samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

INSTRUCTIONS

DUTCH SECURITY SYSTEM FOOD SUPPLEMENTS FOR TOP-CLASS SPORTS (NZVT) MANUAL

In collaboration with NOC*NSF and the Dutch Doping Authority, NPN has developed the Dutch security system food supplements for top-class sports (NZVT system). This system aims to minimize the risk of inadvertent doping use through food supplements. Manufacturers and providers of food supplements can take part in this NZVT system. Participants are required to stick to the conditions mentioned in the NZVT manual. This manual provides you with step-by-step instructions of actions that have to be taken. For more detailed descriptions of all activities is referred to the Annexes of this manual.

Step 1
If you would like to participate in the NZVT system, please read and sign the Agreement HACCP-plus/NZVT system (Annex 1) and send this signed document to NPN.

Step 2
Use the following documents to make sure your production system meets the NZVT norms:
- Danger identification and risk estimation (Annex 2)
- Procedure of line release (Annex 3)
- Supplier assessment (Annex 4)
- Checklist risk raw materials (Annex 5)

These documents are meant for your own company's archive.

Step 3
Samples need to be taken according to the Sampling protocol (Annex 6).

Triplicate samples have to be prepared. Subsequently, the following is performed:
- One sample should be sent to the selected laboratory, together with the completed 'Samples submission form' (Form 2).
- One sample should be sent to WFSR (before RIKILT), which is the quality guarantee laboratory.
- One sample should be kept for the archive of the company. This sample functions as a backup.

Prepare triplicate samples of the same batch of consumer units or at the same time of production. The minimum number of triplicate samples needed to be taken per batch, depends on the amount of consumer units (see Sampling protocol Annex 6). Every sampling requires a product dossier, including product information as described in the Sampling protocol (Annex 6). The company should keep this product dossier for own archive.

Step 4
When sending samples to the laboratory and WFSR, please complete the checklist with points of attention (Form 1: Checklist POA) and send this document, together with a copy of the Samples submission form (Form 2) to NPN. For this you can use either email: info@npninfo.nl, post: Henry Dunantstraat 36b, 3822 XE Amersfoort, The Netherlands or fax: 0031 33 2460602.

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

Promotion
The NZVT system enables different kinds of promotion activities as described in the 'NZVT promotion possibilities' (Annex 7). Possibilities for promotion activities are related to the frequency of NZVT testing. Products of which all batches are analyzed by NZVT are allowed to have the NZVT logo on the product label. In order to use this promotion option it is required to have an agreement with NPN on the use of NZVT for promotion activities.

Costs
Fees for the NZVT analysis can vary in time, but are approximately € 605,- per batch. This is the fee for the analysis which will be charged by the laboratory (LGC).

Annexes:
1. Agreement HACCP-Plus/NZVT system
2. Danger identification and risk estimation
3. Procedure of line release
4. Supplier assessment
5. Checklist risk raw materials
6. Sampling protocol
7. NZVT promotion possibilities

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

ANNEX 1: AGREEMENT HACCP-PLUS/NZVT SYSTEM

NZVT (*Nederlands Zekerheidssysteem Voedingssupplementen Topsport*) is the Dutch security system food supplements for top-class sports.

The aim of the HACCP-Plus/NZVT system is to produce high quality food supplements for top-class sportsmen and -women. Moreover, it aims to perform an additional check on these supplements in order to minimize the risk of a positive doping test as a result of using these products.
The NZVT system is developed by NPN in collaboration with NOC*NSF and the Doping Authority and in consultation with the Ministry for Health, Welfare and Sports (VWS) and the National Institute of Public Health and the Environment (RIVM), now WFSR.

NPN is proprietor of the NZVT system and also responsible for it. She gives both her members and non-members the opportunity to produce food supplements according to the NZVT system and have them tested subsequently. If a company and its product comply with this system, the product will be stated on a special website of the Doping Authority: https://www.dopingautoriteit.nl/nzvt. This website informs top-class sportsmen/women and coaches on products that meet the norms of the NZVT systems. These quality norms for food supplements are based on the most recent doping list of the IOC and the World Anti-Doping Agency (WADA) and are formulated under guidance of the Doping Authority.

The NZVT system consists of:

- Additional attention to all parts of product composition, production, packaging, labeling and sale, in a similar way as the legally required HACCP system. This so-called HACCP-Plus/NZVT system of NPN is meant to minimize the risk of a positive doping test.
- A batch-wise control method conform the NZVT doping analysis, which is performed by laboratories especially appointed for this purpose. This analysis is paid by the company.
- An assessment regarding compliance with the specified norms, concerning the whole batch of the product sample.
- Reporting the batch of products that meet all specified norms on a special website of the Doping Authority: https://www.dopingautoriteit.nl/nzvt
- A control trial of the system carried out by WFSR; meaning that some of the samples are investigated again at random as an extra security. For this, companies are required to send an additional sample of the batch to WFSR next to sending samples to the laboratory.
- Top-class sportsmen/women and their coaches are recommended by NOC*NSF and the Doping Authority to use NZVT tested food supplements notified on the website of the Doping Authority.

