

Nutritional and Ergogenic Supplements: Aircrew Guidance and Policy

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This document is a major revision and update from the previous policy. It is intended to be a succinct guide that creates an informed and realistic policy based on the latest scientific literature and lessons learned from the fleet. This document covers, at the time of this writing, the most relevant over-the-counter supplements encountered by persons engaging in flight duties. It is a living document in the sense that it will provide practical “rules of engagement” for flight surgeons and their patients, but be aware that new products are constantly being brought to market and many are not specifically covered in this document.

The Naval Aerospace Medical Institute (NAMI) does not have the capability to systematically evaluate, test, monitor and provide post approval surveillance for the human use of dietary supplements. The FDA has this responsibility. However, based upon the millions of people consuming food supplements and the low adverse outcome rate, there is no sound evidence suggesting that most common dietary supplements pose a significant aeromedical risk. NAMI accepts that some dietary supplements may be safe for consumption but others do pose a real and preventable aeromedical risk. This policy strives to set common sense and reasonable restrictions while continuing to prohibit the consumption of substances that are known to be dangerous.

In the military, all personnel are “tactical” athletes as they regularly participate in physical training in a variety of disciplines. An athlete’s ability to sustain consistent intensive training and competition without succumbing to chronic fatigue, injury, and illness is influenced not only by the types of foods eaten, but also by the amount and timing of food intake. Many believe that a normal diet will not suffice for optimum performance and decide to use dietary supplements as part of their regular training or competition.

A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandular extracts, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. Supplements commonly used include vitamins, minerals, protein, and various other “ergogenic” compounds.

Congress has defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994 and considers dietary supplements as foods and not drugs. Information on the efficacy and safety of many, if not most, of these products is limited. In some cases, evidence is lacking entirely. In other cases, the cited so called “evidence” comes from studies of isolated lab tissues exposed to amounts of the supplement that are unrealistic. In Naval Aviation, it is the job of Flight Surgeons (FS), Aviation Medical Examiners (AME), Aerospace and Operational Physiologists (AOP) and other Aviation Medical Officers (AMO) to inform, educate and regulate the use of nutritional supplements as a method of exercising Operational Risk Management.

GENERAL DIETARY SUPPLEMENTATION GUIDELINES

- FS, AME and/or AOP should inform aircrew that the U.S. Food and Drug Administration (FDA) does not regulate dietary supplements in the same way it regulates medicines. The FDA does not test dietary supplements or authorize their use prior to their being marketed. A dietary supplement can be sold with limited or no research on how well it works. The FDA can order the removal of a dietary supplement from the marketplace if it feels that it is unsafe for consumers.
- FS, AME and/or AOP should educate aircrew that dietary supplements may cause side effects, trigger allergic reactions, or interact with prescription and nonprescription medicines or other supplements they might be taking. A side effect or interaction with another medicine or supplement may make other health conditions worse. FS, AME and/or AOP should recommend that aircrew members avoid starting a new non-prohibited substance within 24-hours before flying. This is especially important when an aircrew member is consuming supplements above the Food and Drug Administration Recommended Daily Allowance.
- FS, AME and/or AOP should inform all personnel to not assume that the ingredients listed on the supplement label are present in the amounts stated unless marked with USP or CL seals. There are no regulated manufacturing standards in place for many herbal compounds, and some marketed supplements have been found to be contaminated with toxic metals or other drugs. Be aware that herbal supplements sometimes include anabolic steroids, ephedrine, caffeine, and other substances that may not be listed on the label and may cause a failure of drug testing and/or damage a person's health. Herbs can be especially dangerous when taken with certain prescription drugs or over-the-counter medications. Some supplements have been found to exceed the maximum limits for substances such as arsenic, cadmium, lead and mercury.
- FS, AME and/or AOP should educate all personnel that so-called "muscle building" anabolic herbs are unlikely to have any effect on muscles. The plant steroids/sterols found in many of these herbs cannot be converted by the human body into testosterone or other anabolic steroids. If it sounds too good to be true, it probably is. Don't expect herbal supplements to take the place of quality training as a means of improving performance.
- FS, AME and/or AOP should warn all personnel to not consume Energy Beverages or Pre-workout supplements with stimulants and/or vasodilators before, during or after strenuous activities. Some of the deaths allegedly due to energy drinks occurred when a person consumed energy drinks before and/or after performing strenuous activities.

