Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Food Safety and Veterinary Office FSVO
Food and Nutrition

- To the cantonal inspection authorities for foodstuffs legislation
- To the foodstuffs inspection authority of the Principality of Liechtenstein
- To the interested parties

Bern, 1st February 2024

Information letter 2021/7.1[1]: Self-supervision of non-regulated other substances in food supplements

1 Background

The entry into force of the completely revised Foodstuffs Act on 1 May 2017 entailed the abandonment of the "positive principle". This means that any foodstuffs that comply with the legal requirements may also now be placed on the market, unless specified to the contrary in the legislation. The Swiss definition of foodstuffs has been congruent with that of the EU since 1 May 2017. Additional requirements apply to food supplements, among them maximum permitted levels for vitamins and minerals and restrictions on certain other substances. The list of other substances which may be present in food supplements is no longer exhaustive. As part of their self-supervision activities, companies must examine whether the other substance that is not specifically regulated is safe and in compliance with the requirements of the foodstuffs legislation.

This information letter describes the conditions under which other substances that are not specifically regulated may be used. It provides manufacturers, importers and distributors with information on ways of performing self-supervision in this area. It seeks to provide assistance to the enforcement authorities when examining products of this type and in the context of manufacturers' self-supervision activities and to ensure harmonised enforcement.

[1] Updated on 01.02.2024 (Question 6: 2nd section: Adaptation of the categories in the novel food definition; 4th and last section: Adaptation of the designation «Novel Food status Catalogue» of the EU)

Federal Food Safety and
Veterinary Office FSVO
Schwarzenburgstrasse 155, 3003 Bern
Tel. +41 58 463 30 33
info@blv.admin.ch
www.blv.admin.ch

2 Legal framework

Legal provisions:

- Definition of foodstuffs: According to Art. 4 of the Foodstuffs Act (FSA, SR 817.0)
- Food safety: Art. 7 FSA, Art. 8 of the Ordinance on Foodstuffs and Utility Articles (FSO; SR 817.02)
- Self-supervision: Art. 26 FSA, Art. 73-75 FSO
- Prohibition of deception: Art. 12 FSO
- Provisions governing food supplements: FDHA Ordinance on Food Supplements (FoodSO; SR 817.022.14)
- Provisions governing novel foods: Art. 15-19 FSO, FDHA Ordinance on Novel Foods (SR 817.022.02)
- List of prohibited plants, plant parts and preparations manufactured from them: Annex 1 of the FDHA Ordinance on Foodstuffs of plant Origin, Fungi and Table Salt (VFO; SR 817.022.17)
- List of prohibited substances: Annex 4 of the FDHA Ordinance on the Addition of Vitamins, Minerals and other Substances to Foodstuffs (AVMO; SR 817.022.32)
- List of prohibited substances: Annex 4 of the FDHA Ordinance on Flavourings and Food Ingredients with Flavouring Properties in or on Foodstuffs (Flavourings Ordinance; SR 817.022.41)

Resources and basis of enforcement

- Report on “Criteria for distinguishing therapeutic products from foodstuffs with reference to orally administered products” by Swissmedic and the FSVO
- Information letter 2020/2: Marketability of fungi as foodstuffs
- Information letter 2021/4: Use of “substances” in the categories plants, fungi, lichens and algae and preparations manufactured from them as foodstuffs or food ingredients; cf. the FSVO website “Substance lists for plants and fungi”, https://www.blv.admin.ch/blv/de/home/lebensmittel-und-ernaehrung/lebensmittelsicherheit/einzelne-lebensmittel/stofflisten-pflanzen-pilze.html (not available in English).

General comments on the Ordinance on Food Supplements

- Annex 1 Part A FoodSO (authorised vitamins and minerals): exhaustive
- Annex 1 Part B FoodSO (other substances with restrictions on use): not exhaustive
- Annex 2 FoodSO (authorised combinations of vitamins, minerals and regulated other substances): exhaustive.

