

LEEDS BECKETT UNIVERSITY CARNEGIE SCHOOL OF SPORT

Ethics Guidance Document	Effective Date: January 2023	
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Guidelines for food supplement use within teaching and research activities in the Carnegie School of Sport		

Note: this guide can be a reference point for both staff and students

Food	Legal Definition -	
Supplements	Directive	
Supplements	2002/46/EC of the	
	European Parliament and of	
	the Council	
	(DEP)	

Working definition of food supplements for the purpose of the guidelines:

Foodstuffs, the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients (e.g., vitamins and minerals) or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities (Legal Definition - Directive 2002/46/EC of the European Parliament and of the Council)

1) Purchasing of food supplements

1a) Information

- Research has shown that some supplement products may be contaminated/adulterated with low levels of steroids, stimulants or other substances which are prohibited by the World Anti-Doping Agency (WADA). Competitive athletes therefore need to be vigilant, regarding the risks associated with supplement use.
- UK Anti-Doping (UKAD) provide clear guidance to athletes only batch-tested supplement products should be used to minimise the risk of inadvertent doping. Athletes should also make sure they check the actual batch number on the product aligns to that on the batch testing evidence prior to use. UKAD refers athletes to the Informed Sport¹ website (<u>https://sport.wetestyoutrust.com/</u>) to check the products that have been batch-tested so that they can make informed decisions on which products present less risk if used (in terms of potential health harms/committing an inadvertent anti-doping rule violation). Whilst a growing number of supplements are available for purchase in a batch-tested form, other supplements are not. Also, no supplement testing programme can test for all substances which would be considered prohibited in sport.
- Several assurance certification systems for food supplements in sport have been established over the last 15 years. These certification systems all have in common:
 - systemic and batch-specific testing of products on behalf of the industry
 - providing manufacturers certificates of the tests performed
 - having a publicly accessible database of certified product batches
- At the time of the publication of these guidelines, seven established certification systems were identified across the world. In alphabetical order, these systems are:
 - BSCG Certified Drug Free
 - o Cologne List
 - HASTA[™] Human and Supplement Testing Australia
 - o Informed Choice
 - Informed Sport
 - NSF Certified for Sport
 - NZVT Dutch Safeguards System for Dietary Supplements in Elite Sport
- In the Carnegie School of Sport, the expectation is that both staff and students only use batch-tested products by Informed Sport, as this is aligned with UKAD policy.

1b) Recommendations to minimise the risks of supplement use to staff and students

- Purchase batch tested products (i.e., by Informed Sport) where available and report batch number and batch expiration date. Please also check storage requirements as well as the best-before and expiry dates of the products to ensure products are stored appropriately and used as per manufacturer recommendations.
- If a batch-tested product is not available, a strong and justifiable rationale and risk
 minimization strategy needs to be provided to use a product that has not been through
 a rigorous certification programme. Cost of food supplements should not be a key
 driver for informing the decision for which product to use. For any questions/queries

 ¹ Informed Sport certification is voluntary for supplement companies who wish to certify some, or all, of their products onto the programme. Once certified, products can carry the Informed Sport logo or on-pack descriptor. Athletes who see the Informed Sport mark on a product can be assured it has undergone a rigorous screening programme for banned substances in sport and is safer for use.

please liaise with the Local Research Ethics Coordinators and seek guidance from UKAD National Trainers, Dr Debbie Smith and Dr Meghan Bentley.

- To ensure we are providing accurate information to participants involved in research and/or teaching activities involving ingestion of supplements, the following statements to the participant information sheets will be clearly evident:
 - a) If the supplements in the study are **batch tested***-"Consuming the supplements provided during this experiment does not pose any greater risk than purchasing and consuming these supplements in everyday life. Furthermore, the supplements provided during this experiment have been batch-tested to screen for banned substances (i.e., those substances prohibited for use by competitive athletes by the World Anti-Doping Agency). This significantly reduces the risk of any product contamination/adulteration. However, given the detection thresholds of doping control tests, we cannot provide a 100% guarantee that the supplement is completely absent of banned substances. Please consider this information if you are an athlete subject to anti-doping rules".
 - b) If the supplements are **non-batch tested**** -"Consuming the supplements provided during this experiment does not pose any greater risk than purchasing and consuming these supplements in everyday life. However, given these supplements have not been batch tested, there is a greater risk that they may contain banned substances (i.e., those substances prohibited for use by competitive athletes by the World Anti-Doping Agency). Please consider this information if you are an athlete subject to anti-doping rules".
- Add one of the following statements to the consent form for any experiment involving supplements: If supplements are used in this experiment, I understand that the supplement(s) involved are: *Batch tested/**Non-batch tested [please delete as appropriate]. There is information about supplements classification overleaf, and additional details regarding the supplementation protocol and ingredients can be found in the participant information sheet.