FLIGHT SURGEON AND AVIATION MEDICAL EXAMINER RESPONSIBILITIES

- Shall not recommend the consumption of dietary supplements for medical conditions, performance enhancement or health maintenance. Should the member choose to consume allowed dietary supplements, the FS/AME shall record such use in the aircrew member's health record, typically at their annual flight physical. A simple statement like, "uses dietary supplements and has been informed of the policy" and a list of the supplements is sufficient. If usage or maximum dosage limit recommendations are provided by the FS/AME, those should be documented as well.
- Shall screen aircrew members for those potential diseases in accordance with the current clinical practice guidelines and the Aeromedical Reference and Waiver Guide (AWRG) if they report use of dietary substances for a specific health disorder.
- Shall authorize only allowed dietary supplement products that have the United States Pharmacopeia (USP) Verified Dietary Supplement Ingredient Mark, Consumer Lab (CL) seal of approval, or come from a reputable manufacturer. These trademarked seals are not to be confused with any company or group that manufactures nutritional supplements that use "USP" or "CL" in their name.
- Shall include information about an aircrew member's dietary supplement use in the medical portion of any mishap investigation.
- Personnel inadvertently consuming these prohibited substances should be removed from aviation duty for a minimum of 24 hours after the last use of the substance. Before being returned to aviation duty, the FS or AME should examine the aircrew member and ensure that they are safe for aviation duties.
 - The aircrew members shall be symptom-free of the acute effects of the prohibited substance. If indicated by the clinical situation and setting, appropriate toxicological studies and consultations shall be obtained.
 - The event shall be documented in the member's health record and the on the next flight physical.
 - The aircrew member should be counseled and educated on this policy and NATOPS by the examining FS or AME.

DIETARY SUPPLEMENT POLICY

CLASS A Substances for Flying Classes I, II and III: Use requires documentation at annual flight physical. Use of these substances within the limits noted is NCD.

These are substances for which there is strong evidence of safety and/or efficacy. Limitations on quantity and type of each dietary supplement shall be discussed and documented at the time of the annual physical as described below. Keep in mind that natural products are not always necessarily safe and dosages can be important. It is important to ensure that dosages follow relevant directions on product labels.

1. “Sports” or “Recovery” drinks without prohibited ingredients (*not to be confused with “Energy” beverages or pre-workout supplements*).

For training periods that will exceed one hour of duration, sports drinks can help prevent dehydration and restore important minerals lost through perspiration and produce better hydration than water alone. The proper CHO ratio for sports drinks is 6-8%.

2. Protein supplementation including the use of individual amino acids (except where specifically identified), derivatives, metabolites and combinations such as essential amino acids (EAAs) or branched chain amino acids (BCAAs).

For those individuals who decide to use protein supplementation, it is recommended that exercising individuals need approximately 1.4 to 2.0 grams of protein per kilogram of (fat free) bodyweight (BW) per day.

Note: Protein bars are typically formulated with trace amounts of glycerol (a Class C supplement). Glycerol in this form (when taken as part of a protein bar) does not cause any significant blood sugar response and seems to be eliminated from the body mostly unused. This product is authorized for use by aircrew.

3. Vitamins, Minerals and Essential Nutrients

An essential nutrient is a nutrient required for normal body functioning that either cannot be synthesized by the body at all, or cannot be synthesized in amounts adequate for good health, and thus must be obtained from a dietary source. Categories of essential nutrients include vitamins, dietary minerals, essential fatty acids, and essential amino acids. Intake should not exceed tolerable upper intake level (UL) as determined by the Institute of Medicine (IOM). UL is the maximum amount of daily vitamins and minerals that you can safely take without risking an overdose or serious side effects. Unless otherwise specified, the UL represents total intake from food, water, and supplements.

Note: Essential nutrients are defined by the collective physiological evidence for their importance in the diet and are listed in US government approved tables for Dietary Reference Intake.

4. Caffeine (including guarana, kola nut, cocoa beans)

Intake should be limited to not more than 450 mg per day. Limit caffeine intake to no more than 250 mg over a short time (30 minutes) as this may cause caffeine intoxication.

