



# ANSES opinion on the risks associated with the consumption of food supplements for athletes seeking to develop muscle or reduce body fat

30<sup>th</sup> FP meeting, 8-9 February 2017, Parma

# Background and subject of the mandate

## Background

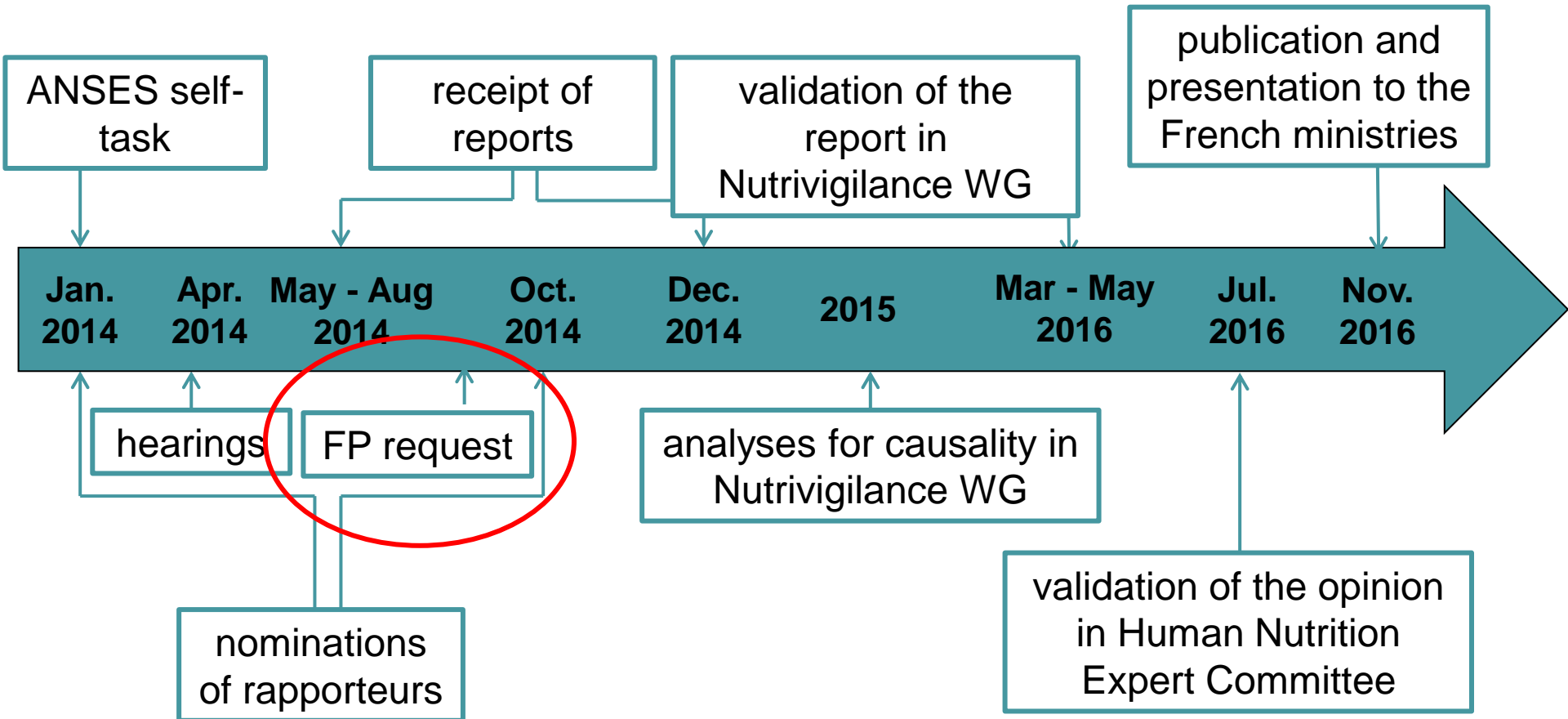
- 49 reports of adverse effects
- Increase of consumption
- Consumption not followed by healthcare professionals

## Subject of the mandate

- Food supplements:
  - exclusively food supplements seeking to develop muscle mass or reduce body fat
  - **intended specifically for athletes**
- No assessment of possible effectiveness of food supplements for athletes



# Assessment



# Methodology of expertise (1)

- **Nutrivigilance reports**


- 49 reports of adverse effects, 17 underwent a causality analysis
- Adverse effects: cardiovascular & psychological ++, hepatic, renal, neurological, dermatological, gastroenterological