In addition to the above, add also the following statement in the consent from: "If any type of supplements or food need to be consumed, I can confirm that I am not allergic to any of the ingredients listed on the label".

- In the Stage 2 ethics form, applicants should also acknowledge whether the supplements are batch-tested or non-batch tested. The safeguards put in place within the participant information sheet and consent form should also be highlighted within the Stage 2 form.
- In terms of supplement purchasing behaviour, staff are asked to refrain from requesting that Learning Support Officers (LSOs) purchase supplements from the internet -especially from unknown companies based abroad. Such behaviour carries increased risk. The purchase of supplements should only be done by the LSO team and not by the applicants

NOTE: Since botanicals and herbs (i.e., CBD oil, maca root etc.) are either associated with increased risk of contamination/adulteration with banned substances or legal status is debatable, the Carnegie School of Sport have taken the decision to not permit their use for any undergraduate or MSc projects. Use of colostrum is also not permitted. Colostrum is not prohibited by WADA, but it contains certain quantities of IGF-1 and other growth factors which are prohibited and can influence the outcome of anti-doping tests. For any questions/queries please liaise with the Local Research Ethics Coordinators.

2) Preparation of supplements

2a) Information

• The risks associated with incorrectly preparing supplements has been highlighted by the accidental overdosing of caffeine in a sports science department at a UK university. Therefore, for each project involving the use of supplements by students the approved supplement calculation sheet needs to be signed by their supervisor before data collection commences.

2b) Recommendations for the preparation of supplements prior to consumption

- All supplement dosage calculations are to be checked by the module or seminar leader for teaching activities, or by the primary supervisor for research activities and dissertations.
- Applicants (e.g., students primarily and/or staff) must be supervised by an appropriately trained Learning Support Officer when preparing supplements, in the current designated areas (CSSG11 and CSS125). Applicants should lalso comply with the approved Nutrition Laboratories and Changing Facilities Standard Operating Procedures (<u>https://docs.google.com/document/d/1V2LfyBz-ke6mi1JiKsQDaxy09k5Mblg9/edit)</u>. The current risk assessment (<u>https://docs.google.com/document/d/1t52leJG5fqAtV6i006VrBj_ShebroSRm/edit)</u>) for supplement preparation must be included in ethics applications and followed for all activities involving supplement use.

The safeguards highlighted in the above recommendations should be referred to within the Stage 2 ethics form.

3) Administration of supplements

3a) Information

• In addition to incorrect preparation of supplement dosage highlighted above (2a), special consideration should also be given on the administration protocol, which should also be outlined within the supplement calculation sheet. For example, if for an activity a participant is expected to ingest daily 500 mg/kg of body weight of sodium bicarbonate for a period of five days (serial loading), it would be imperative to clarify within the supplement calculation sheet that the daily dosage (e.g., 40 g for an 80 kg individual) will be split into four smaller doses (e.g., 20x4) tin order to avoid gastrointestinal side effects as a result of sodium bicarbonate ingestion.

3b) Recommendations

- The participant information sheet must state the ingredients contained within the supplements that are to be used during the experiment. It must be stated that participation is not allowed for anybody who has any known allergies to the ingredients or who has experienced any adverse reactions to the ingredients. participants should confirm that they are not allergic to any ingredients in the consent form.
- Participants must not be provided with more than one dose of caffeine supplementation for consumption away from the laboratory (i.e., the participant must collect separate doses at the relevant time for any studies involving caffeine consumption on multiple occasions).

The safeguards highlighted in the above recommendations should be referred to within the Stage 2 ethics form.

Table 1. Below you can find an indicative list of batch-tested products we have purchased in the past. This is not an exhaustive list, and the historical information below should not be used as evidence that products will be batch-tested at the time of a future purchase. **You should always check Informed Sport if a product is batch-tested before you proceed with a purchase*.

Batch tested supplement	Product label	Companies
Whey Protein	Clear Whey Protein/Elite All Blacks Ultimate Whey Protein Blend	Healthspan Elite
	Cutting Edge Protein	Bulk Powders
Creatine	Creatine Monohydrate	Maximuscle
		NutritionX
		Healthspan Elite
		Science in Sport
BCAA	Zero Sugar BCAA	Maximuscle
	BCAA Perform	Science in Sport
	Informed BCAA Powder	Bulk Powders
Beta Alanine	Beta Alanine (tablets)	Science in Sport
	Beta Alanine Powder	NutritionX
Beetroot Shots	Beet It Sport Nitrate 400 Shot	James White Drinks
Caffeine Gum	Kick-Start Gum	Healthspan Elite
Caffeine Tablet	Kick-Start Caffeine	Healthspan Elite
Multivitamin	Gold A-Z Multivitamin	Healthspan Elite
Isotonic Gel	Go Isotonic Energy Gel	Science in Sport