CLASS B Supplements for Flying Classes I, II and III: Use not prohibited but information is required. Flight surgeon or AME approval and documentation at the annual flight physical is required for use. Use of these substances within the limits noted is NCD.

These are substances for which evidence of risk is minimal. Use requires consultation with a flight surgeon or AME and documentation in the medical record. The flight surgeon or AME should counsel the member on any specific dosage limits for aircrew, possible risks, benefits, and side effects.

1. Glucosamine (glucosamine sulfate, glucosamine hydrochloride, or N-acetyl-glucosamine) with or without chondroitin

Dosage should not exceed 1500 mg per day for glucosamine and 1200 mg per day for chondroitin.

Warning: There are several reports showing that taking chondroitin with glucosamine increases the effect of warfarin on blood clotting. This can cause bruising and bleeding that can be serious.

Grounding: 24 hour local grounding after first dose.

2. Saw Palmetto (*Serenoa repens*)

Dosage for the liposterolic extract of saw palmetto berries (containing 85–95% fatty acids and sterols) is up to 320 mg daily.

Grounding: 24 hour local grounding after first dose.

3. Creatine (phosphocreatine, creatine monohydrate)

Warning: During creatine supplementation, water intake should be >64 ounces per day and sufficient to maintain proper hydration level. Creatine functions by drawing water from the rest of the body and holding it in the muscles. During creatine use, the need to drink more water than normal is needed. Some individuals may experience gastrointestinal symptoms, including loss of appetite, stomach discomfort, diarrhea, or nausea. Diabetes medications, acetaminophen, and diuretics may have interactions with creatine and should not be used together. Taking caffeine with creatine can increase the risk of side effects.

Grounding: 24 hour local grounding after first dose and if experiencing GI symptoms.

4. Melatonin

For sleep disturbance or jet lag and upon permission from flight surgeon or AME, up to 5 mg may be taken at bedtime. It should not be taken for longer than 2 weeks.

Grounding: At a minimum, 24 hour local grounding after dose. Member should be free from “sleep hangover” symptoms before flying duties.

5. Ginger

For motion sickness and upon permission from flight surgeon or AME, 250 mg up to 1 g may be taken prior to situations where motion sickness may be an issue. Dosage not to exceed a total of 4 g daily.

Grounding: None.

CLASS C Supplements for Flying Classes I, II and III: Not authorized for use. Use of these substances is CD.

Dietary Supplements and other preparations containing the following incapacitating or dangerous substances shall not be used by aircrew. There are no regulated manufacturing standards in place for many herbal compounds and some marketed supplements have been found to be contaminated with toxic metals or other drugs. Many of these substances have either (1) proven to be hazardous or (2) have not been proven to be safe with no clear proven benefit.

In addition to the supplements listed below, any supplement not listed in this guide should be classified as Class C. A supplement is of particular concern if its effects can be shown (or suspected) to lead to sedation, lead to excitation (stimulant), lead to hallucinations, have cardiovascular or hemodynamic effects (vasodilatation, vasoconstriction, hypertension, hypotension, tachycardia, etc), or act as or block neurotransmitters. Supplements containing known (or suspected) toxic compounds are also of particular concern. Personnel taking these substances should be removed from aviation duty for a minimum of 24 hours and until effects are no longer evident.

Special Note:

Energy Beverages / Energy Shots: Class C. For the purposes of this guide, Energy Beverages (EBs) are beverages that (typically) contain as main ingredients caffeine, taurine, glucuronolactone, B vitamins, guarana, l-carnitine, sugars, antioxidants, and trace minerals. Energy shots are 2-3 oz beverages that contain as much caffeine as regular energy drinks as well as mega doses of vitamins and other compounds such as taurine, l-tyrosine, phenylalanine, and guarana. The negative effects of excess caffeine have been proven, but the positive effects of many of the other additives, such as taurine and glucuronolactone, remain unproven, as does the combined effect of these ingredients. The active ingredient of concern for this product line is caffeine and other methylxanthines. Some EBs, mixes, or energy shots have up to 500 mg of caffeine per bottle. Aside from the main ingredient (caffeine), most other ingredients tend to be below the quantity expected to deliver therapeutic benefits or cause adverse reactions. EBs have been shown to increase heart rate, blood pressure, and can have a net dehydrating effect. There have been several case reports of seizures and caffeine-associated deaths when EBs are paired with exercise or intense physical activity. Research (at the time of this publication) indicates that while EBs may increase gross motor reflex reaction time, fine motor skills and cognitive processing accuracy may be impaired and extend the time it takes to complete a complicated, precise tasks correctly. EBs and derivatives (shots, gels, gum, chews, inhalers, nasal sprays, etc.) are not authorized for use by personnel on flight status who are actively performing duties in an aircraft. Personnel consuming EBs should be grounded for at least 24 hours before resuming flight duties.