Substances not listed in Annex 1 Part A (e.g. silver, gold, vanadium) and combinations not listed in Annex 2 FoodSO are therefore not authorised unless they are authorised novel foods.

3 Other substances

“Other substances” in food supplements are substances other than vitamins and minerals which have a nutritional or physiological effect. The terms “nutritional” and “physiological” are not defined in the foodstuffs legislation.

Food supplements may contain a wide range of nutrients and other ingredients, including vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts (see recital 6 of European Directive 2002/46/EC[2]).

The other recitals of Directive 2002/46/EC should also be taken into account:

(4) Consumers, because of their particular lifestyles or for other reasons, may choose to supplement their intake of some nutrients through food supplements.

One of the decisive elements in classifying a foodstuff as a food supplement is its intended use “to supplement the normal diet”. A nutritional or physiological effect must be described and demonstrated scientifically in all cases.

(9) Only vitamins and minerals normally found in, and consumed as part of the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary.

In this recital, the formulation “normally found in, and consumed as part of the diet” is relevant. The “nutritional effect” refers to the consumption of vitamins, minerals and other substances used for nutrition. Kügel/Hahn/Delewski[3] see the “nutritional effect” as part of the “physiological effect”. In this context, the “physiological effect” can be seen as a generic term. The term “physiological effect” refers to any effect of a substance on functions of the human body. “There are substances which are consumed by humans and absorbed into the body through the mucous membrane of the gastrointestinal tract but which do not provide nutrition because they do not contribute to the provision of either fluid or energy, nor do they act as building materials for cells and tissues. However, these substances may have a positive effect on physiological processes which are in equilibrium. Examples include certain secondary plant compounds ...”[4]

(11) The chemical substances used as sources of vitamins and minerals in the manufacture of food supplements should be safe and also be available to be used by the body.

The passage “also be available to be used by the body” is relevant; this does not mean that digestion and any absorption are sufficient.

What is required is a nutritional or physiological effect which does not equate to a pharmacological effect. A medicinal (i.e. pharmacological, metabolic or immunological) or psychotropic effect is already excluded by the definition of a foodstuff.

“In addition to substances with a nutritional or physiological effect, food supplements may also contain ingredients which do not have this effect. Ingredients of this type are not, however, ‘characteristic substances’ within the meaning of Art. 3 para. 1 FoodSO. They may not, therefore, be highlighted prominently as effective ingredients/substances, nor may their quantity be stated in accordance with Art. 3 para. 2 FoodSO.”[5]

---

2 Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183 of 18.7.2002, p. 51)

3 Kügel/Hahn/Delewski, Nahrungsergänzungsmittel-Verordnung Kommentar § 1 Rn. 82

4 ALS-Arbeitsgruppe „Diätetische Lebensmittel, Ernährungs- und Abgrenzungsfragen“ «Stellungnahme Nr. 2015/31: Nahrungsergänzungsmittel mit sonstigen Stoffen im Regelungsbereich von NemV, HCV und LMIV»

5 ALS-Arbeitsgruppe „Diätetische Lebensmittel, Ernährungs- und Abgrenzungsfragen“ «Stellungnahme Nr. 2015/31: Nahrungsergänzungsmittel mit sonstigen Stoffen im Regelungsbereich von NemV, HCV und LMIV», modified to reflect Swiss law

With the exception of a small number of substances, the use of other substances in foodstuffs is not harmonised within the EU. In its 2008 report[6], the European Commission stated that in this area the other legal provisions governing foodstuffs (e.g. for novel foods) and the national legal provisions already provide an adequate legal framework for regulation.