Both members and non-members of NPN that wish to obey the rules of the abovementioned quality system can join. These companies may promote their participation in the NZVT system conform the ‘NZVT promotion activities’ (Annex 7). Companies participating in the NZVT system with at least two batches of the same product per year are allowed to advertise according to phase 2 of Annex 7. This has to be announced by the company in advance in the Checklist POA (Form 1).

In agreement:
Initials: _____

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

In order to participate in the NZVT system it is required to sign this agreement form meaning your company agrees with the system. Thereby the company commits itself to follow the complete system and all its instructions. It is not possible to carry out the HACCP-Plus/NZVT system partly, for example only the batch-wise control method. Only if all of the conditions are accomplished, a company can submit samples for the batch-wise control. Confirmation of compliance gives a company the rights for placing their product on the NZVT-website.

Although NPN has developed the HACCP-Plus/NZVT system with all available knowledge on HACCP and doping indicative substances, the participating company is and ultimately remains responsible for a careful execution of the HACCP-plus/NZVT system and for its products meeting all legal and doping norms. If it becomes evident that, for whatever reason, a product does not meet the norms set for the laboratories analysis by means of WFSR's control trial or by use of sportsmen/women, NPN or its NZVT related partners cannot be held legally responsible for this. Companies themselves remain wholly responsible for their products.

Signed in agreement:

Date: _____

Name of person responsible: _____

Company name: _____

Signature: _____

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

ANNEX 2: Danger identification and risk estimation HACCP-plus / NZVT system (F04-05)

Explanation of symbols

Table design:

DANGER IDENTIFICATION				RISK ESTIMATION			
Process step	**Danger**		**Precautionary measures**	**Questions**			**CCP.**
	Description	**Nature (M, C, P, A)**		**Ch**	**S**	**R**	**POA**

Nature of danger:

Nature of danger (M, C, P, A)	Example
Microbiological danger	Bacteria, mould, yeast, virus
Chemical danger	Remainders of disinfectant, detergent and pesticide, overdose of active material
Physical danger	Wood splinters, sand, stones, splinters of glass, metal, plastic, vermin
Allergens	Nuts (peanuts, cashew)

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

Questions:

S=SERIOUSNESS	**Ch** = CHANCE: FREQUENCY OF OCCURANCE (IN END PRODUCT / FOR CONSUMER)		
Great (G) Fatal consequences, serious/chronic disease, irreparable problems	3	4	4
Moderate (M) Substantial problems, taking action immediately or at long term	2	3	4
Little (L) Inconvenience, normal recovery possible	1	2	3
	Great (G) Will probably never happen	**Moderate (M)** Can take action (wrong use, storage, handling)	**Little (L)** Will happen (very) often

R=Risk classification	**Type of management measure**	**Undertake the following action**
1	No separate management measure necessary	Verify if the precautionary measures work.
2	Periodical measure	Review periodically the implemented measure on current insights. Verifiable record in audit/verification plan.
3	General management measure (POA)	For example: adequate hygiene measurements, cleaning procedure, purchase procedure, pest control, complaint handling. Apply decision tree; in case no CCP then automatically a POA. Demonstrable recording in audit/verification plan.
4	Specific management measure (CCP)	A measurement especially developed to control the risk. Apply decision tree. If: 1) no CCP then automatically a POA ↑ 2) CCP, develop monitoring system

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

Danger identification and risk estimation

- Date on which DI (Danger Identification)/RE (Risk Estimation) is carried out:
- Date of checking/verifying precautionary measures (or earlier, in case of changes in product/process):

DANGER IDENTIFICATION				RISK ESTIMATION			
Process step	**Danger**		**Precautionary measures**	**Questions**			**CCP.**
	Description	**Nature (M, C, P, A)**		**Ch**	**S**	**R**	**POA**
1. Development of recipes	Negative side effects as a result of a wrong choice or combination of raw materials or incorrect/unsafe dosage	**C**	1. When formulating new or editing existing recipes, test the raw materials with the NPN-checklist dispensing development (only available in Dutch) and the Food Law. Moreover, consult experts and perform literature research. 2. Have new or adjusted recipes tested by the supplier. The supplier confirms the test in writing. **Ch**ance is **M**oderate: interchange mcg and mg, too high dosages. **S**eriousness is **M**oderate: long-term use or high dosage might give adverse side effects.	M	M	3	POA
b. HACCP-Plus/NZVT	Use of certain raw materials by sportsmen/women could give positive doping result.	**C**	1. During recipe development, make use of the list with doping-indicative substances of the NPN-checklist risk raw materials. **Ch**ance is **M**oderate: the chance for choosing an incorrect recipe while using the NPN-checklist risk raw materials, is small regarding the target group of sportsmen/women. **S**eriousness is **G**reat: a positive doping result has serious consequences for a top class sportsman/woman.	M	G	4	POA

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

DANGER IDENTIFICATION				RISK ESTIMATION			
Process step	**Danger**		**Precautionary measures**	**Questions**			**CCP.**
	Description	**Nature (M, C, P, A)**		**Ch**	**S**	**R**	**POA**
2. Choice of packaging	Stability of the product in the package intended for it. Influence of light, moisture and temperature.	**M C P**	Stability studies. Correct advice on storage on the label. Sealed package.	M	L	2	n/a
b. HACCP-Plus/NZVT	No additional risk regarding NZVT.		**Ch**ance is **M**oderate: with precautionary measures, chance is small **S**eriousness is **L**ittle: deviations in smell and taste, but no direct health risk				n/a