CLASS C SUPPLEMENT LIST BY EFFECT:

This list is not all-inclusive and is presented for informational purposes only. It contains commonly known and marketed supplements.

Sedation:

- Effects may be additive with other over-the-counter or prescription agents with sedative properties.
- The duration of action is unpredictable.
- **Plant products known or likely to be sedatives:** *indicates anticholinergic properties
 - *Valeriana officinalis* (Valerian)
 - *Rauwolfia serpentina* (Indian Snakeroot)
 - *Atropa belladonna* (Deadly Nightshade)*
 - *Chelidonium majus* (Celandine)
 - *Humulus lupulus* (Hops)
 - *Conium maculatum* (Hemlock)
 - *Lycopodium serratum* (Jin Bu Huan)
 - *Papaver somniferum* (Opium Poppy)
 - *Passiflora incarnata* (Passion Flower)
 - *Scutellaria laterifolia* (Skullcap)
 - *Lactuca virosa* (Wild Lettuce)
 - *Aconitum napellus* (Wolfsbane)
 - *Hyoscyamus niger* (Henbane)*
 - *Datura stramonium* (Jimson Weed)*
 - *Scopolia carniolica* (Scopolia)*

Hallucination:

- **Plant products known or suspected to cause hallucinations or altered sensorium:**
 - *Psilocybe semilanceata* (magic mushrooms)
 - *Exchscholzia californica* (California Poppy)
 - *Piper methysticum* (Kava-Kava)
 - *Mandragora officinarum* (Mandrake)
 - *Myristica fragrans* (Nutmeg) in large quantities
 - *Cantharanthus roseum* (Periwinkle)
 - *Datura stramonium* (Thorn Apple)
 - *Corynanthe yohimbe* (Yohimbe Bark, Yohimbine HCL)

Cardiovascular Effects:

Cardiac glycosides

- May precipitate dysrhythmias; especially when found in association with electrolyte abnormalities such as would occur with poor hydration status (digitalis family).
- **Plant products known to contain cardiac glycosides or cardioactive substances:**
 - *Digitalis purpurea* (Purple Foxglove)
 - *Urginea maritima* (Squill)
 - *Cystisus scoparius* (Broom)

- *Convallaria majalis* (Lilly of the Valley)
- *Adonis vernalis* (Pheasant's Eye)
- *Strophanthus kombe* (Strophanthus)
- *Scilla maritima* (White Squill)
- *Digitalis lanata* (Yellow Foxglove)

Stimulants:

- Contain sympathomimetic agents that directly stimulate the heart and blood vessels.
- Implicated in deaths due to stroke or heart attack attributed to precipitous increases in pulse rate and blood pressure.
- **Substances known to be potent cardiovascular stimulants:**
 - *Ephedra sinica* (Ma-Huang, Ephedra, Ephedrine)
 - *Citrus aurantium* (Bitter Orange, Synephrine)
 - *Sida cordifolia* (bala, malva branca, country mallow, heart-leaf sida or flannel weed)
 - *Pelargonium graveolens* (geranamine, geranium oil)
 - *Evodiae fructus* (evodiamine, Evodia, Evodia Lepta, Wu-Chu-Yu)
 - *Coryanthe Yohimbe* (Yohimbe, Yohimbine, Yohimbine HCl, 11-hydroxy Yohimbine, Alpha Yohimbine HCl, Yohimbinum Muriaticum):

Note: Yohimbe has been linked to reports of severe side effects including irregular/rapid heartbeats, kidney failure, seizure, and heart attacks.

