

The state and ways for improving a normative and legislative base of food supplement turnover in Russia.

Boris P. Sukhanov

**Sechenov's Moscow Medical Academy,
Institute of Nutrition RAMS**

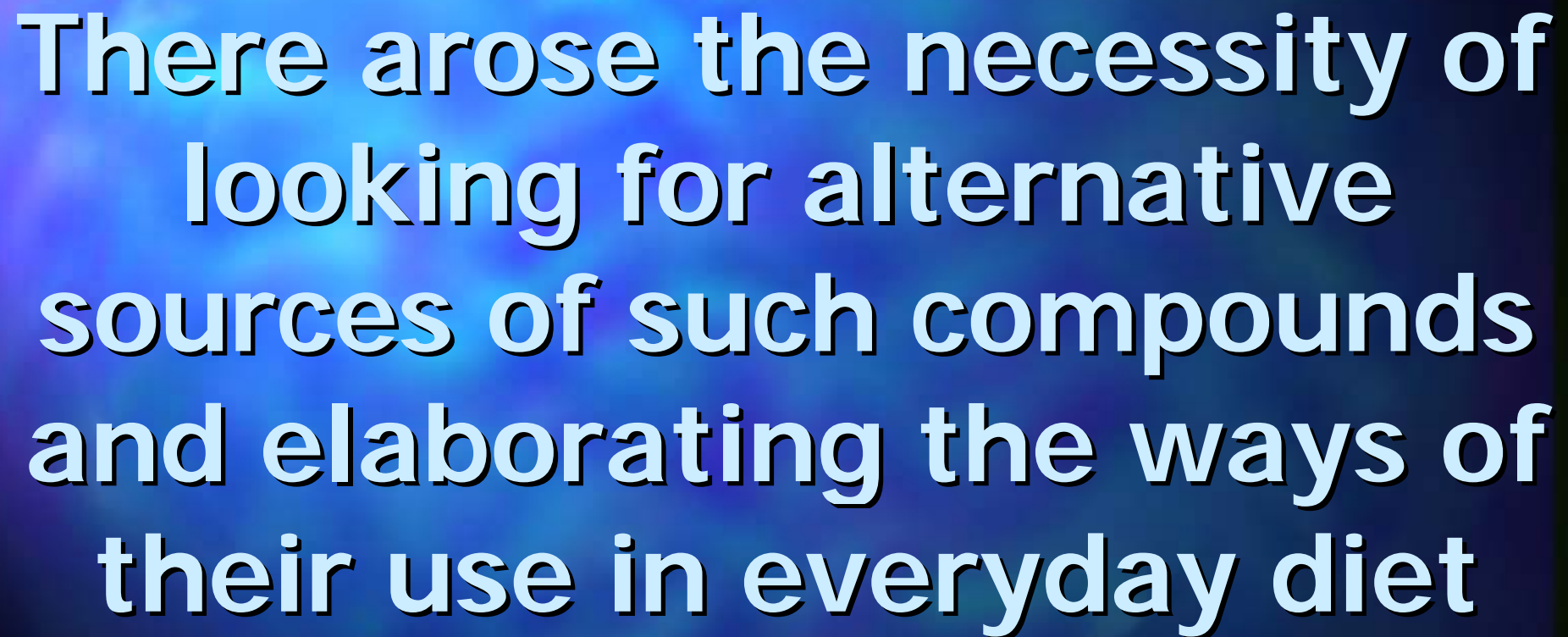
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In Russia food supplements market started developing since 1990. By 2005 there were more than 3000 food supplements. In 2005 Russian food supplements market capacity was about 1.1 billion US dollars

RF government approved in 1998 the concept “On State Policy in Healthy Nutrition of the Population of the Russian Federation by the year 2005”. It was for the first time that food supplements were defined as the means of quick elimination of micronutrient deficiency in the diet. A goal of active development of domestic manufacturing of food supplements was set

By the end of the twentieth century human energy consumption had decreased to 2000 kcal/day. It led to a reduction of the role of food as a source of micronutrients and biologically active compounds

The amount of food guaranteeing energy consumption at the level of over 3000 kcal/day provided a man with the main dietary and biologically active substances. Smaller amounts of consumed food couldn't provide people with adequate amounts of micronutrients and minor food components



