PRESS RELEASE from the Nordic Food Supplements Alliance

The National Food Agency's (Sweden) instructions contravene Swedish and EU law

The Supreme Administrative Court of Sweden has affirmed in its judgment of 13 November 2018: Swedish municipalities that imposed a sales ban on food supplements acted in contravention of applicable Swedish and EU law.

In 2015, the National Food Agency issued a handbook to Sweden's municipalities comprising instructions on how to implement controls of such items as food supplements. The agency handbook addressed the so-called recommended ULs (Upper Limits) levels from EFSA* (2006) on vitamins and minerals, although ULs are not officially prescribed as legally binding maximum permitted levels (MPL´s) threshold values – neither in Sweden nor the rest of the EU.

Consequently, Swedish municipalities banned companies and retail stores from selling completely safe and legal products. This has entailed Swedish consumers missing out on products and caused companies to suffer considerable economic losses.

In accordance with the Supreme Administrative Court's judgment of case number 3160-17, Swedish municipalities are not entitled to institute local sales bans on food supplements deemed to be safe in accordance with the Food Supplement Directive (FSD). Therefore, municipalities that have imposed a sales ban on a food supplement in reference to its quantity (levels) of vitamins or minerals have done so entirely without statutory support.

The National Food Agency's handbook, *Kontrollwiki*, contains gross errors

"There are no official, legally binding maximum permitted levels (MPL´s) threshold values for vitamins or minerals, neither under Swedish law nor within the regulatory framework of the European Commission. On the other hand, food supplement contents are regulated by the Food Supplement Directive 2002/46/EC, issued by the EU Commission with the aim of harmonising the trade of food supplements, and which is incorporated into Swedish law," explains Rolf Forslund of Kenkou Selfcare AB, one of the companies seriously impacted by the National Food Agency's erroneous information to municipalities.

Protests by both business owners and lawyers against the erroneous information in the National Food Agency's control handbook were lodged with municipalities, government agencies and the minister responsible. However, no amendments have been made to the misleading information. Municipalities are still being encouraged to impose sales bans and to submit reports to the EU's safety-alert system for hazardous substances in foodstuffs, the Rapid Alert System for Food and Feed (RASFF), if food supplements are found to exceed the so-called UL values.

"This means that Swedish municipalities are being encouraged to act arbitrarily, without any legal basis and that the crucial RASFF system is being abused," Rolf Forslund continued. "This is very dangerous, as it undermines the system's vital functions. RASFF is meant to warn of the presence of hazardous substances like poisons, heavy metals and bacteria (i.e. Salmonella) in food, not for vitamins in completely safe doses."

A judgment by the Supreme Administrative Court is precedent-setting

"Now that this is a judgment by the Supreme Administrative Court, precedent has been set. " Marcus Angström, attorney at 7Wise Law firm explains.

"It is completely unacceptable for companies and consumers to be subjected to such arbitrary treatment by Swedish government agencies. As business owners, we already apply the principles referred to in the Food Supplement Directive by means of clear labelling and the stipulated control procedures," explains Patrick Wahlberg of Greatlife Group AB, which recently received an amendment to the previous ruling against its product with a daily dose of vitamin D 125 µg.

Government agencies must now conform to the court judgment

"I have great sympathy for the affected companies suffering from the National Food Agency's and many municipalities erroneous actions. I now presume that the National Food Agency will immediately align its instructions according to this verdict so that correct information from now on will go out to all the Swedish municipalities." says Marcus Angström, attorney at 7WISE Law Firm.

"If and when maximum permitted levels (MPL´s) threshold values for vitamins or minerals are imposed within the EU or at a national level in Sweden, the Court of Justice of the European Union (CJEU) has already in related verdicts clearly stated that the most recent research has to be taken into account. The balance between risk and benefit must also be given more careful consideration, according to the European Commission and risk assessment institutions like TNO." Rolf Forslund says.