- *Methylhexanamine* (MHA, dimethylamylamine, DMAA, 1,3-dimethylamylamine):

Note: Vasoconstrictor which can elevate blood pressure and may lead to shortness of breath and MI. Formerly patented as a nasal decongestant, it is similar in structure to ephedrine and amphetamine.

- *Norcoclaurine HCL* (higenamine, Norcoclaurine):

Note: Beta-2 adrenergic agonist and is found in a variety of plants including *Nandina domestica* (fruit), *Aconitum carmichaelii* (root), *Asarum heterotropioides*, *Galium divaricatum* (stem and vine), *Annona squamosa*, and *Nelumbo nucifera* (lotus seeds). Has been traditionally been used as an anti-asthmatic.

Hypotensive Agents:

- These substances may relax blood vessels and lower blood pressure. Such products would potentially affect Gz tolerance
 - *Pinus pinaster* (Pycnogenol, Pine Bark extract)
 - *Coenzyme Q* (CoQ10, ubiquinone, ubiquinone) with or without niacin (vitamin B3, nicotinic acid and vitamin PP).

Note: CoQ10 has the potential to lower systolic blood pressure by up to 17 mm Hg and diastolic blood pressure by up to 10 mm and should not be used by any person who experience >4Gz forces.

Diuretic Agents:

- These herbs may have effects on water balance and may affect blood pressure. Commonly used for weight loss.
 - *Taraxacum officinale*

- *Verbena officinalis*
- *Lithospermum officinale*
- *Equisetum arvense*
- *Arctostaphylos uva-ursi*
- *Arctium lappa*
- *Silene saxifrage*

Hepatotoxins:

- A number of plants elaborate pyrrolizidine alkaloids, known to cause harm to the liver
- Damage is often irreversible, and may result in permanent disability or death.
- **Substances known or believed to be toxic to the liver:**
 - *Senecio spp.* (Thread Leafed Groundsel and Life Root)
 - *Larria tridentata* (Chaparral)
 - *Symphytum officinale* (Comfrey)
 - *Teucrium spp.* (Germander)
 - *Usnic Acid* (Usnea)

Other Adverse Effects and Drug Interactions:

- **Substances known or believed to have adverse effects and drug interactions:**
 - *Hypericum perforatum* (St John's Wort, Tipton's Weed, Chase-devil, Klamath weed)

Other Nutritional Supplements of Concern:

- *Pangamic Acid (Vitmain B15)*: Pangamic acid is considered UNSAFE. There is no standard chemical identity for pangamic acid. Chemicals found in some formulations of pangamic acid may cause cancer.
- *Ginkgo biloba*: Ginkgo contain components that can trigger side effects and interact with other herbs, supplements, or medications. May enhance bleeding due to blood thinning action and may lower blood pressure and cause gastrointestinal distress, headaches, skin reactions, and dizziness.
- *Ginseng*: There are four common ginsengs; American, Chinese, Siberian (Eleuthero Root) and Indian (Ashwagandha). Most supplements that list ginseng refer to Panax ginseng (AKA Asian ginseng, Chinese ginseng and Korean ginseng). This type of ginseng should not be confused with American ginseng or Siberian ginseng, which are entirely different herbs and have differing uses, dosing schedules and effects. Panax ginseng may have interactive effects with commonly prescribed medications.

Warfarin/Blood Thinning Medications: Research studies in humans do not show this herb to affect blood clotting. However, studies done in laboratory settings show it to reduce blood clotting.

Diabetic Medications/Insulin: Ginseng may lower blood sugar levels.

Hypertension: Ginseng has been reported to increase blood pressure at a low dose but can decrease blood pressure at higher doses.

Autoimmune: Ginseng seems to stimulate the immune system. In people with an immune disorder such as multiple sclerosis (MS), rheumatoid arthritis

(RA), systemic lupus erythematosus (SLE), psoriasis or eczema (ectopic dermatitis) it may worsen the condition.

Due to the wide variety of cardiovascular, neurologic and immune system effects, dosage effects and the multiple varieties of ginseng marketed, ginseng is not approved for use by aircrew.

