=template&act=view3&template_id=129&lang=e

Other Issues

It should also be noted, that in addition to the position on supplement use adopted by the CCES, international agencies including the World Anti-Doping Agency (WADA) and the International Olympic Committee (IOC), strenuously urge athletes to stay away from supplements because of the possible doping and health risks associated with their use.

The risks associated with supplement products stem from several key issues:

Lack of Regulatory Process

In Canada (and throughout the world) the industry that manufactures supplements is largely unregulated. The absence of specific regulation, and for substantial portions of industry, proper manufacturing standards, has led to instances of improper labelling of constituents, product contamination, and adulteration. In other words, the lack of regulation and poor quality practices results in the inability to determine the purity and quality of these products.

There is also a lack of regulation on the marketing practices of those selling supplement products. As long as a manufacturer does not make claims concerning a supplement's effect on certain diseases or disorders, the current regulatory situation permits a manufacturer to market a product without pre-approval. Since pre-market approval is not necessary, contamination is a key concern. What manufacturers claim is in the bottle may in fact not be there; or alternatively, what is in the bottle may not be listed on the label. Several athletes have argued that improper labelling and contamination have been the causes for their positive drug test results.

Lack of Scientific Research

Most supplement products have undergone little scientific research. Many questions remain as to the safety, efficacy, and correct dosages for products⁴. The premise of usefulness for supplement products is based largely on biochemical theory of chemical reactions within the body. The peer reviewed clinical studies providing evidence of the biochemical theory has, up to this point, been lacking. If the industry is to convince the sports community of the benefits and safety of using supplement products, independent peer reviewed evidence will become a necessity.

While some producers have done science-based research in developing and supporting their products, research that answers some of the questions below is needed to restore any credibility to the industry as a whole and reduce the overall confusion concerning the effectiveness and safety of supplements;

- Product use effects on performance
- Physiological effects for athletes and the normal population
- Identifying individuals who would benefit most from a particular supplement
- Interactions with other drugs,
- What are the dangers for people with unknown underlying medical conditions?

Because the patenting of supplements is difficult to obtain, there is very little incentive for manufacturers to invest in clinical trials.

⁴ For comprehensive review of current dietary supplement research and accepted scientific protocols refer to the Australian Institute of Sport Nutrition Department website at <http://www.ais.org.au/nutrition/CSNsupp.htm>

Industry

As a result of the lack of regulations, the growth of the supplements industry continues at a rapid rate. The range of participants varies from the multinational pharmaceutical companies and food manufacturers through to the backyard homeopathic remedy salesperson or the ‘fly by night’ entrepreneur out to make a few quick dollars.

The unfortunate situation has arisen where the reputable, reliable manufacturers that follow high quality manufacturing standards cannot be distinguished from those with questionable motives and practices. The inconsistency in standards and the irresponsibility of some producers, has allowed a tarnished image of the industry as a whole to permeate the sporting community.

Moreover, it seems the less reputable have little incentive to regulate their practices, which might potentially stifle their growth and potential for profit, when the willingness of consumers to purchase products with minimal product safety or efficacy information, continues unabated.

Examination of Possible Solutions

Surveys conducted by the CCES asked athletes what should be done about the risks associated with supplement use. The majority of responses centered on some form of harm reduction approach, which would “guarantee” the product is safe from a doping point of view. Indeed several national anti-doping organizations have already implemented harm reduction schemes attempting to reduce the risks certain products may pose. However, as discussed in the introductory section, the problems stretch over a broad range of issues, not just harm reduction. Any long term solution will need to look at areas such as education, research and industry reform.

The CCES has neither the mandate nor the expertise to support or promote the use of supplements by athletes. Our goal is to ensure athletes have the information they need to pursue sporting excellence in a fair and doping-free way. This will require an examination of a wide range of possible solutions to the problem.

It is not the intention of the CCES to provide a false sense of security to athletes who wish to consume supplement products. The principle of strict liability of the athlete will continue to be a foundation of Canada’s anti-doping programme, as required by the World Anti-Doping Code to which the Canadian sport community must become compliant by the start of the Athens 2004 Olympic Summer Games.

This section will examine possible solutions to several of the key issues raised in the previous section. Where indicated, some of the initiatives have already begun, while others will require further investigation as to their suitability for a CCES action plan. Some will require action by others - such as by manufacturers or government regulators. The CCES is already engaged in informal discussions with representatives of both.

A brief overview of the possible solutions follows;

1. **Harm Reduction**
 1. A. Listed Products
 1. B. Quality Products
 1. C. Approved Products

2. **Industry Reform**
 2. A. Industry Collaboration
 2. B. Regulation

- 2. C. Athlete Action
- 3. **Education**
 - 3. A. Poster Campaign
 - 3. B. Informed Decision Making Models
 - 3. C. Substance Fact sheets
 - 3. D. Coach Education
 - 3. E. Global Drug Information Database
 - 3. F. Pharmacists Initiative
- 4. **Research**
 - 4. A. CCES Research
 - 4. B. Academic Research

1. **Harm Reduction**

A harm reduction approach refers to a program that gives athletes reliable information about the products they wish to use with the goal of reducing potential harm from uninformed use of supplements. The level of reliability of information is dependant upon the level of commitment of supplement producers and the degree of ‘regulation’ or oversight by a designated authority, be it the CCES, a sporting body, an accredited laboratory and/or a third party or independent agency participating in the program.

The degree of oversight has influence in three key areas:

- **Athlete Protection** - the degree to which the athlete is protected from the risk of inadvertent ingestion of a prohibited substance.
- **CCES Responsibility** - the degree to which the CCES or other oversight body has the responsibility of minimising the athletes’ risk of inadvertent ingestion of a prohibited substance is minimised.
- **Manufacturer Responsibility** - the degree to which the manufacturer has the responsibility of ensuring the athletes’ risk of inadvertent ingestion of a prohibited substance is minimised.

1. A. *Listed Products*

The principle behind a Listed Products approach is that products that meet minimal standards are listed in a publicly-accessible database for access by athletes. The minimal standards requirement in this case would be a substance analysis performed by an independent laboratory, checking for the presence of prohibited substances. A key feature of this framework is the athlete entering into a one on one relationship with the manufacturer through a written guarantee (including an offer of compensation) issued by the manufacturer ensuring their product does not contain substances which would cause the athlete to produce a positive test result. For this scheme, oversight (by the CCES or some other body) would be limited to maintaining the database, and ensuring that the requisite analysis and guarantee are provided and kept current. The overseeing body would offer no direct assurance that listing on the database assured that products were doping risk free. However, listing (involving independent analysis plus a manufacturer’s guarantee) would generate information with a degree of reliability about supplements that does not currently exist.