4 Self-supervision

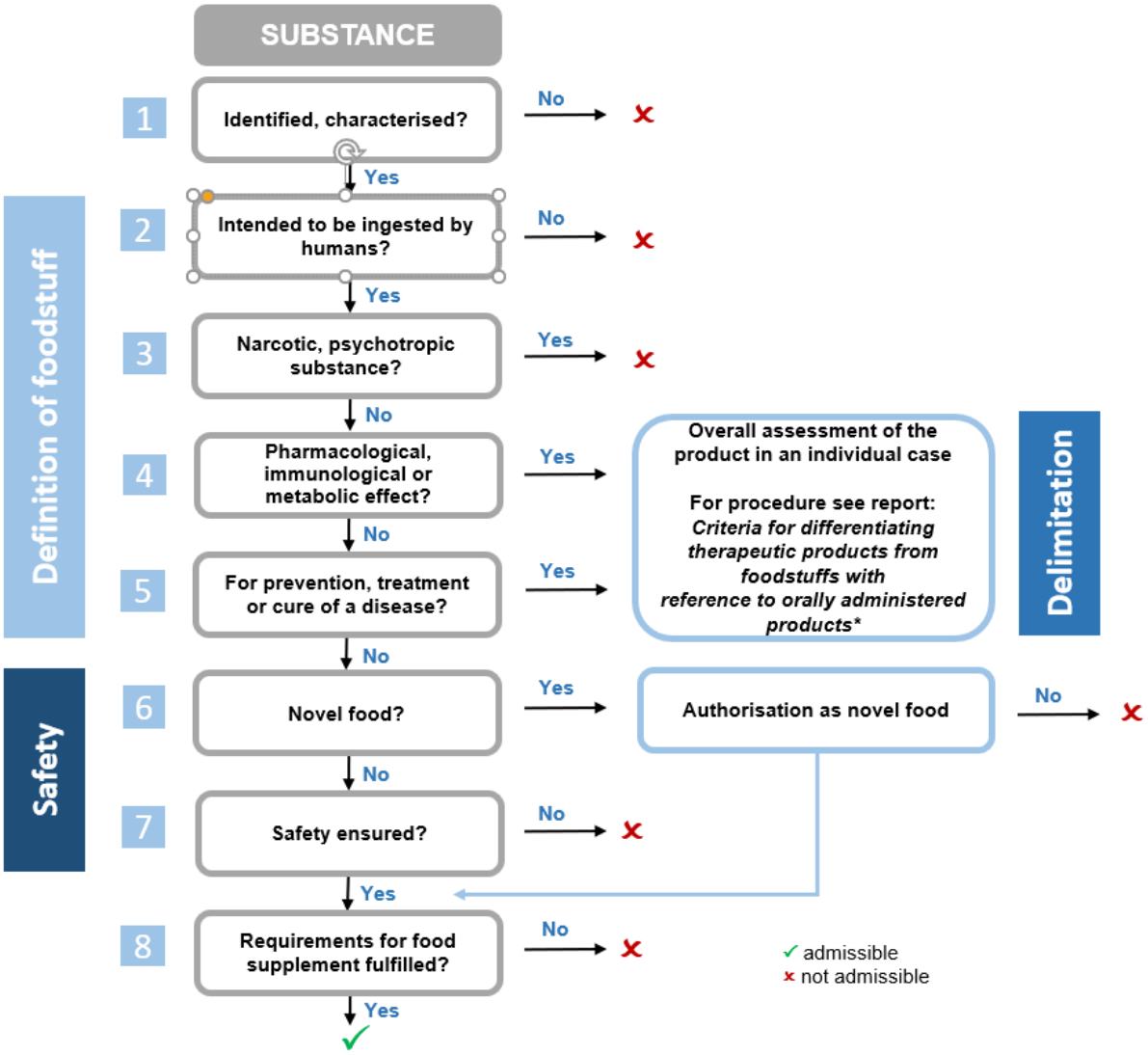
Any person who manufactures, handles, stores, transports, places on the market, imports, exports or carries in transit foodstuffs or utility articles is obliged to ensure self-supervision in accordance with Art. 26 FSA.