**There arose the necessity of
looking for alternative
sources of such compounds
and elaborating the ways of
their use in everyday diet**

Pharmaceutical forms: pills, capsules, extracts etc. turned out to be quite optimal for this purpose. By using biologically active substances in these forms one could stick to a strict dosage depending on a person's need, sex, age, health, occupation and other factors

The scientific component necessitating an additional use of biologically active substances was a proof of their important role in ensuring vital activity and on the other hand their deficiency in the diet of a modern man

Various groups of flavonoids (flavonols and their glycosides – quercetin, kemferol; flavons – luteolin, apigenin; proanthocyanidins, catechins and many others) - functions are diverse and important for decreasing the risk of development of cardiovascular, oncological and other diseases

Indoles – regulation of the activity of enzymes at the first and second stages of metabolism and rendering foreign substances harmless

The important role of organic acids, fenolic compounds, beta-sitosterols, isoflavons, isotiocyanates, polyfrutanes, inulin, glucosamines, chondriotisulphate, chitosan and many others has been proved

**We have discovered over 120
biologically active compounds of
plant, animal and biotechnological
origin related to minor
components of food which
mechanism of work has been
decoded thus providing them to be
used in food supplements**

Medicinal plants, sea food traditionally not used for nutrition, biotechnological and less often chemical synthesis products can be used as alternative sources of such compounds. Their use is quite justified by higher biologically active components content in them comparing to a traditional food

**Legal part of food supplements
turnover is regulated by Russian
Federation Laws:**

- “On Sanitary and epidemiological
well-being of the population” (1999),**
- “On Quality and safety of food stuffs”
(2000),**
- “On Consumer rights protection” (**
2001),
- “On Advertisement” (2006)**