"However, maximum permitted levels (MPL´s) threshold values are not really needed, neither nationally or within the EU. Again, the Court of Justice of the European Union (CJEU) has already clearly established that food supplement labelling that gives the consumer clear information is the most proportionate measure that allows free trade between the Member States to continue whilst at the same time provides adequate protecting to the consumers. Many EU countries already practice this. Västerås Municipality in Sweden has also recently begun to apply this principle since several administrative court verdicts have confirmed the validity of this practice. " concludes Rolf Forslund.

The Judgment of case no. 3160-17 can be read in its entirety here:

http://www.hogstaforvaltningsdomstolen.se/Templates/Pages/DV News.aspx?id=60310

Facts about the Supreme Administrative Court of Sweden: The Supreme Administrative Court of Sweden is the highest authority among Sweden's administrative courts. Its primary function is to set precedents. The court tries the appeals of judgments and verdicts announced by the country's four administrative courts of appeal. Out of the 9000+ applicants for rights to appeal in this court only about 2% (approx. 200 cases per year) gets approval to be looked at, when/if precendent-setting verdicts are needed.

Facts about the Nordic Food Supplement Alliance: In 2015, when erroneous instructions from the National Food Agency began to be applied, 12 of the companies impacted by the sales bans decided to jointly examine the decisions by legal means.

The companies in the alliance comprise: Alpha Plus AB, Bättre Hälsa AB, Edura AB (Thorne Research), Egenvårdspoolen AB, Great Earth AB, Greatlife Group AB (Innate Response), Holistic Sweden AB, Hälsokraft (chain store), Kenkou Selfcare AB (Lamberts), Nordic Premium Group AB (Solgar, Terranova, Nordiq), RevivaBio AB, Au Naturel Inc (Solaray). The legal and scientific coordinators comprised of Rolf Forslund and Lennart Holmgren, as well as Marcus Angström of 7WISE Law Firm.

***History:** Sweden is divided into 290 municipalities, each being independently governing control authorities. The control handbook issued by the Swedish National Food Administration is presently known as *Kontrollwiki*. It is the means by which municipalities are informed that they can impose sales bans on food supplements exceeding so-called Upper Limit values derived from the informal preparatory work report for the discussion paper presented in 2006 by the European Food Safety Authority, EFSA. The contents of food supplements are regulated by the Food Supplement Directive 2002/46/EC, issued with the aim of simplifying trade in food supplements and increasing consumer protection. This directive is incorporated into Swedish law.

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Captions text for images:

1.) Rolf Forslund, Kenkou Selfcare AB, is one of the business owners who does not accept the government agency's erroneous sales ban of safe food supplements.

2.) Marcus Angström, 7WISE Law Firm, won a Supreme Administrative Court case against the Muncipality of Nacka (Planning and Environmental Services Committee).

[Translation from Swedish into English]

THE SUPREME ADMINISTRATIVE COURT
JUDGMENT

Case no.
3160-17

issued in Stockholm on 13 November 2018

APPELLANT
Greatlife Group AB, corporate ID number 556899-2605

Legal representative: Marcus Angström (Attorney)
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OTHER PARTY
Planning and Environmental Services Committee in the Municipality of Nacka
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RULING APPEALED AGAINST
Administrative Court of Appeal in Stockholm's judgment of 11 May 2017 in Case no. 397-16

THE MATTER
Prohibition on sale and recall of food

RULING OF THE SUPREME ADMINISTRATIVE COURT

The Supreme Administrative Court declares that the Planning and Environmental Services Committee in the Municipality of Nacka did not have the required constitutional support when it intervened against Greatlife Group AB's sale of the food supplement Vitamin D3 5000 with reference to it providing an excessive daily intake of vitamin D.

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The Supreme Administrative Court otherwise grants leave to appeal in the case and revokes the rulings of the Administrative Court of Appeal and the Administrative Court and also the decision made by the Planning and Environmental Services Committee in the Municipality of Nacka.

BACKGROUND

Vitamins and minerals that are intended to be eaten in a concentrated form are defined as food supplements and counted as food. Food supplements are intended to supplement the normal diet and are sold in the form of capsules or the like.

The food legislation comprises different instruments of EU law that are supplemented by national rules. The overall aim of the legislation is to both maintain the free movement of goods and ensure a high level of protection of human health.