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

DANGER IDENTIFICATION				RISK ESTIMATION			
Process step	**Danger**		**Precautionary measures**	**Questions**			**CCP.**
	Description	**Nature (M, C, P, A)**		**Ch**	**S**	**R**	**POA**
3. Ordering from supplier	Presence of contaminants in products as a result of non-compliance of quality arrangements by supplier.	**M C P**	1. Conclude the Quality Agreement (suppliers question list) with suppliers. Procedure for qualification of suppliers, list of acceptable suppliers. **Ch**ance is **M**oderate: there are suppliers that do not comply very accurately with quality norms. **S**eriousness is **M**oderate: impure raw materials or contaminations can cause health problems.	M	M	3	POA
b. HACCP-Plus/NZVT	Positive doping results due to contact with doping-indicative substances. Intentional tainting (“spiking”) with doping-indicative substances.	**C**	- Only suppliers/producers who adhere to the **HACCP-plus** system and have signed the Supplier assessment (F-08-03) with explicit emphasis on doping-free (points 7 and 8) are allowed to supply raw materials/products for NZVT-products. - If possible, audit supplier at least once per year. - Supplier of raw materials has to be familiar with the doping list WADA and should guarantee in writing that the raw materials/products supplied comply with the norms set (see supplier’s evaluation F-08-03). - Purchase risk raw materials which are being tainted sometimes (e.g. Ginseng, Creatine, Ephedra, Guarana) only with the guarantee of the supplier incl. certificates. In case a supplier is from outside EU, certainly including the USA where no obligation for HACCP exists, the supplier has to guarantee via a certificate and quality analysis per batch that the product complies with the norms of NZVT. **Ch**ance is **M**oderate: there are suppliers that do not comply very accurately with quality norms. **S**eriousness is **G**reat: positive doping result for top class sportsmen/women.	M	G	4	POA

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

DANGER IDENTIFICATION				RISK ESTIMATION			
Process step	**Danger**		**Precautionary measures**	**Questions**			**CCP.**
	Description	**Nature (M, C, P, A)**		**Ch**	**S**	**R**	**POA**
4. Quality	Presence of chemical, physical and microbiological contaminations such as PAHs, PCBs and heavy metals that could be present naturally in raw materials or through production process.	**M C P**	1. Be familiar with the specifications of raw materials and their origin. 2. Follow the information in the NPN newsletter accurately (only available in Dutch) 3. Checklist of specifications semi-manufactured goods (only available in Dutch) 4. Supplier provides a certificate of analysis together with the order confirmation or on delivery of the goods. 5. The supplier keeps a sample of each charge as a backup. If any problems occur an analysis can be carried out. 6. Visual control on receipt. Beware on accurate and closed packaging. All incoming products have to be assessed and released by the management or its stand-in (record on *registration form*). **Ch**ance is **M**oderate: Products with increased contents of undesirable substances are present on the market from time to time. **S**eriousness is **M**oderate: in case of impure raw materials and contaminations, too high contents of trace elements or water-soluble vitamins. However, acute problems do not occur usually.	M	M	3	POA
b. HACCP-Plus/NZVT	Cross-contamination of doping-indicative substances during production and packing.	**C**	1. Procedure of line release /or separate production lines 2. Procedure for traceability by supplier and distributor **Ch**ance is **M**oderate: if process is fallowed adequately. **S**eriousness is **G**reat: positive doping result.	M	G	4	POA

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

DANGER IDENTIFICATION				RISK ESTIMATION			
Process step	**Danger**		**Precautionary measures**	**Questions**			**CCP.**
	Description	**Nature (M, C, P, A)**		**Ch**	**S**	**R**	**POA**
5. Making label	A wrong recommended dosage, absence of obligatory warnings.		1. Use NPN-Checklist labelling, which is for sale and only available in Dutch. 2. Double check test text. **Ch**ance is **L**ittle: if using the NPN-checklist labelling, which is for sale and only available in Dutch. **S**eriousness is **M**oderate: in the absence of warnings such as 'do not use during pregnancy', health risks can occur.	L	M	2	n/a
b. HACCP-Plus/NZVT	Sportsmen/women that without knowing use products that can lead to a positive doping result		1. Products containing Ephedra or caffeine (by nature), must have this stated clearly on the product label. In the list of ingredients, Ephedra sinica should be notified as such and not referred to with a fantasy name. Behind its Dutch name, "Ephedra" should be written between brackets. In case caffeine containing raw materials appear in the list of ingredients, state behind the ingredient "contains caffeine (by nature)" between brackets. **Ch**ance is **L**ittle : if using the NPN-checklist labelling, which is for sale and only available in Dutch. **S**eriousness is **G**reat: positive doping result.	L	G	3	POA