A suitable self-supervision concept must exist which ensures that the other substance complies with the definition of a foodstuff, is safe and complies with all other legal provisions, particularly those concerning protection against deception. The documents required to evaluate the marketability of the other substance and which demonstrate this must be available. They must be presented to the enforcement authorities on request. In this context, the aspects described in the following section must be taken into account in particular.

6 Report from the Commission to the Council and the European Parliament on the use of substances other than vitamins and minerals in food supplements of 5.12.2008, SEC(2008)2976, SEC(2008)2977

5 Assessment

The permissibility of other substances which are not specifically regulated can be assessed using the following approach:



* https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/hilfsmittel-und-vollzugsgrundlagen/abgrenzungskriterien.html

The eight aspects shown in the evaluation template must be examined and the investigations undertaken must be documented in order to determine the marketability of other substances not regulated in Annex 1 Part B FoodSO.

Question 1: Identification and characterisation of the other substance

It must be ensured that the substance has been identified and characterised. This means that the following documents, in particular, must be available:

- Specifications with information to identify the substance (nomenclature, structure);
- Certificates of analysis (physical, chemical and microbiological parameters);
- For herbal preparations (e.g. extracts): Information about the starting materials (scientific name with author, part of plant used) and description of the manufacturing process (production steps with information on enrichment/reduction of substances and standardisation pro-

cesses, extractants used, other ingredients, additives, processing aids, information about the drug-extract ratio [DER] if applicable);
- If applicable, further documents showing the composition (content of substances relevant for the desired physiological effects, content of undesirable or toxic substances).

Further substance-specific documents concerning the identification and characterisation of the substances may be necessary, as described in the EFSA guidance on novel foods[7].

Question 2: Intended to be ingested by humans?

It is necessary to determine whether the substance or product is intended to be ingested by humans. "Ingestion by humans" should be taken to mean oral intake through the digestive tract[8]. If the substance or product is not intended to be ingested by humans it is not a foodstuff.

Foodstuffs are defined in Art. 4 para. 1 FSA. They are defined as all substances or products which are intended to be, or may reasonably expected to be, ingested by humans in a processed, partially processed or unprocessed form.

Question 3: Narcotic or psychotropic substance?

If the substance or preparation is a narcotic or psychotropic substance, it is not permitted to place it on the market as a foodstuff. According to Art. 4 para. 3 letter g FSA, narcotic and psychotropic substances are not foodstuffs.

The definitions of narcotic and psychotropic substances can be found in Art. 2 letter a and b of the Narcotics Act (NarcA; SR 812.121). Narcotic and psychotropic substances are shown in the lists in the Narcotics Lists Ordinance (NarcLO-FDHA; SR 812.121.11).

Question 4: Substance with a pharmacological, immunological or metabolic effect?

The Foodstuffs Act does not apply to substances and products covered by the legislation on therapeutic products (Art. 2 para. 4 letter d FSA). The term "therapeutic products" is applied to both medicinal products and medical devices. Medicinal products are not deemed to be foodstuffs (Art. 4 para. 3 letter d FSA). These are substances or products with a pharmacological, immunological or metabolic effect. Nor are medical devices foodstuffs.

The following resources may be used to perform this check:
- Report on "Criteria for distinguishing therapeutic products from foodstuffs with reference to orally administered products"[9];
- Authorisation of medicinal products: Search platform for Information for healthcare professionals and Patient information for authorised human medicines (AIPS) www.swissmedicinfo.ch, compendium of medicinal products https://compendium.ch;
- Pharmacopoeias (Ph. Eur.);
- Swissmedic List of active substances, www.swissmedic.ch;
- Classifications and publications by competent authorities;
- Monographs, e.g. by the Committee on Herbal Medicinal Products (HMPC) of the European Medicines Agency (EMA), the European Scientific Cooperative on Phytotherapy (ESCOP) and the World Health Organisation (WHO);
- Analysed scientific findings, e.g. "Plant monographs" in Hager's Handbook of Pharmaceutical Practice[10].