A Listed Products approach may involve some of these steps:

1. Supplement manufacturers pay to have their products tested by an independent laboratory
2. After receiving the analysis certificate, the manufacturer decides whether to provide athletes with a legally binding written guarantee (i.e. guarantee absence of any prohibited performance enhancing substances)

3. Manufacturers who are willing to issue a guarantee become part of a Listed Product Database
4. Athletes who contact the CCES in regard to the status of a supplement are given information as to whether the manufacturer is willing to guarantee that product
5. Athlete is required to contact the manufacturer to obtain the written guarantee
6. Manufacturer writes a letter to the athlete guaranteeing the purity of its product
7. Athlete has legal recourse with the manufacturer should a positive test result occur
8. Manufacturer may “back” the guarantee with a promise to compensate an athlete for a positive test result and post a substantial (seven figure) bond to provide the money for that purpose

Other key features of this approach include:

- The manufacturer has a high level of responsibility in this approach. The athlete is relying on information from the manufacturer and by providing a written guarantee to the athlete, they are ensuring a duty of care to the athlete.
- The level of intervention by the CCES is minimal. The CCES acts as a conduit for the athlete to access information as to which manufacturers have had their products tested and which ones are willing to provide a written guarantee.
- While not simple, such an approach could be set up reasonably quickly and at a minimum cost, and would be a marked improvement in reliability of information currently available to athletes about supplements.

The Australian Experience

A Product Guarantee program was recently implemented for athletes in Australia. The project team developing the program consisted of Australian Sports Drug Agency (ASDA), the IOC accredited laboratory in Australia, Australian Government Analytical Laboratories (AGAL) and the countries top sport training centre, the Australian Institute of Sport (AIS). The Project team went with a guarantee system for several reasons;

- This system attempts to put the onus of responsibility back onto the manufacturers and industry, which are ultimately responsible for their products. A critical mass of companies guaranteeing their product would leave those not providing a guarantee with a disadvantage in being able to market their products to athletes
- Manufacturers ‘owning’ the problem may instigate positive change in the industry
- This system is relatively cost effective to the Project members, most costs are borne by the manufacturer
- It limits the liability of the Project members in the incidence of an athlete testing positive from an approved product

Some of the process issues this program encountered are:

1. **Testing Laboratory** – On completion of analysis of the product, AGAL issues a certificate of analysis only. This is not a certificate of quality assurance. The indication was that any IOC accredited lab would not provide a quality assurance certificate under any circumstances. The certificate is for the sample provided only, not for the entire production batch, or product line, it is up to the company to determine if they guarantee the entire product line from one test sample. If a product changes in any way, be it ingredients, source of ingredients, or manufacturing procedures, it is up to that company to have the product reanalysed.
2. **Testing procedures** – To provide the most accurate test results, the product would need to undergo a substance analysis, as well as an excretion study using volunteers. This second test

was not mandatory to begin with. Since testing had started, it was discovered that not all constituents can be verified by substance analysis alone, so the excretion study has become a mandatory requirement for inclusion in the product database. The combined testing for each product, depending upon the type of product, could cost between \$2000 and \$5000 Australian dollars (\$ 5000 AUS = approx \$4500 CAN). While this may be cost prohibitive for smaller manufacturers with several products, it could have the effect of ensuring that only manufacturers truly committed to providing “clean” products participate.

3. **Guarantees** – By agreeing to provide athletes with a guarantee under this program, companies were agreeing to provide a duty of care to the athlete to ensure what goes into the product does not cause a positive test result. Athletes were informed via education tools to only accept guarantees that conformed to certain standards e.g., letterhead paper, certain wording of statements, signatories etc. Any company deviating from these standards would have their product erased from the company database.
4. **False sense of security** – It is possible that by providing the athlete with a guarantee for a product that they would be provided with a false sense of security regarding the product’s safety. A large part of the education following the start of this program has needed to focus on the fact that the athlete is still under strict liability.
5. **Endorsement** – The manufacturers having their products tested under the program had to agree not to advertise any involvement or link between their company and the three agencies involved. The analysis was not an endorsement of that product, and the company was only to state that they offer a written guarantee for their product.
6. **Manufacturer participation** - Some larger companies felt that being unable to use an endorsement from the program may provide little incentive to be involved and leave little scope for marketing. It will take a critical mass of participating companies before the incentive can be realised by participants. Some long term thought is required to highlight that those not taking part in the end will be at the disadvantage.

Although only in its infancy, initial reports indicate a mixed response from athletes. One segment of the community are pleased that something is being done about the problem, as they now have some practical information when it comes to choosing a product. Others feel that not much has changed, and feel that it will not benefit them in the long run. Most athletes felt that this program has allowed them to make a more informed decision when choosing products and dealing with supplement companies.

1. B. Quality Products

The basic principle behind a Quality Product approach is that manufacturers and their products would meet a set of criteria that designates them as having met high standards of manufacturing practices, as well as product safety and efficacy. In this case, the products meeting these requirements would receive a ‘Quality Seal’, directly from, or recognized by, a designated sporting authority or other overseeing body. The steps required to issue a Quality Seal may involve:

- An authority (as yet undetermined) would develop a set of measurable criteria for manufacturers to meet to obtain a ‘Quality Seal’
- These criteria would designate standards the product must meet in areas such as manufacturing, quality control, labelling, and marketing claims made by supplement companies
- Independent product testing would be required to meet the criteria

- Supplement companies that meet all the criteria are given permission to place a 'Quality Seal' label on their product

The 'Quality Seal' would assure consumers of three things:

- there are no prohibited substances in the product
- the product will do no harm and is safe for consumption
- any marketing claims are backed by scientific evidence

Some key features of this approach include;

- This approach represents an increased involvement by a sporting authority such as the CCES compared to the listed products model. Since the reliability of information about supplements is enhanced, the level of protection afforded to the athlete is also increased. They would have an increased level of assurance that the product with the 'Quality Seal' meets high standards and will not cause a positive test result.
- The level of responsibility is shared more evenly between the manufacturer and the sporting authority. There would still be some reliance on the information provided by the manufacturer, but that would be cross-referenced with the experts in the field of manufacturing, nutrition etc, depending upon the agreed criteria. By allowing products to use the seal of quality, the sporting authority takes some responsibility in ensuring the athlete does not inadvertently ingest a prohibited substance.
- This approach would be accessible to all manufacturers in the supplements industry. Those manufacturers with already high standards of quality control and labelling will meet the set criteria comfortably, while those who do not meet the high standards set will have incentive to improve their practices.
- This approach represents a relatively simple system for access by all athletes, regardless of age and ability, as well as the general population, to have more practical information when choosing supplement products.
- A 'Quality Seal' probably carries some connotations of *general approval* regardless of what is said to the contrary. To limit the possible exposure associated with the stated responsibilities above, education of the athlete would need to convey that the product meets high standards but has stated limitations.