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

DANGER IDENTIFICATION				RISK ESTIMATION			
Process step	**Danger**		**Precautionary measures**	**Questions**			**CCP.**
	Description	**Nature (M, C, P, A)**		**Ch**	**S**	**R**	**POA**
6. Inspection of goods on receipt	Physical contaminations in the product as a result of damage during transport. Interchange of products.	**P**	1. Every received product is being checked on: undamaged packaging, visual assessment of content, charge number, USE BY DATE, correct label and if necessary analysis certificate. 2. The final release takes place after the manager or his/her stand-in checked all products. 3. In the event that products are not delivered correctly, to be dealt with in accordance with procedure “Corrective and preventive measures” (return to supplier). **Ch**ance is **M**oderate: there is a chance that products are damaged during transport or delivered incorrectly. **S**eriousness is **L**ittle: double checking prevents that customers are provided with inadequate products.	M	L	2	n/a
b. HACCP-Plus/NZVT	Non-guaranteed batch placed on the website		See above mentioned measures number 1, 2 and 3. **Ch**ance is **M**oderate: see above. **S**eriousness is **G**reat: chance of getting a positive doping result.	M	G	4	POA

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

DANGER IDENTIFICATION				RISK ESTIMATION			
Process step	**Danger**		**Precautionary measures**	**Questions**			**CCP.**
	Description	**Nature (M, C, P, A)**		**Ch**	**S**	**R**	**POA**
7. Labelling and packing by yourself	Polluted product: dirt (dust) or other material. Deviated amounts present in the package. Interchange of or wrong labels.	**P**	1. Check both open and closed package. 2. Check during packaging procedure 3. Check labels after packaging procedure **Ch**ance is **M**oderate: irregularities can arise in the package. **S**eriousness is **M**oderate: an incorrect label means incorrect prescriptions too.	M	M	3	POA
b. HACCP-Plus/NZVT	In case label is incorrect, there is a chance that the raw materials of a product give a positive doping result.		See above mentioned measures number 1, 2 and 3. **C**hance is **L**ittle: in case of accurate control during and after packaging procedure. **S**eriousness is **G**reat: an incorrect label might result in a product giving a positive doping result.	L	G	3	POA
8. Sampling during production/ packaging	Inaccurate sampling might result in unreliable analysis results.		1. Take samples during production/packing according to the sampling protocol: in triplicate, for purposes of check by appointed quality laboratory, WFSR and as a backup for yourself. **C**hance is **L**ittle: it might occur that one does not adhere to the sampling protocol. **S**eriousness is **G**reat: possibility of positive doping results in case analysis results unreliable.	L	G	3	POA
b. HACCP-Plus/NZVT							

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

DANGER IDENTIFICATION				RISK ESTIMATION			
Process step	**Danger**		**Precautionary measures**	**Questions**			**CCP.**
	Description	**Nature (M, C, P, A)**		**Ch**	**S**	**R**	**POA**
9. Check during storage	Deterioration of products during storage as a result of too long storage time.	**C**	1. A USE BY DATE -check during storage on the basis of overview USE BY DATE reporting. This is provided to the purchaser. He or she decides in consultation with marketing whether or not action must be taken. **C**hance is **L**ittle: In case of adequate buying and warehousing policy there is little question of insufficient USE BY DATE. **S**eriousness is **L**ittle: the products are preservable for quite a long time. When the use-by date expires, there is a higher chance of insufficient working than a food safety risk.	L	L	1	n/a
b. HACCP-Plus/NZVT	No additional danger						
10. Check during storage	Infection by vermin during storage.	**M**	1. Pest control is board out to a pest control firm. Possible instructions given by the firm are followed strictly. 2. The warehouse employees / head of the warehouse regularly carry out checks themselves. **C**hance is **L**ittle: there is little nuisance of vermin. In addition, all products are packed and therefore exposure to vermin is made difficult. **S**eriousness is **L**ittle: products are not exposed to vermin.	L	L	1	n/a
b. HACCP-Plus/NZVT	No additional danger						

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

DANGER IDENTIFICATION				RISK ESTIMATION			
Process step	**Danger**		**Precautionary measures**	**Questions**			**CCP.**
	Description	**Nature (M, C, P, A)**		**Ch**	**S**	**R**	**POA**
11. Order picking	Supplying a wrong product due to incorrect order picking.	**C**	1. The packer controls the order picking. In this way, possible deviations can be noted in time. **Ch**ance is **M**oderate: errors can occur. **S**eriousness is **L**ittle: the customer can return products for free if a delivery error occurs.	M	L	2	n/a
b. HACCP-Plus/NZVT	In case of mail order, the order picker takes the wrong product / wrong batch/ product not approved by NZVT.	**C**	1. Internal: notification and double check of batch number on the order form. 2. External: inform the user on the necessity of checking the batch number on the website of the Doping Authority. **Ch**ance is **M**oderate: errors can occur. **S**eriousness is **G**reat:: possibility of positive doping results.	M	G	4	POA
12. Order picking	To extradite products with a short USE BY DATE.	**C**	1. Note the USE BY DATE during order picking. **C**hance is **L**ittle: this happens rarely because of high rate of circulation and correct application of FIFO and LIFO for return. **S**eriousness is **L**ittle: the products are preservable for quite a long time. When the use-by date expires, there is more likely a matter of insufficient working, than a food safety risk.	L	L	1	n/a
b. HACCP-Plus/NZVT	No additional danger						

