amixon
MIXING TECHNOLOGY

– amixon® whitepaper –

Nutritional supplements

The right mix for health and more performance

The role of the mixing process in the production of food supplements

According to the German Food Association (Lebensmittelverband Deutschland e.V.), €1.439 billion was spent on food supplements (FS) in 2018[1] in Germany. That's 225 million packs. In purely statistical terms, this means almost three packs per capita per year. The most frequently purchased items are vitamin C, multivitamins and the minerals magnesium and calcium.

Statista arrives at slightly different figures for 2019, but still a significant increase: 75 million units (+3 million compared to 2018) of vitamins and minerals were purchased by consumers at a total cost of €1.1 billion (+€240 million). Statista also has magnesium in the lead. Vitamin B products are becoming increasingly popular. Besides magnesium, vitamin C preparations are also important sales drivers. More than two-thirds of the German population have already taken food supplements or can imagine doing so in the future.

The reason for this trend lies in modern society, where what we have been taught for years is important and often even pass on to the next generation: Respect comes to those who perform measurably. And those who face every other challenge with a smile and an "I can do it, yes we can" attitude. This starts at school and does not end after an active working life. Because even the "best agers" want one thing above all: to stay fit and healthy.

However, mental and sporting activity can only be sustained if nutritional deficiencies are prevented and pathogenic agents resisted. Good health is the basis for happiness and contentment. This is particularly so in the current pandemic. "According to a survey by market research company YouGov, involving more than 1,000 people aged 18 and over, 61 percent of respondents would like to boost their general health, 36 percent would like to prevent a cold, 39 percent would like to optimise bodily functions and 33 percent would like to improve physical fitness."[2]

However, even a healthy body needs more fuel for permanent high performance. A balanced diet is usually sufficient, but not always a given. That is why more and more people are taking food supplements in the form of fizzy drinks, soluble powders, sticks, tablets or capsules.

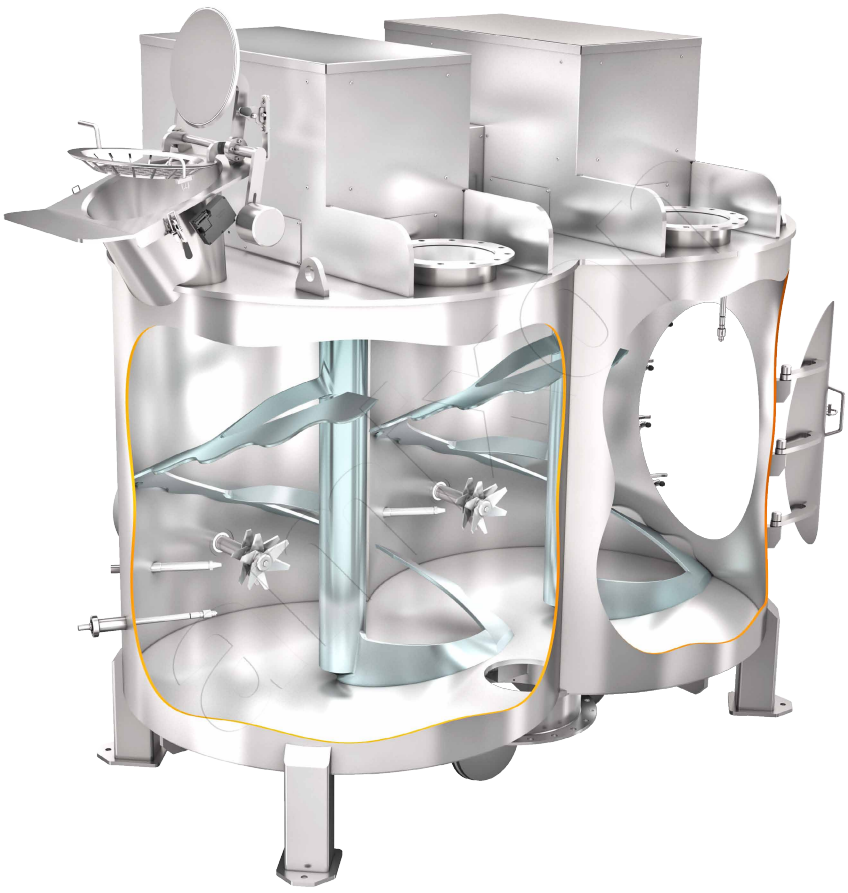
[1] The Food Supplements Working Group in Germany (BLL AK NEM): Total market 2018
[2] Market for vitamins and minerals in Germany 2019, Statista

Nutrition trends ensure more turnover

The keyword “nutrition” is also another reason for the growth in food supplements. Our society is diverse and so is our food. The “omnivore” is only one of many forms of diet. The decision to live as a flexitarian, vegetarian, vegan, etc. is usually a very deliberate one. After all, there are already 1.13 million vegans in Germany in 2020 and the trend is rising. And those who consciously choose a diet usually also consciously supply their body with deficient vitamins and vital substances – as food supplements.