- **Consultation of the Toxicovigilance Coordination Committee (CCTV)**

- Summary of the cases notified to the poison control centres

- **Contact with European & International counterparts**

- Multilateral request to the **Focal points**, 17 answers:
  - Reported cases in Spain, Finland, Italy
  - Adverse effects: hepatic, cardiovascular, renal, dermatological & et psychological
- Request to USA & Canada

 <b>European Food Safety Authority</b> Advisory Forum & Scientific Cooperation Unit	
<b>PART III – SUMMARY OF RESPONSES TO ORIGINAL REQUEST<sup>7</sup></b>	
<b>Replying Institution:</b> ANSES <b>Country:</b> France <b>Date of summary:</b> 18/12/2014	
<b>Requesting Institution:</b> <b>Country:</b> FRANCE <b>Date of request:</b> 30/09/2013 <b>Request Number<sup>2</sup>:</b> 13/2	Most countries do not have information related to the consumption of bodybuilders' food supplements: - Portugal - Czech Republic - Slovenia - Belgium - Estonia - Poland - Cyprus - Slovak Republic - Iceland - but discussions that it is of interest and important to gather such information - Hungary
<b>Title of request</b>	
<b>Description of request (including background)</b>	<p>In Spain: Recently there has been a case of severe hepatitis after the consumption of HAVOC capsules, sold as food supplements. The case was notified via RASFF and the analysis of composition revealed the product contained 2α,3α-epithio-17α-methyl-5α-androstan-17β-ol, a prohormone. Since the substance is a medicine, the product was withdrawn by the Spanish Agency for Medicines and Sanitary products. The link to the notification, as well as to some other related earlier cases, is provided below (in Spanish):  <a href="http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medicamentos/2014/ICM_MI_14-14-havoc.htm">http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medicamentos/2014/ICM_MI_14-14-havoc.htm</a>  <a href="http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medicamentos/2013/docs/ICM_MI_15-2013-epistane18.pdf">http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medicamentos/2013/docs/ICM_MI_15-2013-epistane18.pdf</a>  <a href="http://www.rfeda.es/docs/noticias/metilepitostanol.pdf">http://www.rfeda.es/docs/noticias/metilepitostanol.pdf</a></p> <p>In Norway: Information from the Norwegian Food Safety Authority (NSFA) suggest that Norway has not collected and/or published scientific documents on bodybuilders' food supplements in particular. However, food supplements in different forms in general, notably adverse affects and access to such supplements (i.e. internet), is an area of concern for the NSFA. With reference to your question concerning collection of data concerning adverse effects reported with bodybuilders' food supplements, the NSFA has as far as they can see not received any reports on this in particular. One report on adverse effects on intake of whey powder together with creatine has recently been received by NSFA and is currently under scrutiny. However, whey powder and creatine are not defined as food supplements. NSFA sets forth that such adverse effects are underreported in Norway. The Norwegian Medicines Agency (NMA) confirms that they do not have any data on adverse effects on bodybuilders' food supplements in particular, and that, in general, few adverse effects are reported concerning food supplements and plant-based medicines. A decrease in the reporting the last years has been noted, and NMA confirms a large underreporting of such effects. The NMA manages databases of reported adverse effects for food supplements, and might, upon specific demands, be able to search the databases for reported adverse effects on specific food supplements.</p> <p>In Luxembourg: The only information collected on bodybuilders' food supplements are laboratory analyses done for the search of illicit substances. We don't have any information concerning adverse effects, because we don't have a system of nutrivigilance. No case of adverse effect with bodybuilders' food supplement was reported during the last years.</p>
<b>Addressee(s) of request</b>	
<b>Reply to request to be sent</b>	
<b>Timeline for submission of replies</b>	

<sup>7</sup> This III Part of the form is to be filled in by the Institution responsible for the original request.

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The information provided in this form is not comprehensive and is intended as a quick summary of the request.

# Methodology of expertise (2)

- Hearings

- French Federation of Weightlifting, Weight Training, Athletic Strength and Bodybuilding (FFHMFAC)
- French Society for Exercise and Sport Medicine (SFMES)
- French Association of Dieticians-Nutritionists (AFDN)



- Literature review



# Results from the literature review



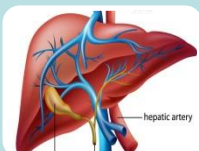
## Cardiovascular effects

caffeine or other sympathomimetic substances (ephedrine, *p*-synephrine, DMAA, clenbuterol, sibutramine) or in association; anabolic androgenic steroids; 2,4-DNP; evodiamine



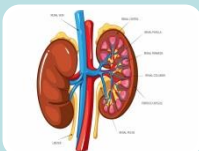
## Neuropsychological effects

caffeine; anabolic androgenic steroids; clenbuterol; 2-phenylethylamine (PEA);  $\beta$ -alanine; 2,4-DNP



## Hepatic effects

*Garcinia cambogia*; DMAA; anabolic androgenic steroids; sibutramine



## Renal effects

creatine; *Garcinia cambogia*; 2,4-DNP



## Dermatological effects

sibutramine; theobromine; 2,4-DNP



## Other effects

creatine (cramps); anabolic androgenic steroids (hormonal disturbance)

- Causality link not always established.
- Absence of data in literature / potential adverse effects of a substance in humans does not guarantee its safety.