Who would provide the Seal of Quality, and how would it be recognised? There are several different possibilities and the choice between them might affect the legitimacy of such an approach. Some of the options are:

1. **Health Canada** - Health Canada already plays a significant role in the regulation of the supplements industry. Although there seems to be a role for Health Canada for more stringent regulation industry-wide (discussed in the next section), it is not clear if it would have the authority or the desire to play the oversight role for a 'Quality Seal' scheme. For example, the connotations of approval associated with a 'Quality Seal' could be an ethical mine field for Health Canada and unlikely to encourage it to play such a role.
2. **Peak Industry Body** – An industry body providing a 'Quality Seal' is not a new concept. One of the better known 'Quality Seals' is the Canadian Dental Association (CDA) Seal of Approval (recognising that it is granted by an association of professionals as opposed to an

association of product manufacturers). The development of a sports supplements peak industry body is an idea that has received some attention particularly in the United States. However, that version has been more concerned with industry health and growth rather than consumer confidence and safety. They do not have a seal of approval for their associated products.

What exactly does the CDA Seal mean? It means that the CDA (representing Canada's dentists) review submissions from manufacturers to verify the acceptability of research and evidence that the statement of claim made by the manufacturer can be scientifically supported. The manufacturer has to prove that what they say works, actually does work, and meets quality standards in the process. If it does, the company pays an annual renewable fee to carry the Seal of Approval on its products.

If the supplement manufacturing industry were to have a peak body with a seal of approval, could it be assumed, given the track record of some in the industry, that its objectivity and ethics would match those of an independent self-governing profession such as dentistry? Is there an option for use of the quality seal for supplements being governed by a committee of professionals representing a recognized profession, rather than a trade organization? Would an organization representing an industry avoid any temptation or avoid any perception of placing the interests of the industry before those of athletes? Would this organization have legitimacy with athletes?

- 3. Athlete Sporting Authority** – This would need to be a body that represented Canada's athletes at all levels of competition. The athletes group, with input from government, CCES, nutritionists, scientists etc. could form their own set of strict criteria, similar to that of the CDA, where the manufacturer has to show they meet the claims on the label.

One possible organization who may be able to fulfill this role is Athletes CAN. This organization represents Canada's National Team athletes.

In a similar role to CDA, Athletes CAN could review submissions from manufacturers to verify the acceptability of research and evidence that the statement of claim made by the manufacturer can be scientifically supported. The manufacturer has to prove that what they say works actually does work, and meets quality standards in the process. If it does, it pays an annual renewable fee to carry the Athletes CAN Seal of Approval on its products.

This type of approach would provide greater assurance to athletes. However, Athlete CAN's involvement would hinge on its capacity and resources to run such a program. It does not appear that such capacity and resources currently exist.

- 4. CCES** – The CCES could also be a credible overseeing body (if it had the necessary capacity and scientific/technical assistance). For CCES to take on such a role, there are additional ethical issues (given our mandate which does not include athlete nutrition, and our current position on supplements and our role in anti-doping). A CCES 'Quality Seal' probably carries connotations of *general approval* for supplement products regardless of what caveats might be stated. In other words, even if the CCES and a manufacturer could agree exactly what is meant by CCES "approval," the CCES would have to anticipate that playing this sort of oversight role would inevitably be interpreted as condoning and even encouraging use of the "Quality Products."

These ethical consequences would be less of a concern if it were handled by an authority separated from anti-doping issues.

Alternatively, the CCES could recognise on behalf of athletes, a Quality Seal developed by a professional or an industry group with independent athlete, government and nutritionist representation. This group could develop the appropriate criteria, and the CCES would take some responsibility in recognising that the products carrying that seal are of a high standard and pose less of a risk than those not carrying the Seal.

1. C. *Approved Products*

The basic principle behind this concept is that supplement products would be tested and approved by a designated authority for use by athletes. “Approval” could go as far as a distinct supplement brand or product line. The authority would have direct input into the manufacture, testing and quality standards control of each product. For the sake of this discussion, the CCES might act as the designated authority, but this role could also be filled by other groups such as a panel of anti-doping experts and/or the Canadian Olympic Committee.

There are two options such a program may pursue:

1. The testing and approving of products made by other manufacturers to develop a group of “Approved” or “Low Risk” supplements.
2. The collaborating and partnering with a manufacturer of nutritional supplements to produce a “CCES” or other sport “brand” of products⁵.

Key features of both of these options are similar in that;

- This model represents the highest level of intervention by the CCES or other sport or oversight body. By becoming involved in the manufacturing and direct testing of products, the level of responsibility to the athlete is higher than in the previous two models.
- The increase in the level of intervention from an oversight body allows more control over the type of approved product being presented to athletes. Any line of approved products would be restricted to those for which there is evidence of efficacy and safety.
- This model represents the highest level of athlete protection. Direct CCES or other sport or oversight body involvement may ensure that the athlete risk of inadvertently ingesting a banned substance is reduced dramatically. The concept of an approved product would give the athlete peace of mind in the knowledge that products have been approved independently of the manufacturers, and that their specific product of choice could be cleared for use.

Several other nations have looked into developing similar schemes.

The Netherlands Experience

In the Netherlands, the Netherlands Centre for Doping Affairs (NeCeDo) is working with government departments and the Netherlands Olympic Committee on a project to realize labeling and control of food supplements concerning doping substances.

All athletes of the Netherlands taking part in the Winter Olympic Games in Salt Lake City were given the chance to have their supplements analyzed for a number of doping substances including

⁵ A recent press report (Globe, 14/03/03) indicates the NFL Players Association is exploring the possibility of supplying their own brand of supplement products. The initial strategy is to make these products available to players through their teams but may be a product line available to all athletes in the future.

stimulants, prohormones and steroids. Dutch athletes provided sixty-nine supplements for analysis. Of the first fifty-five to be analyzed, 25% contained prohibited substances without indication on the labeling or other product information. As yet no product or brand names have been made public. Only the athletes themselves were informed confidentially by the physician of the Dutch Olympic team about the outcome of the analyses. Based on the results and the experiences of this first phase, the project members will try to create an information/labeling system for sports supplements.

The Australian Experience

A similar program was attempted by the Australian Sports Drug Agency (ASDA) some time ago, although it involved categorizing products into sections that may have provided practical information to athletes. It was a joint initiative between ASDA, the IOC accredited laboratory in Australia, Australian Government Analytical Laboratories (AGAL) and the country's top sport training centre, the Australian Institute of Sport (AIS)⁶. These three organizations formed a 'Supplements Doping Safety Taskforce', to develop possible solutions in providing athletes with more practical supplement information. The initial outcome of that taskforce was a program that involved a panel of experts from the medical and nutritional fields placing products into three categories:

- "Low Risk"
- "Unknown Risk"
- "Banned Restricted substance category"

These categorizations were based on the knowledge of the ingredients by the taskforce members.