- *Chromium Picolinate, Phosphate salts, Vanadyl sulfate*: May affect insulin sensitivity and blood sugar levels leading to hypoglycemia.
- *Echinacea*: Echinacea seems to activate chemicals in the body that decrease inflammation, which might reduce cold and flu symptoms. Laboratory research suggests that echinacea can stimulate the body's immune system. However, side effects include fever, nausea, vomiting, unpleasant taste, stomach pain, diarrhea, sore throat, dry mouth, headache, numbness of the tongue, dizziness, insomnia, disorientation, and joint and muscle aches. Additionally, echinacea might decrease how quickly the body breaks down caffeine. Taking echinacea along with caffeine might cause too much caffeine in the bloodstream and increase the risk of side effects.
- *Glycerol* : Glycerol has been used to increase hydration within cells, allowing tissues to remain hydrated during prolonged endurance exercise, when taken in combination with ample amounts of water. Glycerol can cause side effects including headaches, dizziness, bloating, nausea, vomiting, thirst, and diarrhea.

GENERAL GUIDANCE FOR NEWLY DEVELOPED DIETARY SUBSTANCES

The Federal Food, Drug, and Cosmetic Act requires manufacturers and distributors that market dietary supplements that contain "new dietary ingredients" to notify the Food and Drug Administration about these ingredients. According to this act, the manufacturer must "provide a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe." To date, the FDA has not published guidance defining the specific information that these submissions must contain.

When faced with a new supplement that has ingredients that are not covered by this guide, the flight surgeon or AME should advise the member that use is prohibited in aircrew. The number of new supplements coming to market and varieties of new formulations prohibit effective evaluation of the aeromedical safety of the entire range of supplements available. However, flight surgeons or other aeromedical officers with questions about specific supplements may forward available information on the product to the Naval Aerospace Medical Institute. Additions and updates to supplement policy will be made based on questions from the Fleet indicating a need for policy on a particular product.

Some of the considerations used in evaluating a new supplement include:

- What information is provided on the container?
- What are the claims and are they potentially hazardous during flying duties?
- Are the servings/doses standardized (CL or USP validated)?
- Does the label or advertisement contain references?
- Does the supplement act to sedate, excite (stimulant), cause or is suspected to cause changes in perceptions, cause cardiovascular or hemodynamic effects (vasodilation, vasoconstriction, hypertension, hypotension, tachycardia, etc), or block or affect neurotransmitters? Does it contain known (or suspected) toxic compounds?
- What are the potential interactions with other supplements or medications?
- What literature or publications are available indicating safety?

ADDITIONAL RESOURCES:

- U.S. Army Public Health Command
<http://phc.amedd.army.mil/topics/healthyliving/n/Pages/default.aspx>
- The Center for Food Safety and Applied Nutrition
<http://www.fda.gov/Food/default.htm>
- Office of Dietary Supplements
<http://ods.od.nih.gov>
- Medline Plus
<http://www.nlm.nih.gov/medlineplus/medlineplus.html>
- Supplement Watch
<http://www.supplementwatch.com/>
- ConsumerLab.com
<http://www.consumerlab.com/>
- Gatorade Sports Science Institute
<http://www.gssiweb.com/>
- Human Performance Resource Center
<http://hprc-online.org/>
- WebMD Vitamins & Supplements
<http://www.webmd.com/vitamins-supplements/default.aspx>
- Institute of Medicine (IOM)
<http://www.iom.edu/>
- Council for Responsible Nutrition
<http://www.crnusa.org/>
- Nutrition.Gov
<http://www.nutrition.gov/dietary-supplements>
- United States Department of Agriculture/ National Agricultural Library
<http://fnic.nal.usda.gov/dietary-supplements>

PRINTED RESOURCES

- PDR for Nutritional Supplements
Sheldon Saul Hendler, PhD, MD, FACP, FACN, FAIC
David Rorvik, MS
Publisher: Thomson Healthcare; 1st Edition (March 15, 2001)
ISBN-10: 1563633647
ISBN-13: 978-1563633645

- PDR for Herbal Medicines
Thomson Healthcare
Publisher: Thomson Reuters; Fourth Edition (September 15, 2007)
ISBN-10: 1563636786
ISBN-13: 978-1563636783