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

DANGER IDENTIFICATION				RISK ESTIMATION			
Process step	**Danger**		**Precautionary measures**	**Questions**			**CCP.**
	Description	**Nature (M, C, P, A)**		**Ch**	**S**	**R**	**POA**
13. Packing and making ready for despatch	Physical contaminants in the product outer-package (broken glass, cathode ray tubes, artificial nails, jewellery, dust, food and drink remains).	**P**	1. Adequate complying with hygiene instructions. 2. Supervision by team leader. **C**hance is **L**ittle: instructions are followed carefully. **S**eriousness is **L**ittle: the product itself is packed in the original package of the supplier and is not exposed to possible contamination. However, from a quality point of view this is not desirable.	L	L	1	n/a
b. HACCP-Plus/ NZVT	No additional danger						
14. Transport	Damaging of package during transport (broken glass).	**P**	1. Correct packing of products in outer cartons. 2. Products must not be loose in the package, no rattling. **Ch**ance is **M**oderate: damage can always occur. **S**eriousness is **L**ittle: the consumer can return damaged packages for free.	M	L	2	n/a
b. HACCP-Plus/NZVT	No additional danger						

samen in gezondheidsproducten

ANNEX 3: PROCEDURE OF LINE RELEASE: TABLET PRODUCTION DEPARTMENT

1 General

This procedure describes the actions required to be taken by the department head during line release.

2 Objective

To describe an effective check on cleaning activities, in order to prevent interchanges and cross contamination.

3 Procedure

3.1 Principle

The line release consists of the following control activities:

I Check the cabin to ensure absence of product and materials from previous operations used during production (see further 3.2.1).

II Check on cleanliness of the cabin and of the equipment present in there (see further 3.2.2).

- On each change of product, both of the abovementioned control activities should be performed by the head of the department (I + II).
- It is sufficient to perform only control activity I, in case of a change of charge of the same product or a product with the same active ingredient at a higher concentration, or another product with the same active ingredient in combination with another active ingredient.

3.2 Activities

3.2.1 Check the cabin to ensure absence of product and materials from previous operations used during the production

Before starting the production, the cabin is cleaned by production personnel according to the cleaning procedure in force. The head of the department or his/her delegate checks the room to ensure absence of labels for production purposes, remnants and droppings from the previous production process.

3.2.2 Check on cleanliness of the cabin and of the equipment present in it

After dismantling components, the present equipment is cleaned according to cleaning procedures in force. Prior to the assembly of components, the cabin and the machine are checked for cleanliness and the absence of previously processed product. After cleaning, the label “CLEAN” should be put on the present equipment.

3.2.3 Release of the room by head of the department

After checks have been performed and accepted, the week card on the outside of the cabin is signed and dated by the departmental head. This in order to indicate the “CLEANED” status of the room.

samen in gezondheidsproducten

ANNEX 4: SUPPLIER ASSESSMENT (F0803)

This document is for own archive

1.	Did your company set up an HACCP system yet? Outside the EU: does your company have a quality system? Yes, namely: Does your company have certification? If so, by which body …… (enclose copy)
2.	If not, are you already busy with setting up a system? When will it be ready? Or does your company have another system? Yes, namely:
3.	Give a rough description of the production steps and process starting from receipt of raw materials till finished product (incl. storage). Preferably enclose a schematic reproduction.
4.	What critical points are identified (HACCP) in the production process (incl. storage). How are these managed and checked? In particular in respect of hygiene, keeping qualities, bacteriological safety, resistance to undesirable substances and contaminations, etc.? Preferably submit as appendix.
5.	Does your company have a traceability procedure (from raw material to finished product)?
6.	Regarding batches of semi-finished products to be produced for <business>, are there new raw materials purchased or are raw materials from your own stock used? Is this laid down in a procedure in relation to the keeping qualities of the raw materials?
7.	Does the company produce products with stimulants and/or pro-hormones and/or steroids (such as those included on the WADA-list)?
8.	Can you give a guarantee that risk raw materials are not tampered (“spiked”) with stimulants/ pro-hormones?
9.	Your company hereby declares that no remnants from an earlier produced batch (cross contamination) are mixed with a newly to be produced product. Agreed: yes/no Can you briefly describe how cross contamination is prevented? Is there a procedure for line release? If so, please enclose!
10.	Your company hereby declares that raw materials used in the products do not contain doping indicative substances. Agreed: yes/no
11.	a) Which categories of raw materials are used in your company? 0 vitamins 0 enzymes 0 animal raw materials 0 ..... 0 minerals 0 fish oils 0 botanical raw materials 0 ..... 0 amino acids 0 probiotics 0 ..... 0 ..... b) Do the semi-finished products (tablets, capsules) comply with EU legislation regarding contaminants? Yes/no c) Your company uses for <business> only non-irradiated raw materials. It is only possible to deviate from this regulation with the prior approval of the quality manager of <business>. Agreed: yes/no d) Your company uses for <business> only animal constituents (such as organs, organ extracts and gelatin) that have a BSE-free declaration. Agreed: yes/no e) Your company uses only non-genetically manipulated (GMO) raw materials. It is only possible to deviate from this regulation with the prior approval of the quality manager of <business>. Agreed: yes/no f) The specifications of all raw materials (including suppliers’ names) are available on request. Agreed: yes/no
12.	What laboratory analyses are performed (and with what frequency) which give insight in the quality of the produced semi-finished products (for example level of active substances, microbiological quality and undesirable substances)? Preferably submit as appendix. Outside of the EU: what laboratory analyses are performed (and with what frequency) which give in the absence of pro-hormones and stimulants in products? Preferably submit as appendix.