# Problems identified



Adverse effects sometimes important +  
Widespread consumption +  
Large diversity of ingredients

} **health risks**



Absence of specific advices by healthcare professionals  
despite inter- & intra-individual variability



Insufficient training of healthcare professionals in athlete  
nutrition +  
lack of multidisciplinary approach involving sports managers  
& healthcare professionals



Extremely hypothetical benefits expected



Widespread practice, even cultural



Lack of efficient information for practitioners





# Recommendations

## For consumers

- ANSES **strongly advises against** the consumption of food supplements aiming to develop muscle or reduce body fat:
  - for people with cardiovascular risk factors or suffering from heart disease, impaired kidney or liver function, or neuropsychiatric disorders;
  - for children and adolescents;
  - for pregnant or breastfeeding women.
- The consumption of food supplements containing caffeine should be **avoided before and during any sporting activity**, as well as by any individuals susceptible to the effects of this substance.
- The **concomitant consumption** of several food supplements or their combined consumption with medicinal products **should be avoided**.
- The consumption objectives of the food supplements should be discussed with a **healthcare professional**.
- The individual's doctor and pharmacist should be **informed** that he/she is taking food supplements.
- Athletes should pay attention to the **composition** of the products consumed, and favour products complying with AFNOR standard NF v94-001 as well as supply channels with the best oversight by the public authorities.





# Recommendations

## For sport managers

- The use of food supplements should only be considered as part of a **multidisciplinary approach** involving both sports managers and healthcare professionals;
- **Efficient information** for practitioners, especially targeting young athletes, should be provided.



# Recommendations

## For public authorities

- Considering the **widespread** consumption of these food supplements, the Agency recommends that the public authorities conduct a debate on the **appropriateness of distributing these products** at sites where sports are practised
- ANSES considers useful to undertake:
  - **Consumption** surveys;
  - Additional studies on the **interactions** between the multiple ingredients found in the same food supplement;
  - Additional studies on the **fate in the body and the long-term toxicity** of the plant extracts and certain substances found in food supplements for athletes



# Recommendations

## For healthcare professionals

ANSES reminds healthcare professionals of the importance of **reporting** to its nutrivigilance scheme any adverse effects likely to be related to the consumption of food supplements for athletes about which they become aware



Anses Agence nationale de sécurité sanitaire Alimentation Environnement Travail Page 1 sur 1



## Nutrivigilance

**Téledéclaration d'effet indésirable susceptible d'être lié à la consommation de complément(s) alimentaire(s) ou de certains produits alimentaires**

Dispositif national de nutrivigilance sur les produits alimentaires - Art. L. 1313-1 du Code de la Santé Publique  
Vous recevrez un accusé de réception par courriel après validation finale de votre déclaration (sous réserve d'un courriel valide).

**FICHE DE NOTIFICATION D'EFFET(S) INDESIRABLE(S) SUITE A LA CONSOMMATION D'UN PRODUIT ALIMENTAIRE**

**A - Déclarant**  
Les coordonnées du déclarant sont requises pour permettre, si nécessaire, de compléter l'information

**Profession** ☐ Médecin ☐ Pharmacien ☒ Autre

**Autre, précisez**

**Nom \***

**Adresse \***

**Code postal \***

**Ville**

**Téléphone**

**Telecopie**

**Courriel**

**B - Données relatives au consommateur**

**Nom\* (2 premières lettres)**

<https://pro.anses.fr/nutrivigilance/> 19/01/2017

**Thanks for your answer to our multilateral request  
in the context of this ANSES self task**

**For more information:**

**Press news:**

**<https://www.anses.fr/en/content/food-supplements-athletes-risks-health-and-uncertain-benefits>**

**ANSES Opinion in English:**

**<https://www.anses.fr/en/system/files/NUT2014SA0008EN.pdf>**

**ANSES Opinion and collective expertise report in French:**

**<https://www.anses.fr/fr/system/files/NUT2014SA0008Ra.pdf>**