At an EU law level, the fundamental principles and requirements within the food chain are laid down in a Regulation that applies to food in general. In addition to definitions and general principles, the Regulation includes provisions about responsibilities for, among others, food business operators. Furthermore, a requirement is laid down that food may not be placed on the market if it is not safe and it specifies the considerations to be taken into account when determining whether this is the case. There are also rules about intervention in the case of a failure to comply with the legislation. The European Food Safety Authority (EFSA) was also established through the Regulation.

According to the General Food Law Regulation, the responsibility for food, including food supplements, meeting the requirements for safety lies primarily with the individual business operator. It is their responsibility to take measures and inform the competent control authority if it is suspected that a food is unsafe. The control authority may intervene if the food business operator does not take adequate measures.
There is a separate directive for food supplements. The purpose of this Directive is, among other things, to achieve a complete harmonisation of the rules within the Union as regards the use of vitamins and minerals when manufacturing food supplements. There are rules in the Directive

concerning, among other things, what substances are permitted in food supplements and the opportunities to intervene when a food supplement may endanger human health. The special rules for food supplements are intended to apply instead of the corresponding provisions contained in the General Food Law Regulation.

It is stated in the reasons for the Food Supplement Directive that excessive intake of vitamins and minerals may result in adverse effects and the intention is that the Directive should be supplemented by the maximum and minimum levels set by the European Commission for various substances, although this has not yet been done. Until such limits have been set, it is the responsibility of the manufacturer to mark the goods correctly and thereby state both the recommended maximum daily intake for safe use and the minimum daily dose for the supplement to have the intended effect.

Greatlife Group AB imports and sells food supplements to both retailers and consumers and is registered as a food processing plant in the Municipality of Nacka. The company was offering, among other things, the food supplement Vitamin D3 5000 for sale, which provides a daily dose of vitamin D of 125 micrograms.

The Planning and Environmental Services Committee in the Municipality of Nacka decided to intervene against the company's sales of the food supplement through a decision concerning a prohibition on sale and recall. This decision was justified by the food supplement possibly entailing health risks for consumers and therefore not being regarded as safe in accordance with the EU law rules for food. As grounds for this assessment, the Committee referred to EFSA having assessed the maximum safe daily dose of vitamin D to be 100 micrograms.

The company appealed the decision to the County Administrative Board, which rejected the appeal.

The Administrative Court, which rejected the company's appeal, considered that the decision neither contravened EU law nor national provisions. The Administrative Court also found that the

Committee was justified in its assessment that the food supplement was not a safe food and also assessed that the measures decided were proportionate.

The company appealed to the Administrative Court of Appeal and stated, among other things, the following. The food supplement in question is safe. The Committee did not conduct its own risk analysis but based its decision exclusively on a report from EFSA. However, the report, which is from 2012, should not be understood as the authority having determined in it the maximum safe daily dose of vitamin D. The issue concerned instead a working tool for the Commission's ongoing work to produce supplementary rules. Subsequent research shows that significantly higher daily doses of vitamin D do not have any harmful or adverse effects. As no limits for vitamins in food supplements have been determined, the company has not breached any rules and there are therefore no grounds to intervene against the sale.

The Administrative Court of Appeal rejected the company's appeal. The Court concluded that there are special provisions concerning food safety for food supplements. As no limits for the maximum daily intake of vitamins have been determined in accordance with these provisions, the Administrative Court of Appeal considered that the general provisions on food safety could be applied instead. The Administrative Court of Appeal found that this legislation gave the Committee lawful grounds to intervene as regards the issue of food supplements that are not assessed to be safe. The Court considered that the food supplement in question could probably entail a risk to human health and thereby could not be regarded as a safe food. According to the Administrative Court of Appeal, the prohibition on sale was a proportionate measure and, as the food supplement was already on the market, there was no other alternative for meeting the high requirements for the protection of human health than to require a recall.

APPLICATIONS, ETC.