DECLERATION OF AGREEMENT

The undersigned declares having completed the above questions to the best of his/her knowledge and belief. The undersigned guarantees that he/she will inform <business> in time if unexpectedly charges or batches of the product appear not to comply with the information provided above. For example, as a result of wrong production or calamity. This to ensure that <business> is enabled to undertake action in time.

Company name/-stamp: / Place and date:
Name and position of the undersigned (authorized signatory): / Signed in agreement:

samen in gezondheidsproducten

ANNEX 5: CHECKLIST RISK RAW MATERIALS

1. Doping indicating substances

1.1.: **stimulantia**: ephedrine/ephedra, pseudo-ephedrine, nor-ephedrine, norpseudo-ephedrine, methylephedrine,strychnine, amphetamine, metamphetamine, 3,4-methyleendioxymet-amphetamine (MDMA=XTC), 3,4-methyleendioxyamphetamine (MDA=Love), N-ethyl-3,4-methyleendioxyamphetamine (MDEA=Eve), fenfluramide

1.2.: **steroids:** 19-nor-4-androsteen-3b,17b-diol, 19-nor-5-androsteen-3b,17b-diol, 19-nor-5-androsteen-3,17-dion, 19-nortestosteron (nandrolon, 17a- en 17b-isomeren), 4-androsteen-3b,17b-diol, 5-androsteen-3b,17b-diol, 4-androsteen-3,17-dion, dehydroepiandrosteron (DHEA), epiandrostreron, 1-androsteendion, 1,4-androstadiendion, adrost-1-een-17b-ol-3-one testosteron (17b-isomers), methandienon

2. Maxima of doping indicating substances

2.1.: **stimulantia**: 100 ppb (0.1 mg/kg) with exception of caffeine.

2.2.: **steroids:** 10 ppb (5 mg/kg); forbidden by the food legislation.

3. Risk raw materials concerning doping indicating substances

3.1: *Ephedra*

Scientific	***&***	***Common names (RIVM report)***
Ephedra antisyphilitica		
Ephedra aspera		Nevada jointfir
Ephedra californica S. Watson		mormon tea, California jointfir
Ephedra distach(y)a		
Ephedra equisetina		Bunge (Mu-ts'ê) Ma Huang
Ephedra fasciculata		Arizona jointfir
Ephedra fasciculata var. clokeyi		Clokey's jointfir
Ephedra fasciculata var. fasciculata		Arizona jointfir
Ephedra funerea Cov. & C. Morton		Death Valley ephedra
Ephedra gerardiana Wallich ex Stapf		somolata
Ephedra gerardiana Wall. *var. saxatilis*		
Ephedra gerardiana Wall. *var. sikkimensis*		
Ephedra intermedia Schrenk & Meyer		Ma Huang
Ephedra helvetica		
Ephedra nebrodensis		
Ephedra nevadensis S.Watson		Nevada jointfir, Nevada ephedra, mormon tea
Ephedra shennungiana Tang		Ma Huang
Ephedra sinica Stapf.		(Ts'ao) Ma Huang
Ephedra trifurca		longleaf jointfir
Ephedra viridis Cov.		green ephedra, mormon tea, squaw tea
Ephedra vulgaris		Ma Huang

See APP. 1.: Summary of common names of Ehpedra plants.

samen in gezondheidsproducten

3.2: Raw materials containing ephedrine
Sida Cordifolia = ephedrine containing raw material

3.3: Synephrine
Synephrine is analysed as ephidrine at doping tests (synonyms)

List of Synephrine containing raw materials:
Citrus Aurantium
Bitter Orange
Sevilla Orange
Citrus florida
Citrus vulgaris
Citrus bigaradia
Sour orange
Neroli orange
Chih-shih=Zhi Shi (young fruit)
Zhi qiao (nearly mature fruit)
Bitter orange - suan cheng - bigarade
Marmalade orange
Seville orange
Brandname: Advantra-Z

APP. 1. Summary of common names of Ephedrine (RIVM report)

Arizona jointfir
ask-for-trouble
bringham tea
bringham young weed
bri(n)gham weed
California ephedra
California jointfir
canutillo
cay note
Chinese ephedra
Clokey's jointfir
Death Valley ephedra

desert tea
green ephedra
horse tail
jointfir
longleaf jointfir
Ma Huang/Hwang (Chin)
mexican tea
miner's tea
mormon tea
Mtshe (Tibetan)
Narom (Pakistani)
Nevada ephedra

Nevada jointfir
popotillo
sand cherry
sea grape
somalata (Sanskrit = 'moonplant')
squaw tea
stick tea
tapopote
teamsters' tea
whorehouse tea
Sea gooseberry

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

ANNEX 6: SAMPLING PROTOCOL OF THE NZVT/HACCP-PLUS SYSTEM

1 General

This sampling protocol is part of the NZVT system, a security system in which products for top-class sportsmen/women are analyzed on a batch-wise manner on doping indicating substances and stimulatia.