Products in the Unknown Risk category were then to be submitted by the taskforce for further analysis at the expense of the manufacturer to determine their safety. Athletes would then be able to access product status information via the ASDA website.

Aside from difficulties associated with testing and "approving" products discussed in the following section, this concept was deemed to be too large a drain on sport and government resources. The costs to set up the infrastructure, administrative and legal resources to test several thousand products several times a year was thought to be too demanding for the taskforce members.

With increased levels of intervention come added implications for the CCES or other sport or independent oversight body. Some of the issues are:

1. **Ethical** - The CCES is entrusted by the Canadian sporting community with conduct of domestic doping control. A potential conflict of interest arises between CCES' role as an impartial tester for banned substances and any role as a perceived "endorser" of commercial products which under current circumstances may be implicated in a positive test result.
2. **Scientific** - From a scientific and an ethical point of view, the CCES currently questions the credibility and the consequences of the message that high performance sport requires supplements. This raises the fundamental question: what peer-reviewed, scientific evidence is there that supplements are helpful to high performance athletes as opposed to appropriate diet? In the absence of an answer to this scientific question, the interest of the CCES in encouraging supplement use, or product endorsement by sport organizations, is at best unsubstantiated.

⁶ A more detailed examination of the AIS Nutritional Supplements policy and the circumstances leading to the formation of this Project Group, can be found below at Annex 4

3. **Capacity** - The CCES is not itself a testing laboratory and as a practical matter does not have its own capacity to evaluate individual products or substances. Even if the CCES had this capability, it does not currently have the budget for such product testing by itself or by an appropriate laboratory. Moreover, any proposed partnership may encourage individual athletes to use the supplements in question and likely require them to sport the manufacturer's logos and trade marks. The CCES has serious concerns about the effect this could have on Canada's domestic doping control program and the message this sends to young people that elite sport requires supplements.
4. **Risk of Positive Tests** - If the CCES were to evaluate and "approve" products, it would refuse to do so in the case of many supplements, due to the considerable risk of a positive test result. In the absence of adequate regulation, or reliable means of distinguishing between responsible and irresponsible manufacturers, the CCES could not ensure that particular batches of the supplements would not cause a positive test. Even if one or a few batches of supplements were found to be "safe", there is no guarantee that all batches of products of all supplement manufacturers are safe. That level of assurance would entail a quality assurance role that is outside the scope of the CCES and as a practical matter is probably beyond the capacity of the Montreal (or any other) IOC accredited laboratory
5. **Industry standards** - The CCES has concerns whether all supplement manufacturers can guarantee that all of the ingredients to their products (and the ingredients of those ingredients) will never be contaminated. In the absence of adequate regulation, the CCES could not ensure that industry standards alone are adequate to prevent positive tests. The CCES is unaware of the evidence demonstrating that supplement manufacturers have quality control equivalent in sensitivity to that of IOC-accredited labs.
6. **Testing Laboratory** – The CCES believes that an IOC accredited lab would have to be involved in any testing of a product to ensure that it does not contain banned substances. Regardless of the sophistication of the manufacturer, the sensitivity of IOC accredited laboratory testing for banned substances is unmatched. It is unlikely that manufacturers have the experience and technical capacity to match expertise and sensitivity of that testing. But even an IOC accredited lab will not be able to give a 100% guarantee on a product they have analysed. The analysis report would read "We have analysed 99% of this product and it contains...." There is always one percent of a product that is unable to be analysed.
7. **Liability** - The basic concern of the CCES for an approved product approach can be stated by a question: what would happen if an athlete tested positive for a substance that implicated a supplement subject to a CCES "approval" or a sport organization sponsorship? Specifically:
 - What responsibility would the CCES or manufacturer take for a positive test result?
 - What responsibility would the sport organization take?
 - What responsibility would the CCES take if it had played a role in approving the product or the sponsorship?
 - How would the manufacturer compensate the athlete, the sport organizations and the CCES for damages for a positive test result that resulted in a doping infraction?
 - How would such compensation be determined and what collateral legal proceedings might that create?
 - Could money ever compensate an athlete for loss of up to four years of eligibility?

2. **Industry Reform**

The CCES is proposing several areas of action in which athletes, sporting authorities, government and manufacturers could bring about positive industry reform for all involved.

2. A. *Collaboration*

The CCES recommends a collaborative approach to industry reform. Manufacturers having input into possible solutions will serve all interested parties to a greater extent and expedite the necessary changes.

In the spirit of this concept, CCES has had contact with several large and small supplement manufacturers and retailers over the past few months. The purpose of this informal contact has been to gain an industry perspective in regard to regulation, the athlete market, and an understanding of what solutions they feel could benefit the industry. This voluntary dialogue with some manufacturers has gone a long way to helping CCES understand the underlying issues.

A logical step in this progression may be the development of an industry group, made up of Canadian manufacturers and retailers willing to make the doping and safety issues mentioned earlier a priority within their industry. This group could serve several functions, the first of which could be a representation of reputable companies who genuinely wish to change the supplement landscape not only for the benefit of athletes but for their own industry. The second primary function could be as a group to work with the government in developing possible new regulations.

2. B. *Regulation*

At the moment Canada's regulations regarding supplements are confusing at best. Some supplements, for example vitamins, have fallen under drug regulations. Some have fallen under food regulations, and others fallen under a special category called Products under Special Measures. These three sets of regulations have different standards for substance production and packaging. Some areas of concern stretching across these regulations are:

Claims made by the manufacturer in regard to the benefits of the product

- Labelling and ingredients
- Manufacturing standards and quality control during processing
- Lack of scientific data to support the safety and efficacy of each individual product

Recently Health Canada published new *Natural Health Products Regulations* (NHP Regulation's) that will address some of these concerns for natural health products. The definition for natural health products includes vitamins, minerals, amino acids, probiotics, herbal remedies, as well as Chinese and homeopathic medicines. Supplement products that will not be covered by these new regulations because they are classified as either food, drugs or as other products include; energy and recovery drinks and bars, protein powders, creatine products, fat burners and weight reduction products. The implementation of the new regulations will be a staged approach, with all current products being required to meet the requirements of the regulations within 2 years. New products to the market will need to meet these requirements within 4 to 6 years.