Greatlife Group AB requests that the Supreme Administrative Court remits the case to the Administrative Court of Appeal for new processing as the company was denied a verbal hearing there and thereby the opportunity to present additional evidence. In the event that the case is not remitted, the company requests that the Supreme Administrative Court holds a verbal hearing in

the case and the substantive issue of whether the decision of the Planning and Environmental Services Committee should be revoked. The Company states, among other things, the following. There are neither national nor EU law provisions that determine limits for vitamins in food supplements. The company has thus not traded in violation of applicable food legislation when offering its food supplement for sale. Thus the Committee was not lawfully able to intervene against the company's sale of the food supplement.

The Planning and Environmental Services Committee in the Municipality of Nacka considers that the appeal should be rejected.

REASONS FOR THE RULING

The issue in the case

Leave to appeal in the Supreme Administrative Court may, according to Section 36 a, first paragraph of the Administrative Court Procedure Act (1971:291), be restricted to apply to a certain issue in the case ('precedent issue'), the consideration of which is of importance to the application of law. Pending such a consideration being made, the issue of granting leave to appeal relating to the case may otherwise be stayed.

The Supreme Administrative Court has granted leave to appeal in respect of the issue of a control authority having had the required constitutional support when it intervened against a business' sale of a food supplement with reference to it providing an excessive daily intake of a certain substance. The issue of leave to appeal in the case has otherwise been stayed.

Legal regulation, etc.

The fundamental principles and requirements for all stages of the food chain are found in Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ('the Food Regulation').

The Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements ('the Food Supplement Directive') contains special provisions for food supplements. This Directive has been implemented in Swedish law through the regulations of the National Food Agency (LIVSFS 2003:9) concerning food supplements.

Rules about official controls of foods are found in Regulation (EC) No. 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ('the Control Regulation').

According to Section 5 of the Food Act (2006:804), the Act supplements such provisions in EC Regulations ('EC provisions') that have the same purpose as the Act and that fall within the Act's area of application. It is provided by Section 22 that, in addition to that prescribed by the EC provisions that are supplemented by the Act, a control authority may issue the directives and prohibitions required for compliance with the Act, the regulations and decisions issued pursuant to the Act, the EC provisions supplemented by the Act and the decisions issued pursuant to the EC provisions.

Assessment of the Supreme Administrative Court

The Planning and Environmental Services Committee in the Municipality of Nacka has made a decision concerning a prohibition on sale and recall of a certain food supplement for the reason that it cannot be deemed safe as, in the assessment of the Committee, it provides an excessive intake of vitamin D.

The point of departure is that it should be possible to freely offer for sale within the Community a food supplement that satisfies the requirements contained in the Food Supplement Directive. It is consequently stated in Article 3 of the Directive that the Member States shall ensure that food supplements may be marketed within the Community only if they comply with the rules laid down in this Directive. It is also laid down that the Member States shall not, for reasons related to their

composition, prohibit or restrict trade in such products as comply with the Directive (Article 11.1).

The vitamins and minerals that may be included in a food supplement are specified in the Food Supplement Directive. Only vitamins and minerals listed in Annex I to the Directive, in the forms listed in Annex II, may be used for the manufacture of food supplements (Article 4). Vitamin D is one such substance that may be included in a food supplement. Furthermore, the manufacturers of food supplements are responsible for stating on the products, as established by a scientific risk assessment, a recommended maximum daily intake and the minimum daily intake required for the supplement to provide a health effect (Article 5).

The assessments that the manufacturers make in respect of safe daily intakes and required minimum doses may differ. Therefore, maximum limits also need to be determined for vitamins and minerals with known risks, and similarly minimum levels decided, so that the regulation of food supplements is harmonised within the EU. The determination of the limits required for the implementation of the Directive (Articles 5.4 and 13.2) has been passed over to the Commission through the Food Supplement Directive. However, the Commission has not yet done this.