One distinct form of human optimisation is body hacking or biohacking, but this does not always involve invasive methods. Body hackers often add substances to their bodies, which they are convinced have a positive effect on their own performance, making them clearer in the head, faster thinkers, more lively talkers and more responsive at sports. Everything for performance!

Consumer demands on the performance of food supplements are therefore also high. The form of administration should be convenient, and intake should be quick, easy and possible everywhere. Combination preparations are in demand and the shelf life of the products is important. That is why it is sometimes necessary to coat certain active substances before mixing them with other powders. The taste must also be pleasant. Regardless of whether it is a bulk pack, tablet or sachet, the distribution of the active ingredient must always be consistently accurate.



Strictly regulated on the borderline to medicine

§ 1 of the NemV (Food Supplements Ordinance) defines food supplements as foodstuffs which:

1. are intended to supplement the general diet (intended use);
2. are a concentrate of nutrients or other substances with a nutritional or physiological effect, alone or in combination (composition), and
3. are brought to the market in dose form, in particular in the form of capsules, pastilles, tablets, pills and other similar dosage forms, sachets of powder, ampoules of liquids, bottles with droppers and similar dosage forms of liquids and powders for ingestion in measured small quantities (dosage form).

Food supplements are therefore foods that serve to supplement the general diet with vitamins, minerals or other substances such as amino acids, dietary fibres or secondary plant substances. They contain the nutritionally effective nutrients in concentrated form and in dosed quantities.

Demarcation from drugs is not always easy. Food supplements must not have pharmacological properties, as required by the definition of medicinal products in § 2 of the German Medicines Act (AMG), or give the consumer such an impression.

Distinguishing them from foods for general consumption can sometimes be difficult as well. According to the definition of the term “food” in Art. 2 of the Basic Regulation, this includes all substances or products which serve the purpose of nutrition, whereas food supplements are intended to supplement the normal diet.

Production according to pharmaceutical guidelines

The requirements for the production technology used to prepare FS for pleasant intake by the consumer, correspond to those for food and pharmaceutical production according to relevant technical specifications as specified by GMP/FDA.

Because ever newer packaging variants and ingredients for FS are entering the market, many manufacturers rely on the services of contract manufacturers. They know the high demands in production very well and are able to produce the required outstanding and consistent quality.

FS manufacturers take advantage of the production flexibility of contract manufacturers and their readiness to tackle new challenges. This is because the different dosage forms require different, sometimes specialised and investment-intensive, manufacturing and packaging processes.

However, when sales volumes reach a certain level, Herbalife Nutrition, for example, which produces about 65% of its food supplements itself, takes over the production in-house and expands the existing know-how and process knowledge internally.

High quality under strict observation

Since the products must be 100% traceable, as is also the case in the pharmaceutical industry, quality assurance usually begins at the incoming goods stage. Many manufacturers, including Herbalife Nutrition and Nutrichem, monitor quality at various points in the production process. The focus is on the feeding of the mixers, the mixing process including sampling and precisely reproducible mixing ratios, right through to routine packaging inspection and an accurate cleaning analysis carried out on all product contact surfaces throughout the process.

Nutrichem produces food supplements in the form of powdered products with trace elements, vitamins and minerals which can be mixed with water and consumed as a drink by the consumer. The company does 100% of the production itself.

“The quality of our products is examined in multi-stage control procedures consisting of chemical, physical and microbiological processes. Regular internal and external audits as well as continuous staff training help us to achieve and maintain an especially high product quality,” says Alexander Voitl, Opex Manager at Nutrichem Diät + Pharma GmbH, describing their special challenges.

The foundation stone for homogeneity and thus for the outstanding quality of powdered products in particular is therefore laid as a first step by a stable and reproducible mixing process, and not only at Nutrichem. A reproducible and homogeneous mixture also has a positive effect later in the process, because efficiency on the packaging line increases due to a uniform product flow.

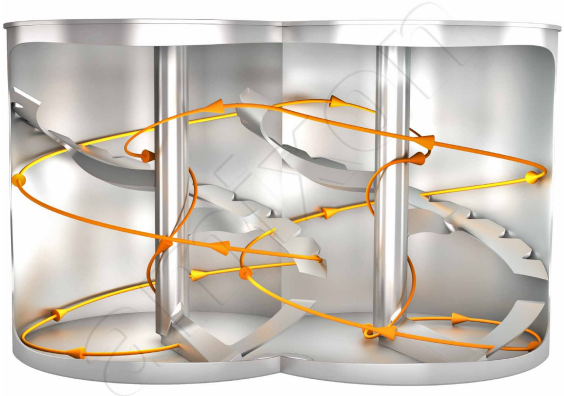
Precision and cost advantages for large batches

Mixers in the production of food supplements are therefore subject to particularly high demands on the achievable homogeneity of the mixture.

