

# **DOD INSTRUCTION 6130.06**

# USE OF DIETARY SUPPLEMENTS IN THE DOD

<b>Originating Component:</b>	Office of the Under Secretary of Defense for Personnel and Readiness
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Approved by:	Gilbert R. Cisneros, Jr., Under Secretary of Defense for Personnel and Readiness

Purpose: In accordance with the authority in DoD Directive 5124.02, this issuance:

• Establishes policy, assigns responsibilities, and provides procedures for dietary supplement education and use throughout the DoD.

• Establishes policy, assigns responsibilities, and prescribes procedures for administering the DoD Operation Supplement Safety (OPSS) Program and OPSS Advisory Board.

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# **SECTION 1: GENERAL ISSUANCE INFORMATION**

#### **1.1. APPLICABILITY.**

This issuance applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this issuance as the "DoD Components").

#### 1.2. POLICY.

It is DoD policy that:

a. Mandatory dietary supplement education is required for all Service members and those who provide health-related services (e.g., health promotion specialists, fitness leaders, athletic trainers, strength and conditioning specialists) as well as health care personnel, including DoD military, civilian, and contract providers.

b. An OPSS website, hosted and maintained by the Consortium for Health and Military Performance (CHAMP), Uniformed Services University of the Health Sciences (USU) personnel, is established and provides a list of dietary supplement ingredients prohibited by the Department of Defense (known as the DoD Prohibited Dietary Supplement Ingredients List), which will be updated when a U.S. Food and Drug Administration action occurs or as new scientific information emerges.

c. Service members will not use products on the DoD Prohibited Dietary Supplement Ingredients List found on the OPSS website, unless authorized by a DoD health care provider.

d. DoD, contract, appropriated, non-appropriated, and retail facilities (commissary, exchanges, and other retail facilities under contract with the Army and Air Force Exchange Service) will not sell products containing ingredients on the DoD Prohibited Dietary Supplement Ingredients List on the OPSS website.

# **SECTION 2: RESPONSIBILITIES**

#### 2.1. ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS (ASD(HA)).

Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness (USD(P&R)), the ASD(HA):

a. Develops and oversees policy for use of dietary supplements.

b. Establishes OPSS as a program under the leadership of the DoD Nutrition Committee under DoD Instruction (DoDI) 6130.05 and its Dietary Supplements and Other Self-Care Products Subcommittee, and with the support of an OPSS Advisory Board chartered by that subcommittee and operating in accordance with DoDI 6130.05.

c. Approves and publishes the list of DoD Prohibited Dietary Supplement Ingredients on the OPSS website.

d. Reviews and approves exceptions to the use of ingredients on the DoD Prohibited Dietary Supplement Ingredients List on the OPSS website.

e. Approves dietary supplement training modules for health care professionals every other year and as required by new scientific evidence. All education and training updates must be approved by the ASD(HA). Approved education and training resources will be available on the OPSS website.

# **2.2. DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH READINESS POLICY AND OVERSIGHT (DASD(HRP&O)).**

Under the authority, direction, and control of the ASD(HA), the DASD(HRP&O):

a. Serves as the proponent for dietary supplement policy development and establishes key policy compliance parameters.

b. Monitors DoD Component policy compliance and reports to the ASD(HA) no less than annually.

c. Co-chairs the DoD Nutrition Committee in accordance with DoDI 6130.05.

d. Assigns a health readiness policy and oversight representative to take part in the OPSS Advisory Board.

e. Defines the key elements of a comprehensive dietary supplement education program.

# **2.3. DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH SERVICES POLICY AND OVERSIGHT.**

Under the authority, direction, and control of the ASD(HA), the Deputy Assistant Secretary of Defense for Health Services Policy and Oversight:

a. Develops and reviews measures of effectiveness for safe dietary supplement use and recommends updates to policy, as required.

b. In coordination with the Director of CHAMP, USU and consultation with the U.S. Food and Drug Administration, monitors and provides no less than annual updates to the ASD(HA) on unsafe ingredients.

c. Assigns a health services policy and oversight representative to take part in the OPSS Advisory Board.