Features of these new regulations include:

- **Product Licensing System** - all products defined by the new regulations must obtain a product license. Licensed products must carry a product ID number preceded by the prefix NPN, or in the case of homeopathic medicines preceded by the letters DIN – HM.
- **Evidence of health claims** – Products making health claims must either make reference to a Natural Health Product Monograph or make a submission of other evidence of safety or health claim. The NHPD is finalizing standards of evidence framework to indicate what information is necessary to support health claims where an NHPD monograph is not available.
- **Site Licensing** – The system requires that all manufacturers, packagers, labellers and importers be licensed, and where applicable sites have procedures in place for handling storage and delivery of products.
- **Good Manufacturing Practices (GMP's)** – Manufacturers must meet GMP requirements. The requirements relate to manufacturing, storage, handling and distribution of products. The provisions include standards for premises, equipment, personnel, sanitation, quality assurance, records and recall reporting.
- **Labelling requirements** - Products must meet labelling requirements. Besides standards relating to product names, quantities and ingredients, the labels must also include information relating to recommended dosages, warnings, contra indications and possible adverse reactions.

The new NHP regulations do not come into effect until January 2004. Their practical impact on sport will be uncertain until products subject to the new regulations are widely available to the consumer. Regulation of this industry is a step in the right direction in providing safer natural health products to consumers.

There are concerns that the new regulations do not go far enough in protecting the consumer. There are fears that by allowing products with no clear medicinal or health benefits to obtain a product license, the government is legitimizing the product in the eyes of the consumer. The public may assume that because a product has passed government standards, it is safe and effective. The regulations are non-specific as to what constitutes evidence of safety and efficacy, as well as being non specific about how quality and safety are regulated in the manufacturing processes.

The Australian Experience

Of relevance to the product regulation discussion in Canada is a recent situation in Australia where the largest manufacturer of natural health products in the country, Pan Pharmaceuticals, was found to have breached quality and safety regulations. This situation has sparked a massive product recall of over 1300 products.

Pan Pharmaceuticals, who manufacture up to 70% of Australia's natural health products on behalf of companies throughout the Asia Pacific region, have had their license to manufacture suspended following audits of the company's manufacturing premises. The audits revealed widespread and serious failures in the company's manufacturing and quality control procedures, including the systematic and deliberate manipulation of quality control test data. The massive product recall

will have long lasting ramifications for the natural health product industry in that country, as well as consumer confidence in natural health products, for many years.

This experience is relevant to the Canadian situation because laws similar to the new NHP regulations here in Canada, have been in effect in Australia for several years. Pan Pharmaceuticals had to that point enjoyed an international reputation for quality and safety in a regulated environment. From this reputation the company became one of the largest manufacturers in the Asia Pacific region. It is widely thought that a lack of resources from government prevented a regular auditing process to enforce the regulations, which in turn allowed standards and quality control to slip unnoticed.

In Canada's case, industry regulation may only be effective if the resources are in place to enforce the new regulations. The Australian case highlights the point that even with regulations in place that mean to protect the consumer, there may be no guarantee of product safety if the system doesn't enforce its own standards. This is a relevant issue, if athletes are being asked to rely on industry regulation to identify safe products for consumption.

The CCES' initial investigations into the Canadian food and drug regulatory system have identified several priority tasks to allow the CCES to have more significant input in this area.

1. Establishment of a formal relationship with Health Canada.
2. CCES in partnership with Sport Canada should encourage Health Canada to change its current regulations and practices and become more sensitive to the issues for sport posed by supplements. For example, if a regulatory solution is feasible, Health Canada could develop legislation guaranteeing the purity of supplements similar to the way in which pharmaceuticals are regulated.
3. Continued regular communication with both Health Canada and Sport Canada on co-creating programs and campaigns related to supplements that are targeted to parents, athletes, coaches and sport administrators. For example, to develop educational materials on whether products with a DIN are "safe" from the point of view of doping.

Note that it is likely this will be a long term strategy, with changes in regulations and the proposed effect filtering down to the industry – and therefore to athletes - over a considerable period of time. Nonetheless, once proposed changes and standards have been met, it may be possible for users to develop a level of consumer trust more associated with pharmaceutical and food products, hopefully eliminating the risk associated with supplements, if lessons from the Australian example are considered.

In the meantime it would seem prudent to have a safety measure in place which may provide more practical information to athletes. A harm reduction approach, as described in the previous section may be an interim solution which heeds caution on the part of the athlete, and prepares the makers of supplement products to be more vigilant in upholding standards for their products, before adequate regulations and enforcement of those regulations can come into place.

2. C. *Athlete Action*

The CCES may employ the strategy of initiating Athlete Action to promote the issue of supplement industry reform with those that have a more direct influence on regulation and manufacturing of the products. The overriding strategy would be to raise the profile of the issue through a concerted effort

of contact, where athletes communicate directly with Members of Parliament and appropriate government ministries.

This method has been used by those on the other side of the issue, with lobbyists who wish to deregulate the supplements industry in the United States. There are a number of websites that provide a form letter for disgruntled supplement users to write to their congressman or woman and demand that ephedrine and pro-hormone substances be freely available in products over-the-counter! Although that position is definitely not supported by the CCES, there is no reason why the tactic might not work in the opposite direction

Raising the issue through athletes will stress the importance of a solution that meets athlete needs and could promote a quicker response from those within the government and industry that have the ability to foster change.

The CCES' role in this strategy would be to assist athletes by providing the suitable communication tools and information to reach those who can bring about change. In this case, the suitable tools may be an online form letter that articulates athletes concerns and asking for change, which the athlete could then send to their respective Members of Parliament. Other possible strategies may include the CCES facilitating the formation of an athlete action group, recruiting prominent athletes to create a higher profile of the issue.

One of the primary messages would be that as athletes representing Canada they have a pressing mandate to ensure their government provides an environment which is safe and facilitates that representation. As athletes representing their country, the demands of training and competing require nutritional dietary supplementation, and as such they should have the right to use safe nutritional supplements from Canada.

A variation on this strategy would be for the CCES to facilitate an athlete voice directed at the supplements industry itself. The aim of this course of action would be to direct attention at sections of the industry and those manufacturers that pose a threat to their athletic careers by continuing with standards that increase the risk of them providing an inadvertent doping infraction.

The primary message would be that as athletes representing Canada the threat of inadvertent doping should not come from products produced in the Canadian supplements industry, and that the industry as a whole should be doing something to reduce the threat of a positive test result through mislabelling or contamination from the less reliable manufacturers

Athletes taking action would serve several purposes. Firstly, it may create a higher profile within the sporting community of the issues that need to be addressed. This in turn may serve a larger educational role in making younger and pre elite athletes aware of possible issues and the less reliable companies. Secondly, and most importantly, it would allow the athlete to articulate their frustrations and get the point across directly to those posing the risk to their careers and to those that have been slow to act on their behalf.

A critical mass of high profile athletes following this course of action combined with pressure from the CCES and Sport Canada may cause the wheels of change to turn a little faster at the correct level of government.