The pharmacopoeias and the Swissmedic List of active substances contain, in addition to drug substances, ambivalent substances used in medicines and foodstuffs (such as vitamins, etc.). The fact

---

7 EFSA (2018) Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283, Section 2.2-2.5, https://www.efsa.europa.eu/en/supporting/pub/en-1381

8 This therefore excludes nasal sprays, products for administration through the skin and suppositories.

9 Report on "Criteria for distinguishing therapeutic products from foodstuffs with reference to orally administered products" by Swissmedic and the FSVO, https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/hilfsmittel-und-vollzugsgrundlagen/abgrenzungskriterien.html

10 Hagers Handbuch der pharmazeutischen Praxis or Hagers Enzyklopädie der Arzneistoffe und Drogen

that a substance appears in the List of substances is therefore not sufficient in every case as a sole criterion for classifying this substance according to the foodstuffs or therapeutic legislation. The use of such substances in foodstuffs is permitted only in doses in which there is no pharmacological effect.

There are considerable differences between the way these effects are assessed in the different EU Member States and in Switzerland. It is therefore possible for the same product to be classified as a foodstuff in one country and as a medicinal product in another.

The FSVO/Swissmedic report on “Criteria for distinguishing therapeutic products from foodstuffs with reference to orally administered products” deals with the aspects that need to be taken into account for an overall assessment in individual cases (see “V. Procedure for establishing the marketability of a product as a foodstuff, medicinal product or medical device”).

Question 5: Intended for or advertised for the prevention or cure of a human disease, or another form of deception?

A check must be performed to ascertain whether the substance or product is being advertised as having the property of preventing, curing or relieving a human disease and whether the prohibition of deception is being observed (Art. 18 FSA, Art. 12 FSO). If claims to medicinal effects or other deceptive elements are present, they would not be permissible if the substance or product were to be placed on the market as a foodstuff, or else they would have to be corrected.

The presentation and dosage form of food supplements are generally similar to those of medicinal products. In this context it must therefore also be examined whether other elements (presentation, illustrations, references to the intended purpose, etc.) constitute deception of the consumer. The decisive factor is the impression that arises as a result of the sum of all these elements.

The intended use must be included in the overall assessment in the context of distinguishing between foodstuffs and therapeutic products.

Question 6: Is it an unauthorised novel food?

A check must be made to establish whether the substance is an unauthorised novel food (Art. 15-19 FSO, Ordinance on Novel Foods). If it is an unauthorised novel food, it would not be possible to place it on the market as a foodstuff without an authorisation.

According to Art. 15 para. 1 FSO, foods are considered to be novel if they were not used for human consumption to a significant degree prior to 15 May 1997 either in Switzerland or in a Member State of the EU and fall under one of the categories a - j. Both these conditions must be fulfilled cumulatively.

Any person who places foodstuffs on the market must check independently in the context of their self-supervision activities whether the substance used is a foodstuff or food supplement under the terms of Art. 15 para. 1 FSO and must be classified as a novel food.

The following resources are available to assist in determining whether a foodstuff or substance is novel and therefore requires authorisation, or whether authorisation has been granted:

- FSVO novel foods website, https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/bewilligung-und-meldung/bewilligung.html;
- Novel Food status Catalogue of the EU, https://ec.europa.eu/food/safety/novel_food/catalogue_en;
- EU list “Consultation process on novel food status”, https://ec.europa.eu/food/safety/novel_food/consultation-process_en;
- Union list of authorised novel foods in the EU[11];
- Annex to the Ordinance on Novel Foods;
- Document checklist for classification of novel food status, https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/bewilligung-und-meldung/bewilligung.html;

[11] Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351 of 30 December 2017, p. 72)

- Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status[12];
- EU guidance document on "Human Consumption to a Significant Degree", https://ec.europa.eu/food/system/files/2016-10/novel-food_guidance_human-consumption_en.pdf.