2 Objective

The aim of this protocol is to describe the standard sampling procedure which makes it possible to guarantee the absence of doping indicating substances in a batch of products. The sampling procedure is based on the batch number printed on the consumer unit.

3 Area of application

The procedure is applicable to packers and / or distributors who wish to supply supplements for top-class sportsmen/women according to the NZVT-system.

4 Responsibilities

4.1 Packers and distributors are themselves responsible for a correct delivery of the samples to the laboratory and the guarantee body (WFSR).

4.2 The Quality Control (QC) of the company is responsible for an adequate performance of the sampling procedure.

5 Explanations

5.1 Dosage unit:
Tablet, capsule, coated tablet, etc.

5.2 Batch:
The amount of dosage units produced in a production run. A batch is identified by a batch number.

5.3 Batch number:
The unique identification code of a production run. If another batch number than that of the supplier of the dosage unit is used during filling, the coupling between both batch numbers must be traceable.

5.4 Filling:
The filling of jars, boxes, etc. with dosage units.

5.5 Production:
The filling and / or packing of consumer units.

5.6 Consumer unit:
The jar, box or comparable package in which tablets, capsules, coated tablets, etc are packed. The consumer unit has a label showing the information required according to food and food supplement legislation (amongst other things USE BY DATE, batch number, sender).

5.7 Sample:
Unopened consumer unit taken from the batch at random.

5.8 Product:
Food supplement.

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

6 Sampling procedure

The sampling of consumer units is carried out by the Head of QC or his/her delegate. Samples are taken from the same batch. In other words, from a group of products which have the same batch number on the consumer unit. The samples are **unopened** consumer units.

6.1 Product dossier

Product information important for the NZVT system should be documented in a product dossier. This dossier is for the company's own archives and contains per batch number the following information:

6.1.1 Batch number that is printed on the consumer unit
6.1.2 USE BY DATE of the consumer unit
6.1.3 Product description
6.1.4 Product number corresponding to the consumer unit
6.1.5 Number of production units of the consumer unit
6.1.6 Filling date of the consumer unit (at the packers)
6.1.7 Batch number of supplier of the dosage units (at the packers)
6.1.8 Supplier of the dosage units / consumer units
6.1.9 Date of receipt of the dosage units / consumer units
6.1.10 In case of own production, also sampling moment (start and/or time)
6.1.11 Copy of the completed/initialed Checklist POA HACCP-Plus/NZVT (Form 1) of this batch
6.1.12 A copy of the Samples submission form (Form 2)

6.2 Sampling

6.2.1 The Head of QC or his/her delegate is responsible for the sampling.
6.2.2 Sampling occurs during receipt of the batch in question or during production.
6.2.3 Triplicate samples are prepared:

- One for the archive of the company (=A)
- One for the laboratory which analyses the product (=L)
- One for the quality guarantee laboratory WFSR (=R)

6.2.4 The minimum number of triplicate samples that should be prepared per batch depends on the number of consumer units. The required number of triplicate samples is shown in the table below.

Size of batch	Number of samples	Total of consumer units
1 – 5.000	1 triplicate	3
5.000 – 10.000	2 triplicates	6
10.000 – 15.000	3 triplicates	9
etc.		

6.2.5 Triplicate samples are taken from the same box of consumer units or on the same on the same time of production. When multiple samples are taken, it should be done reasonably divided. No more than one triplicate samples is taken from one box of consumer units.

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

6.2.6 An adequate performed sampling is shown below.

	Samples		
Point in time 1	A 1	L 1	R 1
Point in time 2	A 2	L 2	R 2 (only necessary for batch sizes >5.000)
Point in time ... etc.			

In this way, monsters from time 1 (and if needed 2 and 3) are received by A, L and R. In case of multiple monsters, a mixed monster is prepared for analysis by the laboratory.

6.3 Archiving

6.3.2 Samples for the company's archive should be stored in their consumer units, under circumstances (temperature, light) as offered in the retail trade.

6.3.2 Samples for archive should be stored for a minimum of 1 year after expiry of the USE BY DATE. The company should have an updated product dossier for its own documentation.

7 Sending monsters

7.1 Submission Form

Samples intended for L and R should be sent together with the Samples submission form (Form 2). In this form a company gives the order for analyzing monsters on steroid hormones (pro-hormones) and stimulatia, conform the agreement between NPN and the laboratories. The Submission form should contain at least the following information:

7.1.1 Batch number of consumer unit

7.1.2 Amount of sent samples

7.1.3 USE BY DATE

7.1.4 Product description of consumer unit

7.1.5 Request to send the analysis report to NPN and a copy to the company; the invoice for the analysis is sent to the company.