3. Education

3. A. *Poster Campaign*

One of the initial findings of the Athlete Focus Group sessions is that there is still a significant segment of the athlete population that are unaware of the doping risks associated with supplement products. A significant proportion of this group are either younger pre-elite athletes, who have not yet been subject to any formal CCES anti-doping education, or university and college athletes who are relatively inexperienced compared to elite athletes when it comes to anti-doping issues.

A poster campaign, warning of the risks and steps athletes should take to prevent inadvertent doping through supplement ingestion, would be a relatively easy strategy to reach this target audience. This campaign could work through supplying posters to the relevant training centres as well as through the large CIS network associated with university and college athletes.

3. B. *Informed Decision Making Models*

Informed Decision Making Models assist athletes in deciding whether it is worthwhile using a supplement. The CCES uses some aspects of the model provided by the ‘Centre for Substance Use in Sport and Health’ (SUSH)⁷. SUSH advocates a seven-question model called “Taking It” to help individuals make informed decisions regarding the ethical, safety and performance factors that may influence an athletes decision to use a supplement.

There may need to be a review of whether this type of information is appropriate for CCES use, and how this decision making model will fit in with future strategies employed by the CCES, but for the time being, this model seems to help athletes become more aware of the possible ethical and sporting consequences of using supplements and questions the need for supplement use.

3. C *Substance Fact Sheets*

Anecdotal experience suggests that many younger and inexperienced athletes are using supplements even though they have minimal knowledge about them. Some seem to be confused as to the supposed role these products play in performance enhancement or diet improvement.

The development of simple one page substance fact sheets may provide some of these athletes with more knowledge when it comes to making a decision to use supplements.

The documents should contain information pertaining to the supposed use of the substance, reported benefits to diet and performance, possible risks associated with that particular substance, then the general warning CCES provides with other supplement substance enquiries.

It is envisaged these fact sheets would be available on the CCES website, in an electronic format. While these fact sheets would require assistance of scientific expertise the CCES does not currently have, the exercise might be relatively easy to complete with a minimum strain on resources.

Several national anti-doping organizations already employ this strategy to educate athletes about supplements. See Annex 3 for an example from the ASDA website.

⁷ More information on SUSH can be found at the website <http://www.substanceuse.com/en/index>

3. D. Coach Education.

To get a message through to athletes, who has greater credibility with the athlete than the coach? Much of the nutritional and training advice the athlete receives comes from this important part of the support network. We have the situation in some sports, particularly at the club and university level, where supplement manufacturers are an integral part of the sponsorship and marketing strategies. This may lead to a scenario where coaches are compelled to promote the use of products to their athletes, products which may be harmful to the athlete.

The current CCES Education strategy focus is on elite athletes. It would seem that there is little to no education of anti-doping matters directed at the coaches, not only associated with elite athletes, but athletes at the college, university, high school and club level.

It may be argued that coach education is outside of the CCES education mandate, but by casting a wider net and incorporating our messages into the education materials aimed at athlete support staff we may be able to address issues that become more serious as the athlete develops. There may be opportunities to incorporate appropriate messages into Coaching Association of Canada (CAC) programs and NSO coach education materials. This would allow these messages to slowly diffuse through to the grassroots level. The athletes reached at this grassroots level take what techniques they have learned and bring them through to the elite level, including nutritional and supplement information. This may be a longer term strategy that could play a role as these athletes move through the system to the pre-elite and university level.

The Sports Nutrition Advisory Committee (SNAC), who receive support through CAC, has recently developed a number of nutritional education tools aimed at coaches and elite athletes. The SNAC website espouses similar views to the CCES' current position on supplement use, in that it advises caution on the part of the athlete, and advocates a healthy balanced diet over the unproven "shortcuts" of supplement products⁸. The new resources enable the athlete and coach to make informed decisions by evaluating nutritional supplements against the benefits of adequate planning and consuming "real" food as opposed to pills and powders. This type of resource could be a powerful tool, as these messages coming from a coach will have a major impact on the perceived benefits or disadvantages of supplements by the athlete. Recognition of, and direction to, SNAC nutritional education resources, through the CCES, may be a strategy that increases awareness and increases the legitimacy of the messages CCES is trying to disseminate.

3. E GDID – Global Drug Information Database

The CCES is partnering with UK Sport to develop a global online drug information database (GDID). This database will be available to all Canadian athletes and is likely to be operational by December 2003. It will be hosted on an international website portal.

The current UK Sport version, allows UK athletes to check the status of medicines, but does not include supplement products. UK Sport currently takes a similar position to the CCES and do not recommend the use of supplements because of the possible risk of product contamination. It is likely the new global version of this database will have similar information to the current UK version. However with this new tool, it is hoped that there will be an opportunity in the future to include supplement product information.

⁸ For information about SNAC please refer to the CAC website at http://www.coach.ca/e/nutrition/about_snac.htm

Tighter regulation of the supplements industry, or the implementation of one of the Harm Reduction schemes described in section one, would allow this concept to be an excellent resource for Canadian athletes to search for the status of supplements anytime and from anywhere.

It would also be an excellent opportunity for the anti-doping community to collaborate with the supplements industry in developing useful information for athletes on the substances they wish to use.

Due to the current inability of sporting authorities to give more practical information regarding supplement status, this would seem to be a longer term strategy.

3. F. Pharmacists Initiative

The CCES is currently conducting a feasibility study to determine whether there is a need among athletes, coaches, and sport centres to implement a program geared to training local pharmacists about anti-doping policies, prohibited substances and the risks associated with supplements. If the study reveals a need, a national program will be launched in partnership with the Canadian Pharmacist's Association (CPhA) and the Canadian Sports Centre – Calgary (CSC-C). The goal is to promote to athletes, coaches and parents that a network of trained pharmacists exists in their communities that can answer questions related to anti-doping policies, medications, therapeutic use exemptions, and supplements. These trained pharmacists would address health and safety issues regarding medications and reduce the risk of athletes inadvertently testing positive through the improper use of medications.

4. Research

Canadian athlete's use-of-supplements research is limited, while studies from other countries, which often indicate high supplement usage rates, rarely provide information regarding the type of products used and reasons for their use.

Much of the research espousing product efficacy and safety is often questionable due to deviation from accepted scientific methodologies⁹. For these reasons it is important for the CCES to advocate for more research in these areas and to promote peer reviewed scientific research regarding product safety and efficacy.

Some possible solutions in the research area include:

4. A. CCES Research into athlete usage / behaviour

To date, very little research has been conducted and published on the use of supplements by Canadian athletes. CCES has access to Canadian athletes be it through sample collection or education sessions. Data could be collected to determine usage trends, patterns and the prevalence among different sports. Is their use to improve performance, gain a competitive edge or simply to achieve a more balanced diet? Research should include multiple segments of the Canadian athlete population: grass roots, development, elite, and international.