Only so-called “precision mixers” can be used to meet these mixing quality requirements. Precision mixers consist of a fixed mixing chamber and moving mixing tools. These must use the entire space to spread the components about the chamber and to create a random mixture. This is how a technically ideal mixing quality is achieved, one that cannot be improved in practice. In addition, the mixer should work quickly in the production of the food supplements, but not change the particle shape or size of the raw materials. These requirements very much limit the range of mixing systems that can be considered, with a vertical design proving to be particularly suitable.

The outstanding mixing efficiency of this design (see break-out box) is demonstrated when the smallest quantities of anti-caking agents have to be mixed in for further processing in tablet presses. These substances are very light, clumping and very difficult to distribute. However, they lose their actual anti-caking effect very quickly as soon as they are exposed to pressure or shear stress. Ideally distributing very small quantities while maintaining their full effectiveness is a special skill that amixon mixers have mastered with confidence, even with large batches.

Bulk batches have many advantages for manufacturers of FS. The effort for providing and weighing the individual components is drastically reduced. At the end of the mixing time, one-off sampling and evaluation is sufficient. As a result, large batches can often save many thousands of euros.



Alexander Voitl adds another important aspect to the list of mixer requirements: “Some of the ingredients are very sensitive, so low temperature development during the mixing process is very important to us.”

In many applications, including large batches, amixon has been able to demonstrate that energy input is minimal every time. No heat of reaction can be detected in the product, nor is there any appreciable increase in dust content.

The latter is particularly important for the consumer, who expects good solubility and dispersibility of the finished product. It also plays a role when high-performance packaging machines are filling sachets and pouches.

The fact that the temperature of the mixture does not increase as a result of the mixing process is essential for the shelf life of the FS in the global distribution process. If the mixtures were packed warm, they could clump together and micro-condensation could unintentionally discolour them.

For this reason alone, maintaining the stability of the products is of considerable importance to manufacturers for quality reasons. At Herbalife Nutrition, for example, a dedicated team is responsible for FS product stability under different climatic conditions of use and transport. The suitability of new product formulations and packaging is checked in special stability test chambers before they go into production.

The art of cleaning determines the degree of flexibility

Due to frequent recipe changes and because of the strict specifications for pharmaceutical production, the mixers used in the production of FS should be validatable in a short time and easy to clean.

Alexander Voitl gives an insight into mixer selection in practice. “Before we use a mixer, it must successfully and safely pass the qualification and validation procedures. The space-saving vertical twin-shaft mixers from amixon have all passed these tests.”

The installation and operation of the mixer is ensured during this qualification process. For valida tion, the mixing and cleaning processes must also be checked for conformity to the defined specifications. If a mixer does not pass this qualification, it cannot be used in production according to the specifications.

During wet cleaning of a precision mixer, for example, rotating washing heads are lowered/inserted into the mixing chamber from above and from the side. At the same time, the mixing tools rotate and ensure that all surfaces in contact with the product are flushed with water. The wash water is discharged at the lowest point in the bottom of the mixer.

Since the heat capacity of stainless steel is only 11 percent of the heat capacity of water, the mixer heats up very quickly when cleaned with warm water. That is why the machine dries more quickly afterwards. As a rule, no detergents are needed for cleaning.

Multi-stage wet cleaning is only needed if very intensive colours or aromas have been processed. It consists of pre-wetting, foaming and rinsing. The same applies when liquids have to be mixed in micro-droplets into a powder and consequently unwanted adhesions have to be washed off. Given good organisation, washing and drying takes an hour.

Many nutrient processing plants successfully carry out drying and cleaning by mixing one or two rinsing batches. These rinsing batches are properly packaged so that they can be used again later as a recyclable material if the recipe is suitable.

Here it becomes clear how valuable the individual mixtures can be in food supplements. That is why another feature of the mixer is crucial in the manufacturing process - the degree of residue emptying. With the vertical mixer from amixon, the 7,000 litres of mix can be discharged down to a residue of 0.5 litres, or 0.007 percent.

Why does 0.007 percent matter? Because every extra gram that the mixer produces can be sold and does not have to be disposed of. The less residue that remains in the mixer, the easier and faster the cleaning process, the lower the potential contamination and the higher the batch reproducibility.

For good process efficiency, it is the small constants that ultimately influence the cost of producing the FS. So if set-up and cleaning times can be clearly planned and are short, and the product quantities to be discarded are low, the bottom line is higher margins for the food supplement manufacturer.

How does a vertical mixer work?

Two vertically mounted helical mixing tools rotate in the same direction, with the mixing chamber being formed by their enveloping surfaces as they rotate. The components involved in the recipe are poured into the mixing chamber from above or sucked in. The ideal mixing quality is achieved after approximately 50 to 60 revolutions. Depending on the rotation speed of the mixing tools, this corresponds to a mixing time of 2 to 5 minutes. Then a zero-clearance bottom valve opens and the mixture is discharged without segregation.

The thrust flow that takes place here is described as “three-dimensional flow”. The mixing tools transport the goods upwards in the periphery and let them flow downwards under gravity in the centre, along the mixing device shafts. At the same time, the mixture is dispersed radially by the mixing arms.

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