#### 2.4. DIRECTOR, DEFENSE HEALTH AGENCY (DHA).

Under the authority, direction, and control of the USD(P&R), through the ASD(HA), the Director, DHA:

a. Recommends changes or revisions to dietary supplement policy.

b. Publishes procedural guidance necessary to carry out this issuance, including the requirement to:

(1) Document Service members' use of prescription and non-prescription dietary supplements in the Electronic Health Record.

(2) Document and report suspected serious adverse events to dietary supplements in the Reporting Adverse Events field on the OPSS website and in the electronic health record.

c. Develops standardized education and training material on dietary supplements, and tracks completion of education and training as required in Paragraph 1.2.a.

d. Provides consistent messaging on dietary supplement use to all health care providers, commanders, and Service members.

e. Measures the effectiveness of dietary supplement education and training programs by analyzing adverse event data. Provides biannual reports of results to the DASD(HRP&O) in March and September.

f. Measures the effectiveness of dietary supplement safety education interventions and resource materials available on the OPSS website for DoD health care providers and health promotion initiatives of community health educators.

g. Assigns a DHA representative to take part in the OPSS Advisory Board.

#### 2.5. PRESIDENT, USU.

Under the authority, direction, and control of the ASD(HA), the President, USU:

a. In coordination with the DASD(HRP&O), establishes and reviews criteria for determining:

(1) The benefits and effectiveness of dietary supplement ingredients.

(2) The criteria for placing an ingredient on the DoD Prohibited Dietary Supplement Ingredients List on the OPSS website.

b. Hosts an annual meeting to review dietary supplement questions posed to OPSS and discusses the potential and realized impact of unsafe ingredients on Active, Guard, and Reserve Service members' health, readiness, resilience, and deployment status.

c. Develops an annual report for the ASD(HA) detailing the questions received and responses and services provided to Active, Guard, and Reserve Service members, including recommendations regarding policy implications of ingredients found unsafe.

# **2.6. ASSISTANT SECRETARY OF DEFENSE FOR MANPOWER AND RESERVE AFFAIRS.**

Under the authority, direction, and control of the USD(P&R), the Assistant Secretary of Defense for Manpower and Reserve Affairs develops policy to prohibit the sale of products containing ingredients on the DoD Prohibited Dietary Supplement Ingredients List on the OPSS website by the DoD and contract retail facilities as well as criteria for removal of products from DoD facilities.

### 2.7. DIRECTOR, DEFENSE LOGISTICS AGENCY.

Under the authority, direction, and control of the Under Secretary of Defense for Acquisition and Logistics, the Director, Defense Logistics Agency provides subject matter experts to serve on the OPSS Advisory Board.

#### 2.8. OSD COMPONENT HEADS.

The OSD Component heads carry out OPSS dietary supplement education and program funding for compliance with this issuance through the Planning, Programing, Budgeting, and Execution process.

#### 2.9. SECRETARIES OF THE MILITARY DEPARTMENTS.

The Secretaries of the Military Departments:

a. Provide guidance and direction to their respective Departments to monitor compliance with this issuance.

b. Establish procedures to circulate OPSS education and training materials.

c. Issue an enforceable, punitive regulation that prohibits the use of products containing ingredients on the DoD Prohibited Dietary Supplement Ingredients List on the OPSS website.

d. Establish policy to join approved OPSS dietary supplement education in established military safety training at the onset of entry into military service and later advanced training programs.

e. Direct consistent messaging to all clinical and non-clinical DoD health care providers, commanders, and Service members through OPSS.

f. In collaboration with OPSS, establish means to disseminate and communicate new and urgent dietary supplement safety information (e.g., new information on safety, bans, and adverse events) to commanders, Service members, and DoD health care providers.

g. Assign a representative to take part in the OPSS Advisory Board.

#### 2.10. CHAIRMAN OF THE JOINT CHIEFS OF STAFF.

The Chairman of the Joint Chiefs of Staff, in coordination with the Secretaries of the Military Departments and the Combatant Commanders, monitors compliance with the execution of this issuance during all military operations, including deployments, contingencies, exercises, training and during natural and synthetic disasters, when applicable.