In addition to collecting data on Canadian athletes, a compilation of other suitable research would be useful, including data collected from the Sydney and SLC Olympic Games.

⁹ For comprehensive review of current dietary supplement research and accepted scientific protocols refer to the Australian Institute of Sport Nutrition Department website at <http://www.ais.org.au/nutrition/CSNsupp.htm>

With this information, CCES could more effectively tailor the development and delivery of new education programs and messaging campaigns. Assuming access to the data can be secured, resources for this solution may include funding for a statistics expert to help compile the data and results.

4. B. Academic Research

The CCES should consider developing specific research partnerships with Canadian university clinical nutrition departments, elite athlete training centres, and reputable supplement manufacturers. The aim of these partnerships would be to generate research funds that would look at a range of issues surrounding supplement use.

The main priorities for such research would look at establishing the usefulness, efficacy and safety of common nutritional sport supplements as used by Canada's elite athletes.

For example, research funds generated from this partnership could be broken into \$10,000 grants. Each grant would have stipulations in regard to;

- what the research was to investigate, for example the effects of specific vitamin supplementation on elite athletes
- the desired methodology, for example, double blind cross over studies
- and the number and type of participants

Such studies would contribute to the quality and usefulness of information provided to Canada's athletes and would allow them to make more informed decisions in regard to supplement use.

Conclusion

This discussion paper has attempted to define the issues surrounding supplement use and sport. We have outlined possible solutions, and the ramifications of those solutions, in the key areas of education, harm reduction, industry reform and research.

The CCES has an obligation to address the issues related to supplements. We see the CCES playing a vital role in developing solutions to meet the needs of athletes. However, we acknowledge that we may not have the required expertise or resources to carry out some or all of the possible solutions discussed. The CCES sees it as vitally important that those who play a role in the supplement industry, the regulation of the supplements industry, and those that are key stakeholders in the sporting community, contribute to a framework that meets the needs of Canada's athletes.

Annex 1: Index of Nandrolone Cases

FINA	Swimmer B. affiliated to the New Zealand Swimming Federation
	Swimmer B. affiliated to the Romanian Swimming and Modern Pentathlon Federation
	M. affiliated to the Slovene Swimming Federation
	Swimmer affiliated to the Swimming Federation of Latvia
CAS (A-J)	Mr. Fritz Aanes v/ Fédération Internationale de Luttés Associées
	Dieter Baumann / IOC, National Olympic Committee of Germany and IAAF
	Mr. Olivier Bernhard / International Triathlon Union
	USADA v/ Duane Dickey
	Brian Frasure v/ ISOD, IPE & DS/USA
	USADA v/ Pavle Jovanovic
CAS (K-O)	International Tennis Federation v/ Petr Korda
	Alexander Leipold v/ Fédération Internationale des Luttés Associées
	Mr. Andrea Longo v/ International Amateur Athletics Federation
	Mr. David Meca-Medina, Mr. Igor Majcen v/ Fédération Internationale de Natation Amateur
CAS (P-Z)	Ali Saidi Sief & Fédération Algérienne d’Athlétisme c/ Association Internationale des Fédérations D’Athlétisme
CAS (Miscellaneous)	B. / International Judo Federation
	B. / International Triathlon Union
	Union Cycliste Internationale / M. & Federazione Ciclistica Italiana

	Federacion Cubana de Levamiento de Pesas (FCLP) v/ International Weightlifting Federation
IAAF (A-J)	Ms. Elisangela Maria Adriano Mr. Dieter Baumann Mr. Gary Cadogan Mr. Linford Christie Mr. Troy Douglas
IAAF (K-O)	Ms. Mihaela Milente Ms. Merlene Ottey
IAAF (P-Z)	Andre Luiz Ramos Ms. Carolin Soboll Mr. Douglas Walker
CANADIAN CASES	Theresa Brick – Weightlifting Carolyne Lepage – Judo Steen Madsen – Cycling, Biathlon Kelly Guest - Triathlon
OTHER	Spencer Smith – Triathlon I. J. Visagie – South African Rugby Football

Annex 2: Views of High Performance Athletes, Coaches, Medical Staff and Officials on Supplements and Sport⁴

Education:

- ❖ Participants have varying degrees of knowledge about the issues surrounding supplements. Many participants were acutely aware of the contamination problem but few were aware of the lack of scientific evidence to support the efficacy and safety of these products. When informed about the lack of scientific evidence athletes felt that more research and education is required. And, if a summary of the research was available then athletes would probably take it under consideration when making a decision to use a supplement.
- ❖ Many participants believed that athletes should have better access to information about proper nutrition and that an equal amount of attention should be given to developing athletes.
- ❖ Participants have very different views about what should be done about the situation. About a third of the participants felt that education should be the first and foremost and that supplementation for the most part is not necessary. The remaining participants agreed that supplements are necessary and that proactive action, including education, should be taken to resolve the issue to protect athletes.

Need:

- ❖ Participants feel that they cannot meet their nutritional needs through diet alone and require supplementation to achieve their caloric needs. There are many factors that contribute to the athlete's inability to achieve his/her caloric goals such as: travel demands, busy schedule, inability to prepare proper meals, deficiencies, high daily caloric output, etc. Some participants even went as far as to blame the Canadian Sport System and its lack of funding for their dependency on supplements. They argued that if they could devote themselves full-time to their sport that there would be reduced need for supplementation.
- ❖ Participants generally all felt that something must be done for athletes who have and mineral deficiencies. CCES should differentiate between those supplements used for medical health and help clear these products for safe use. Because athletes are afraid to use supplements for medically justified reasons they are causing themselves harm that could have lasting effects.
- ❖ Participants don't understand why CCES isn't able to clear supplements that are not considered performance enhancing (e.g. iron, calcium, zinc). They are not satisfied with the cautionary, "don't take it" response given out by CCES. They would prefer to have messages that are clear and direct: "You can take these but you can't take those." Responses that generate fear and uncertainty cause athletes to perceive CCES in a less credible way.
- ❖ Most participants would argue that supplements work and do have an improved effect on their performance and recovery. Because of this, some athletes are willing to take a risk

⁴ From a total of 7 discussion sessions convened by the CCES and held in Saskatoon (Feb. 4, 2003), Regina (Feb. 5), Winnipeg (Feb.6), Ottawa (Feb. 17), Victoria (Mar.11), Vancouver (Mar. 12) and Calgary (Mar.13). All groups were recruited through the assistance of the Canadian Sport Centre Athlete Services Managers. Participants included athletes, coaches, sport administrators and support personnel including physicians, dietitians, and therapists. Group size depended largely on location and availability of training groups and ranged anywhere from 8 to 60 participants.

regardless of the known uncertainties regarding usefulness, safety, and purity.