7.2 Laboratories

For this batch-wise control system, NPN has a contract with the laboratory mentioned under 7.2.1.
A monster should also be sent to WFSR, the quality guarantee laboratory mentioned under 7.2.2.

Monsters mentioning **'NZVT doping analysis'** should be sent together with the Samples submission form (Form 2), which can be found on our website: www.npninfo.nl/nzvt.

7.2.1 LGC
Att. Sample Receipt
Newmarket Road
Fordham
Cambridgeshire
CB7 5WW
UK
Tel: +44 (0)1638 720500
Fax: +44 (0)1638 724200
Email: info@lgcgroup.com
Website: www.lgcgroup.com

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

7.3.2 Quality guarantee Laboratory
WFSR-Instituut voor Voedselveiligheid Residuen & Contaminanten
Cluster Groeibevorderaars
Att. Drs. S.S. Sterk
Akkermaalsbos 2, gebouw 123
6708 WB Wageningen
Tel: +31 (0)317-480307 (secretariat)
Fax: +31 (0)317-480068
e-mail: saskia.sterk@wur.nl
Website: www.wfsr.nl

8 Assessment of the product

Together with sending the samples to the laboratory and WFSR a completed Checklist POA (Form 1) and a copy of the Samples submission form (Form 2) are sent to NPN. This is possible either by email: info@npninfo.nl or by post: Henri Dunantstraat 36b, 3822 XE Amersfoort, The Netherlands. By completing the Checklist POA a company declares having taken all precautionary measurements to avoid presence of doping indicative substances in the batch.

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

ANNEX 7: NZVT PROMOTION POSSIBILITIES

Phase	Nature of using logo	Requirements	How do sportsmen/women find an NZVT authorized product?	Increasing opportunities for companies for mentioning NZVT and the NZVT logo
1: Company participates on irregular basis	**General means of communication: NZVT logo** **Product specific advertisement: no NZVT statement** **Product/label: no NZVT statement** Company states participation in NZVT in letters, websites and general promotion. On the package of the product or in a brochure related to the product, it is not allowed to refer to NZVT.	Batch-wise control.	An authorized batch can be found on the NZVT website. Products with the batch number in question can be obtained in stores or at central distribution facilities.	Authorized wording in general means of communication: **"(Company) participates in NZVT (Dutch security system food supplements for top-class sports). This system controls in a batch-wise manner, see website antidoping.nl/NZVT".** **Conditions:** This wording or wording with equal tenor can be used by companies participating in NZVT in general advertisement texts, website, price list or letters. For this purpose, the NZVT logo in original colours or black/white can be used. Do not make the size of the logo out of proportion. The company participates at least ones a year in the NZVT system.

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

Phase	Nature of using logo	Requirements	How do sportsmen/women find an NZVT authorized product?	Increasing opportunities for companies for mentioning NZVT and the NZVT logo
2: **Company participates on regular basis:** **At least two batches per product a year are analyzed** The company declares in advance that it will analyze at least two batches per product a year. Already after the authorization of the first batch the company is allowed to promote in this way.	**General means of communication:** **NZVT logo** **Product specific advertisement: NZVT statement is allowed** **Product/label: no NZVT statement** Product specific advertisement of NZVT is only allowed when mentioning that only certain batches of the product participate in the NZVT.	Batch-wise control. The company has all the time NZVT-authorized products in stock (or at distribution partner).	An authorized batch can be found on the NZVT website. Products with the batch number in question can be obtained in stores or at central distribution facilities.	Besides the opportunities mentioned in phase 1, the following can be stated in a **product brochure**: **"This product is tested regularly in a batch-wise manner on the absence of doping related substances, according to the NZVT norms. For more information and batch numbers: antidoping.nl/NZVT".** Mentioning NZVT on a website, brochures and other general means of communication is allowed. It should always be related to the batch-wise control.

samen in gezondheidsproducten

Nederlands Zekerheidssysteem Voedingssupplementen Topsport
antidoping.nl/nzvt

Phase	Nature of using logo	Requirements	How do sportsmen/women find an NZVT authorized product?	Increasing opportunities for companies for mentioning NZVT and the NZVT logo
3: Company participates with <u>every batch</u> of a certain product. Company signs an agreement with NPN.	**General means of communication: NZVT logo** **Product specific advertisement: NZVT statement is allowed** **Product/label: NZVT statement is allowed** Producer is allowed to advertise the product as authorized NZVT product everywhere. NZVT logo on the label of the product.	Every batch is tested before putting on the market. Parties which are not approved and have the NZVT logo, may not be placed on the market as such.	An authorized batch can be found on the NZVT website. Products with the batch number in question can be obtained in stores or at central distribution facilities. NZVT is communicated via advertisement and product label.	Besides the opportunities mentioned in phase 1 and 2 the NZVT logo can be put on the product label. The logo can have a maximum size of 2.3 cm x 3.5 cm (height x width) and should have the original colours. Only the following text can be used: **"Every batch of this product meets the NZVT norms and is tested on the absence of doping related substances. For more information: <u>antidoping.nl/NZVT</u>".** Mentioning NZVT on a website, brochures and other general means of communication is allowed. It should always be related to the product that is tested.