**By RF Government Resolutions,
Russian Federation**

National standards

Sanitary regulations and norms

Methodical instructions

Methodical recommendations

Resolutions of RF Chief State

sanitary doctor

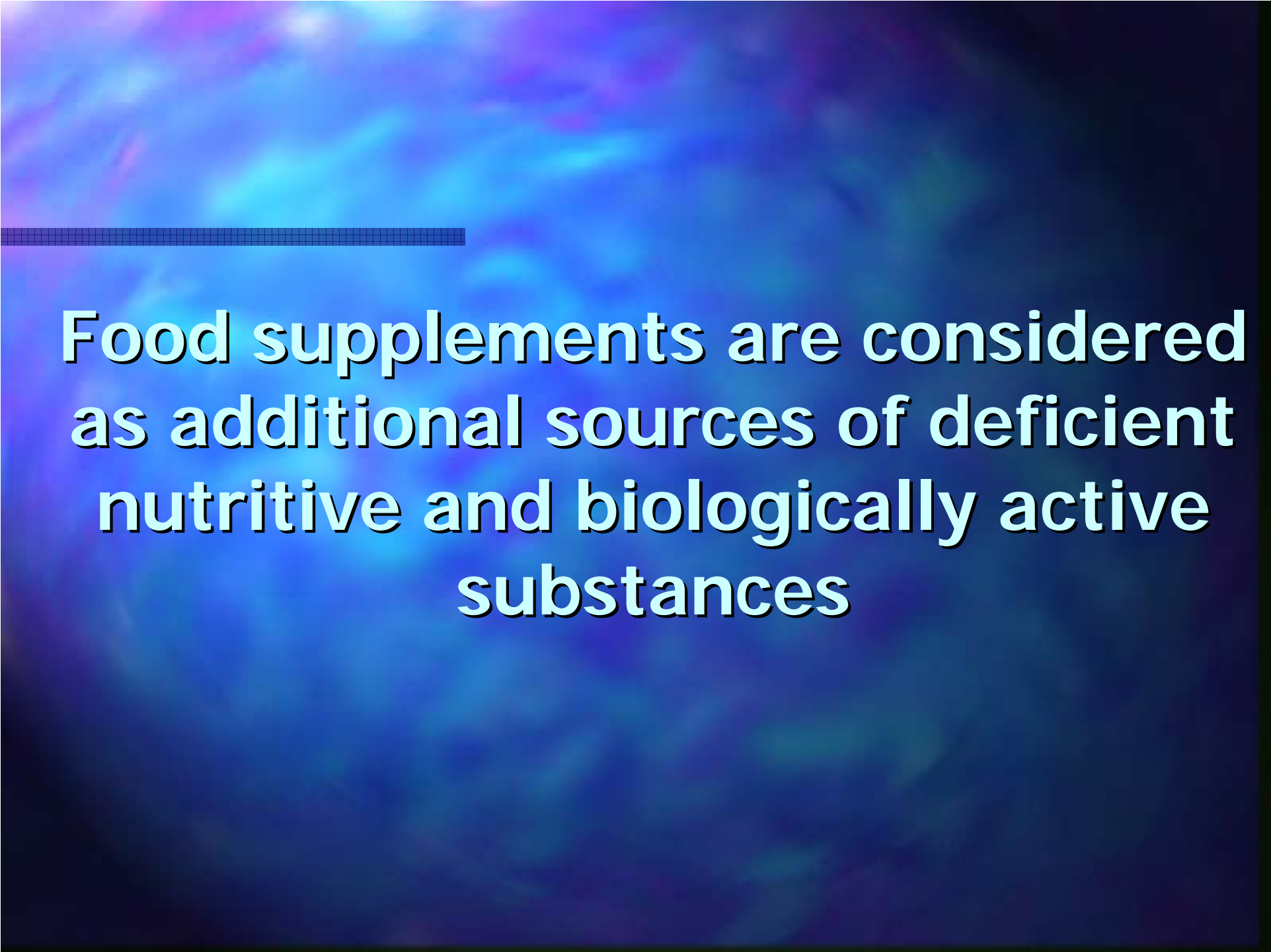
and by other departmental

normative documents

**According to these documents
a manufacturer of products
bears responsibility for their
quality, safety, effectiveness,
authenticity and completeness
of information on the products**

Food supplements in Russia are subjects to State registration, carried out by Rospotrebnadzor on the Federal level. State registration is the confirmation of food supplements quality and safety in accordance with RF sanitary legislation in a given area. State registration data are introduced in the food supplements Federal list

RF Law "On quality and safety of foodstuffs" puts food supplements in the group of foodstuffs and gives them the following definition: food supplements are "natural (identical to natural) biologically active substances meant to be consumed along with food or to be incorporated in foodstuffs". Food supplements are not medicine meant to treat and diagnose human diseases. they are administered only «*per os*»



**Food supplements are considered
as additional sources of deficient
nutritive and biologically active
substances**

In the presence of evidential base through a system of voluntary certification they may have the following wording in the section "Recommendations for the use":

- for optimization of metabolism; for normalization and/or improvement of the functional state of human body organs and systems; for decreasing morbidity risk; for normalization of gastrointestinal tract microflora; as enterosorbents

Mineral substances – not more than 100% of RDA. In other cases their content must be convincingly substantiated by documents

The content of pharmacologically active compounds of a medicinal plant in a daily dose of food supplements should not exceed 50-60% of a single therapeutic dose. At the same time the lower margin of these compounds content in BAS should not be lower than 10% of a single therapeutic dose

**A methodical base helping to
carry on quantitative
identification of more than 120
active substances in the
composition of a given product
has been developed in RF**

**A positive list of components
(over 190 names) which can be
used in the process of BAS
production was approved in
Russia**

A negative list was approved in Russia. It starts with the components containing potent, narcotic, psychotropic and poisonous substances, hormone active tissues of animals, human tissues and organs, hormones, antibiotics as well as substances unnatural for food


Medicinal plants are not allowed to be used in food supplements for children under 14 years old with the little exception (a positive list of nutritive, spicy and medicinal plants, numbering 35 names was approved)

The label should solely contain information as to a source of what components or substances the given food supplement is. It is prohibited to include information concerning any medical effects of a food supplement



**The name of a food supplement
should not reflect its supposed
medical effectiveness**

**Fragrances, dyes, stabilizers,
preservatives, dietary
supplements with the exception of
pediatric nutrition products
allowed for manufacturing, are
forbidden to be used in food
supplements for children under 3
years old**



In the Russian Federation the demands to food supplements are much stricter than that in other countries