Harm Reduction:

- ❖ Many athletes asked about whether there's been any interest from manufacturers to have the products they manufacture tested for purity. Athletes would find it useful to know what manufacturers are reputable and which ones are problematic. (Athletes would like to know that names of the problematic products tested in the IOC study as well as the brands of products that have resulted in Canadian positive tests.)
- ❖ At every session, someone asked if a testing lab exists to have their products and/or urine tested for contaminants. It seems that this would be a sufficient solution for many athletes – at least in the interim.
- ❖ Participants generally liked the idea of a Made in Canada Solution. Many liked the ASDA model, others seemed to prefer the Seal of Recognition model better. The majority agreed that a CCES Line of Supplements would be too onerous and expensive to administer because of the varying needs of athletes and the potential conflict of interest for CCES.
- ❖ Participants are generally less concerned about the efficacy and health risks of taking supplements as they are about testing positive. There is a strong desire to have a system in place to guarantee the purity of products. Someone (an organization) should be responsible for protecting athletes from inadvertently testing positive. A small minority felt that CCES is not the appropriate body to resolve the issues surrounding supplements and instead should focus its efforts on further educating athletes and coaches about the risks of using supplements.
- ❖ Some participants argued that any of these solutions would be too onerous and expensive to administer and felt that pressure should be placed on government to re-regulate and police the manufacturing and labelling of supplement products. Some went as far as to say that any other solution, other than regulation, would generate a false sense of security for athletes.

Research:

- ❖ Participants who demonstrated knowledge and capacity in this area expressed the need for scientific research to demonstrate how supplements are metabolized in the human body. Many feared that their bodies could metabolize a by-product that would result in a positive test even though the product itself contained no banned substances.

Annex 3 – Substance fact sheet example, from the Australian Sports Drug Agency website

Fact Sheet

Creatine

Creatine is a natural compound synthesised by amino acids in the kidney. It is also a normal component of diet derived from meat, fish and poultry.

Creatine plays a key role in the replenishment of anaerobic energy stores. Ninety-five per cent of the body's creatine stores are found in skeletal muscle. The energy for muscle contraction comes from adenosine tri-phosphate (ATP). After ATP is used, it must be regenerated from phosphocreatine stores during intense, brief exercise. Creatine must be available to replenish phosphocreatine stores.

There is consistent evidence that creatine supplementation may help replenish and increase phosphocreatine stores to delay the onset of fatigue during intense exercise, as well as reduce recovery time between maximal bouts of exercise.

From the research conducted, creatine benefits appear to be specific to certain athletes and in certain situations.

Side effects

Athletes using creatine usually experience immediate weight gain of 1-2kgs, most likely due to the increase of fluid stores.

There have been anecdotal reports of muscle cramps, tightness and tears. This could be due to the increased water retention in skeletal muscle, however there is no direct evidence linking creatine use and muscle dysfunction.

Individuals with impaired kidney function that use creatine may be at risk due to the increased creatine delivery to the kidney for excretion.

A widely reported literature review by a French Agency claimed that creatine supplementation can cause cancer. There is no scientific evidence to support this.

A major risk with creatine supplementation is the possible contamination of some creatine preparations. To date there is no evidence that pure creatine supplementation poses problems in healthy people.

Status in Sport

Creatine in its pure form is permitted in sport. It is not listed on the Olympic Movement Anti-Doping Code (Appendix A) Prohibited Classes of Substances and Prohibited Methods - 1 January 2003. However, as is the case with all supplements, creatine supplements are not subject to the same stringent testing as pharmaceuticals. Therefore they may contain impurities that are not listed on the label. Athletes should seek a written guarantee regarding the supplement's purity from the manufacturer.

Annex 4 – Australian Institute of Sport (AIS) Nutrition Department Supplements Project

The Australian Institute of Sport is Australia's primary elite athlete training centre. The Institute runs a variety of centralised athlete scholarship programmes for elite, pre-elite and developmental athletes from over 25 sports. These programmes deliver state of the art training and analysis facilities (biomechanics, physiology analysis), athlete welfare and career advice, as well as medical, physiotherapy, psychology and nutritional services.

In 2000, the AIS Nutrition department launched a sports supplement program. The objective of this programme was to educate athletes as to the correct supplement products they could use to compliment their specific training and dietary programmes. The original process involved the athlete meeting with resident Institute nutritionists, doctors and trainers to determine the specific needs of that athletes training and dietary needs. To minimise the chance of inadvertent doping by that athlete, any medications or supplement products they wished to use were to be checked and approved by designated medical staff at the Institute. There was strong advice that athletes were breaking their scholarship conditions if they were found to be avoiding this approval process.

For most resident athletes this process still continues today. However, for those living off campus or in other cities, or for those elite athletes not on scholarship at the Institute, a 'Supplement Class' system was devised. Based on the expert opinion of Institute medical and Nutrition staff, athletes could access the AIS website to obtain information regarding the products they were thinking of using.

Products were classed according to their effectiveness and probability of doping safety, based on labelling and packaging of the product, as well as the available scientific research on the substances contained in specific products. To ease the athletes monetary burden of obtaining these supplements, the AIS entered into sponsorship deals with several large reliable commercial manufacturers to provide, either at a discounted rate, or for free (depending upon the type of product) a system of bulk distribution to the athlete through resident medical and nutrition programmes. Although all these products were provided by reputable manufacturers, who met all quality and standards, at no time did products undergo substance analysis or quality checks before being provided to AIS athletes.

At the time, there had been multiple press reports regarding the implication of supplement products in high profile positive test results. As a result, many athletes were concerned about the products they were being provided by the AIS. These athletes were making enquiries as to the doping safety of products with the Australian Sports Drug Agency (ASDA), who in turn could not provide a guarantee as to their safety due to the lack of regulation and quality control associated with the manufacture of those products (compared to pharmaceutical grade products that could be guaranteed for their doping safety). The situation had developed where the countries elite athlete training centre was approving and providing supplements to athletes, but neither they nor ASDA could vouch for the safety of those products.

This situation lead to the formation of the 'Supplements Doping Safety Taskforce' described in the Approved Products section above.

AIS Substance Groupings

Group A - Approved or recommended for use by AIS athletes.

- Products within this grouping include sports drinks, energy bars, creatine, multivitamins

Group B - Considered for provision to AIS athletes only under a research protocol.

- Products within this grouping include probiotics, colostrums, Echinacea

Group C - Supplements which have no proof of beneficial effects and are therefore not to be provided to official AIS programmes.

- Products within this grouping include Amino Acids, Gingko, Ginseng

Group D - These supplements are directly banned by the IOC doping rules or provide a high risk of producing a positive doping outcome.

- Products within this grouping include androstenedione, DHEA, Tribulus terrestris