Until the Commission has established limits, the Member States may have national provisions on limits for substances in food supplements. The Member States must then proceed on the basis of the criteria set out in Article 5 of the Food Supplement Directive, including the requirement for a risk assessment on the basis of general acceptable scientific data, and also observe Articles 34 and 36 of TFEU concerning the free movement of goods (see, for example, Solgar Vitamin's France *et. al.*, C-446/08, EU:C:2010:233, pp. 22 to 24 and 27 to 32 and also Noria Distribution, C-672/15, EU:C:2017:310, p. 16). The Member States shall thus determine these levels on the basis of the same criteria from which the Commission must proceed if it issues such rules. Sweden has not introduced any provisions on limits.

The issue of the opportunities available for intervening against a food supplement should, in the opinion of the Supreme Administrative Court, be based on the Food Supplement Directive. The

opportunity to intervene against products encompassed by the Directive is basically restricted there to the situation regulated by Article 12.1 (HLH Warenvertriebs GmbH *et. al.*, C-211/03 *et. al.*, EU:C:2005:370, pp. 70 and 71). It is stated in this Article that where a Member State, as a result of new information or of a reassessment of existing information, has detailed grounds for establishing that a food supplement endangers human health, though it complies with the said Directive or said acts, that Member State may temporarily suspend or restrict application of the provisions in question within its territory.

An application of Article 12.1 presumes that there are applicable maximum levels for the substance being assessed that make the food supplement in question unsafe (Solgar Vitamin's France *et. al.*, pp. 40 to 42). The lack of rules on maximum levels thus means that there is no opportunity pursuant to the Directive to intervene against the offering of a food supplement for sale.

The issue thus arises about whether it is possible instead, pursuant to the Food Regulation, to intervene when a food supplement is not assessed as safe. The Regulation is subsidiary in relation to the Directive and its provisions are thus only applicable in respect of situations not regulated by the Directive (HLH Warenvertriebs GmbH *et. al.*, pp. 38 and 39).

It follows from the Regulation that food shall not be placed on the market if it is unsafe (Article 14.1). Food shall be deemed to be unsafe if it is considered to be, for example, injurious to health (Article 14.2). The considerations to be taken into account when making this assessment are specified in Articles 14.3 and 4.

As regards food products regulated separately, which is the case with food supplements, the point of departure is that they shall be deemed to be safe if they satisfy the aspects covered by specific Community provisions (Article 14.7 of the Food Regulation). The food supplement in question in this case corresponds with the special rules for food supplements as these are now formulated, i.e. when provisions concerning maximum levels have not yet been decided.

However, it is laid down in Article 14.8 of the Food Regulation that conformity of a food with specific provisions applicable to that shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe. The provision thus affords an opportunity to intervene against, for example, a food supplement that certainly in terms of its content confirms with the Directive but that also transpires to include foreign particles or contaminants that are harmful.

However, the decision in question in this case relates to a completely different situation. What the Committee has actually done, in reliance on Article 14.8 of the Food Regulation, is that it has introduced locally such a maximum limit that is to be decided by the Commission for the entire Union or, pending this, by the Member States for their own nation and then applying the rules contained in Article 5 of the Food Supplement Directive and considering Articles 34 and 36 of TFEU.

It follows from that stated above that the Planning and Environmental Services Committee in the Municipality of Nacka has no grounds to intervene against the company in the way that has occurred. The precedent issue that gave cause for leave to appeal shall thus lead to the conclusion that the Committee did not have the required constitutional support when it intervened against Greatlife Group AB's sale of the food supplement Vitamin D3 5000 with reference to it providing an excess intake of vitamin D.

As the Committee did not have the required constitutional support to issue the decision on the matter, there is cause to grant leave to appeal in the case in those parts where the issue of leave to appeal has been stayed and to revoke the rulings of the Administrative Court of Appeal and the Administrative Court and also the decision made by the Planning and Environmental Services Committee in the Municipality of Nacka.

With this outcome in the case, Greatlife Group AB's application for a verbal hearing does not give cause for any measure to be taken.

Henrik Jermsten, Eskil Nord, Anita Saldén Enérus, Per Classon and Ulrik von Essen, Justices of the Supreme Administrative Court, participated in this ruling.
Daniel Böcker, Secretary of the Supreme Court, was the member reporting on the matter.

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