# 2.11. COMBATANT COMMANDERS WITH GEOGRAPHIC AREAS OF RESPONSIBILITY.

The Combatant Commanders with geographic areas of responsibility monitor compliance with the execution of this issuance and have overall responsibility for safe use of dietary supplements for all forces assigned or attached to their respective commands, including during military operations.

## **SECTION 3: PROCEDURES**

#### **3.1. DIETARY SUPPLEMENT EDUCATION AND TRAINING.**

#### a. Overview.

(1) Efforts should be made to deliver dietary supplement education using interactive approaches joined into existing training requirements and communicated through social media and other fast-moving channels.

(2) Unlike drugs, dietary supplements are not intended to treat, prevent, or cure diseases. That means dietary supplements should not make claims, such as "reduces pain" or "treats heart disease."

(3) Dietary supplements include ingredients such as vitamins, minerals, herbs, amino acids, and enzymes. Dietary supplements are marketed in forms such as tablets, capsules, soft gels, gel caps, powders, and liquids.

#### b. Requirements.

(1) All DoD health care providers and other military, civilian, and contractor personnel working with beneficiaries in any capacity on health, wellness, health promotion, rehabilitation, and performance enhancement are required to participate in DoD-approved dietary supplement safety training via the OPSS website. DoD health care providers and others with incomplete training requirements are not authorized to provide guidance related to dietary supplements.

(a) Dietary supplement safety training requirements that are applicable to contracted personnel must be included in applicable contracts.

(b) New personnel described in Paragraph 3.1.b.(1) must take part in dietary supplement safety training within 60 days of first employment or assignment.

(c) Refresher dietary supplement safety training is required when education and training updates are made, typically stemming from new scientific evidence and/or major changes to applicable regulations.

(2) Any applicable bargaining component or other personnel requirements for DoD civilian employees must be met.

#### **3.2. CONDITIONS OF USE FOR DIETARY SUPPLEMENTS.**

#### a. OPSS Advisory Board.

(1) The purpose of the OPSS Advisory Board is to review and make recommendations to the DoD Nutrition Committee for additions to or deletions from the DoD Prohibited Dietary Supplements Ingredient List on the OPSS website, as well as to alert the DoD Nutrition Committee of emerging issues relating to dietary supplements. The DoD Nutrition Committee will make the final determination on recommending to the ASD(HA) approval of the recommendations made by the OPSS Advisory Board as to whether ingredients will be added to or deleted from the list.

(2) The OPSS Advisory Board is chaired by the Director of CHAMP, USU. The OPSS Advisory Board will consist of at least one subject matter expert at the GS-15 or O-6 level from:

- (a) U.S. Air Force, Pharmacy Head.
- (b) U.S. Army, Pharmacy Head.
- (c) U.S. Marine Corps, Pharmacy Head.
- (d) U.S. Navy, Pharmacy Head.
- (e) U.S. Coast Guard, Pharmacy Head.
- (f) U.S. Space Force, Pharmacy Head.
- (g) Office of the Joint Staff Surgeon.
- (h) Combatant Commands with geographic areas of responsibility.
- (i) DHA Food Safety.
- (j) Drug Demand Reduction Program Office.
- (k) Defense Logistics Agency.

#### b. Prohibited Use.

(1) All prohibited dietary supplement ingredients will be listed on the DoD Prohibited Dietary Supplement Ingredients List on the OPSS website, which will be updated quarterly and as new scientific evidence emerges showing benefit or harm of dietary supplement use. Service members are prohibited from using any dietary supplement containing ingredients on the list.

(2) Pursuant to Chapter 47 of Title 10, United States Code, with the exceptions outlined in Paragraph 3.2.c., Service members can be prosecuted for using dietary supplements that contain substances designated on the DoD Prohibited Dietary Supplement Ingredients List on the OPSS website. This includes:

(a) Anabolic steroids listed in Schedule III of the Controlled Substances Act, as well as those outlined in Public Law 113-260 and later amendments.