The "Document checklist for submission of novel food status" can also be used as a resource for independent assessment of novel food status. All relevant information must be available and documented before the assessment can take place.

If plants or fungi are involved, it should be noted in particular that the products manufactured from them, such as extracts, are not automatically assigned to the same classification as the starting material. If, for example, components of the plant or fungus are isolated or enriched using a technological process, the products no longer correspond to the natural composition of the starting material. In this case the novel food status of this preparation must be examined.

An authorised novel food may be used in food supplements if the conditions for use and specifications for this are fulfilled.

If the substance is classified in the EU Novel Food status Catalogue as "not novel" or "not novel as a food supplement", then it does not need an authorisation as a novel food. This classification on its own does not, however, mean that it is marketable as a foodstuff or food supplement in Switzerland. A check must also be made on the other aspects of the foodstuffs legislation.

Question 7: Is food safety guaranteed?

According to Art. 7 FSA and Art. 8 FSO only safe foodstuffs may be placed on the market. Foodstuffs are deemed to be unsafe if they are considered to be harmful to health or unfit for human consumption. The responsible person must ensure in the context of their self-supervision activities that the product is safe.

The plants, plant parts and preparations manufactured from them listed in Annex 1 VFO and the substances listed in Annex 4 of the Flavourings Ordinance may not be added to foodstuffs for reasons of food safety.

With botanical preparations (e.g. extracts) in particular, it is often not clear whether they represent a potential hazard to health because of their natural constituents and may therefore not be used, or may be used only to a limited extent, in foodstuffs. The following information is important in this context:

- Which substances does the extract contain? In what concentration?
- Do they include substances which raise concerns regarding a potential risk to human health in certain quantities?
- What quantity of these preparations is present in the recommended daily intake of the product?
- For which target group(s) are they intended?

A company must perform a safety assessment taking the current state of knowledge into account. If a current risk assessment from a reliable source, in particular from the EFSA, is available, reference may be made to it. Otherwise, a comprehensive literature search needs to be performed, and the sources must be referenced. A quantitative risk assessment must be performed in which exposure from all sources are taken into account.

The following resources may be helpful for the risk assessment:

- Risk assessments by national and international scientific bodies such as EFSA (EU), JECFA (WHO), BfR (Germany), ANSES (France), etc.;
- Compendium of medicinal products, drug monographs;
- EFSA OpenFoodTox database, https://www.efsa.europa.eu/en/data-report/chemical-hazards-database-openfoodtox;

[12] Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 77 of 20 March 2018, p. 6)

- Published scientific studies;
- Where available, the company's own studies.

For botanical substances and preparations:

- EFSA Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements (2009)[13];
- EFSA Compendium of Botanicals, https://www.efsa.europa.eu/en/data-report/compendium-botanicals;
- Information letter 2021/4: Use of "substances" in the categories plants, fungi, lichen and algae and preparations manufactured from them as foodstuffs or ingredients in foodstuffs

The safety assessment of foodstuffs which are not novel may also be performed in line with the corresponding sections of the EFSA guidance on novel food[14].

Question 8: Are the requirements for food supplements fulfilled?

The product must comply with the provisions of the foodstuffs legislation if it is to be placed on the market. For this, it must in particular comply with the definition of and the product-specific requirements for food supplements (see in particular Art. 1 and 2 FoodSO) and the labelling requirements (including Art. 3 and 4 FoodSO). Moreover, the advertising must not give rise to deception. The corresponding provisions for nutritional and health claims relating to substances must be met.

Swiss Federal Food Safety and Veterinary Office

Beer Michael TOQTMR
24.01.2024

Info: admin.ch/esignature | validator.ch

Dr Michael Beer
Vice Director

[13] EFSA (2009) Scientific Opinion, Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements, https://www.efsa.europa.eu/en/efsajournal/pub/1249

[14] EFSA (2021) Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (Revision 1), https://www.efsa.europa.eu/en/efsajournal/pub/6555