(b) Various performance-enhancing drugs and selected substances on the World Anti-Doping Code Prohibited List in classes S0-S5 that are prescription drugs and/or unapproved drugs. The substances will be delineated on the DoD Prohibited Dietary Supplement Ingredients List on the OPSS website. (c) Controlled substances regulated in Sections 802 and 812 of Title 21, United States Code.

c. Permitted Use of Ingredients on the DoD Prohibited Dietary Supplement Ingredients List.

(1) Use of dietary supplements containing ingredients on the DoD Dietary Supplement Prohibited Ingredients List may be permitted when an exception has been submitted to engage in DoD-sponsored or -conducted scientific research pursuant to DoDI 3216.02, which specifies the protection of human subjects through the DoD's Institutional Review Board and the exception has been approved.

(2) Exception request forms to use ingredients on the DoD Prohibited Dietary Supplement Ingredients List on the OPSS website must be completed and submitted to the DoD Nutrition Committee and the OPSS Advisory Board through the OPSS website.

(a) Exception request forms must be submitted through the first O-5 or higher in the Service member's chain of command, reviewed by the DoD Nutrition Committee, and forwarded to the ASD(HA) for decision.

(b) Notice of decision to approve or deny the exception request will be returned within 120 days.

### **3.3. DOCUMENTATION.**

DoD health care providers will:

a. Document the use of prescription and non-prescription (if confirmed by the Service member) dietary supplements in the Electronic Health Record.

b. Document and report suspected serious adverse events resulting from use of dietary supplements to the Adverse Events section of the OPSS website and in the Electronic Health Record pursuant to Paragraph 2.4.b.(2) and Public Law 109-462.

# GLOSSARY

### G.1. ACRONYMS.

ACRONYM	MEANING
ASD(HA)	Assistant Secretary of Defense for Health Affairs
СНАМР	Consortium for Health and Military Performance
DASD(HRP&O)	Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight
DHA	Defense Health Agency
DoDI	DoD instruction
OPSS	operation supplement safety
USD(P&R) USU	Under Secretary of Defense for Personnel and Readiness Uniformed Services University of the Health Sciences

### G.2. DEFINITIONS.

These terms and their definitions are for this issuance.

TERM	DEFINITION
adverse event	Any untoward medical occurrence associated with the use of a dietary supplement in humans, whether or not considered related to such use.
beneficiaries	Active duty Service members, National Guard and Reserve members, retirees, their families, survivors, certain former spouses, and others registered in the Defense Enrollment Eligibility Reporting System.
dietary supplement	Defined in the Federal Food, Drug, and Cosmetic Act as products taken by mouth that contain a "dietary ingredient." Dietary ingredients include vitamins, minerals, amino acids, and herbs or botanicals as well as other substances that can be used to supplement the diet.

TERM	DEFINITION
DoD health care providers	Any military or civilian health care professional who, under DoD regulations, is granted clinical practice privileges to provide health care services in a military medical or dental treatment facility or who is licensed or certified to perform health care services by a governmental board or agency or professional health care society or organization. (Adapted from Section 1102 of Title 10, United States Code.)
minerals	Naturally occurring elements that cannot be made by living organisms.
OPSS	The DoD program dedicated to educating Service members and their families on all aspects of dietary supplements. It includes an educational interactive website supported by Service member education, consultations, and training on dietary supplements and a research agenda. It is a program of the CHAMP, USU.
serious adverse events	An event that results in any of the following outcomes: death, a life- threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.
vitamin	An organic compound and an essential nutrient that an organism requires in limited amounts.

## REFERENCES

- DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," June 23, 2008
- DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research," April 15, 2020

DoD Instruction 6130.05, "DoD Nutrition Committee," February 18, 2011, as amended

Public Law 109-462, "Dietary Supplement and Nonprescription Drug Consumer Protection Act," December 22, 2006

Public Law 113-260, "Designer Anabolic Steroid Control Act of 2014," December 18, 2014

United States Code, Title 10

United States Code, Title 21