

**On Approval of the Temporary Procedure
for State Sanitary and Hygienic Expertise**

**Order of the Ministry of Health Protection of Ukraine
No. 247 of October 9, 2000**

**Registered with the Ministry of Justice of Ukraine
on January 10, 2001
under No.4/5195**

According to the Law of Ukraine “On Ensuring of Sanitary and Epidemic Safety of Population”, the Enabling Rules on the Ministry of Health Protection of Ukraine, as approved by Decree No. 918 of the President of Ukraine, dated July 24, 2000, and the Regulation on State Sanitary and Epidemic Supervision in Ukraine, as approved by Resolution No. 1109 of the Cabinet of Ministers of Ukraine, dated June 22, 1999, it is hereby **ORDERED**:

1. To approve the Temporary Procedure for State Sanitary and Hygienic Expertise (attached hereto).

2. The Chief Sanitary and Epidemiological Department (Berezhnov S.P.) must:

2.1. within a five-day term, submit the Order to the Ministry of Justice of Ukraine for state registration.

2.2. arrange for the conduct of state sanitary and hygienic expertise in accordance with the Temporary Procedure for State Sanitary and Hygienic Expertise.

3. The Chief Doctor of the Ukrainian Center for State Sanitary and Epidemiological Supervision of the Ministry of Health Protection of Ukraine, Chief State Sanitary Doctors of the Autonomous Republic of the Crimea, oblasts, cities of Kyiv and Sevastopol, for water, railroad and air transport, facilities with a special mode of operation, directors of Research and Development institutes of the hygienic and epidemic profile must abide by and ensure compliance with the requirements of the Temporary Procedure for State Sanitary and Hygienic Expertise.

4. To consider as repealed:

Order No.190 of the Ministry of Health Protection of Ukraine, dated October 20, 1995, “On State Sanitary and Hygienic Expertise of Development, Manufacture and Utilization of Products that may have Negative Impact on Human Health”, registered with the Ministry of Justice of Ukraine on January 3, 1996, under No.2/1027;

the Procedure for State Sanitary Hygienic Expertise of Development, Manufacture and Utilization of Products may have Negative Impact on Human Health;

the Regulation on State Sanitary and Hygienic Expertise of Draft Normative Documentation in Bodies, Institutions and Establishments of the State Sanitary and Epidemiological Service;

the List of Products, Normative Documentation for which or Import of which are Subject to Mandatory Consideration in Bodies, Institutions and Establishments of the State Sanitary and Epidemiological Service, as approved by Order No.190 of the Ministry of Health of

Ukraine, dated October 20, 1995, and registered with the Ministry of Justice of Ukraine on January 3, 1996, under No.3/1028, No.4/1029, No.6/1031 respectively.

5. To repeal the Provision on the Procedure for Issuance of the State Sanitary and Hygienic Expertise Conclusion, as approved by Order No.190 of the Ministry of Health of Ukraine, registered with the Ministry of Justice of Ukraine on January 3, 1996, under No.5/1030.

6. The Order shall come into effect on May 21, 2001.

7. Control over the implementation of the Order shall be retained by the undersigned.

. . Bobyliova
First Deputy Minister,
Chief State Sanitary Doctor
of Ukraine

AGREED WITH:

G. I. Myroniuk
Deputy Head of the
State Committee on Standardization,
Metrology and Certification of Ukraine

O. O. Bobyliova
First Deputy Minister,
Chief State Sanitary Doctor
of Ukraine

O. V. Kuzhel'
Head of the State Committee
on Regulatory Policy and Entrepreneurship of Ukraine

APPROVED BY:

Order No.247 of the Ministry of Health
Protection of Ukraine
dated October 9, 2000.

Registered with the Ministry of Justice
of Ukraine
on January 10, 2001,
No.4/5195

TEMPORARY PROCEDURE FOR STATE SANITARY AND HYGIENIC EXPERTISE

The Temporary Procedure for Sanitary and Hygienic Expertise (hereinafter referred to as, the “Procedure”) is developed according to the Law of Ukraine “On Ensuring of Sanitary and Epidemic Safety of Population”, the Law of Ukraine “On Quality and Safety of Foodstuffs and Food Raw Materials”, the Law of Ukraine “On Metrology and Metrological Activity”, the Regulation on State Sanitary and Epidemiological Supervision in Ukraine, as approved by Resolution No. 1109 of the Cabinet of Ministers of Ukraine, dated June 22, 1999, and shall establish procedures of activities of the State Sanitary and Epidemiological Service aimed to identify compliance of items subject to state sanitary and hygienic expertise (hereinafter referred to as, the “Expertise Items”) with the requirements of Ukrainian sanitary legislation, determine medical criteria for safety of human health (indicators and maximum possible levels, contents, concentration, etc.) (hereinafter referred to as the “Safety Criteria”), conditions of use, application, storage, production, transportation, recycling, disposal, consumer information, etc., as indicated, if necessary, on labels, instructions, rules, regulations, etc. (hereinafter referred to as, the “Conditions of Use”), subject to further state sanitary and epidemiological supervision of the Expertise Items.

This Procedure shall apply to central agencies of executive power, local bodies of self-government, enterprises, institutions and organizations, other business entities and entrepreneurs, regardless of their departmental subordination and forms of ownership, and shall establish requirements as to organization of State sanitary and hygienic expertise.

1. Terms and Definitions

Terms and concepts used shall have the following meanings:

“State sanitary and hygienic expertise” shall mean an integral part of State sanitary and epidemiological supervision that consists in complex examinations of Expertise Items and

“Accreditation” shall mean a procedure, whereby the Ministry of Health Protection of Ukraine identifies the competency of an institution (enterprise, organization, establishment) to perform research and examinations for needs of state sanitary and hygienic expertise, scientific justification of Safety Criteria, Conditions of Use of Expertise Items and preparation of draft conclusions;

“Item that is subject to state sanitary and hygienic expertise” shall mean products, raw materials, technology, regulatory documents, techniques of control over regulatory characteristics, design, technical, instruction and methodical documentation, etc, whose implementation, functioning or use (or other similar actions) may have a negative impact on human health and is related to the necessity to observe requirements of sanitary legislation;

“State sanitary and hygienic expertise conclusion” shall be a document in prescribed form, which document contains a description of characteristics of an Expertise Item, a conclusion (positive or negative) on compliance of an Expertise Object with requirements of sanitary legislation (sanitary norms), requirements related to an Expertise Item – the Safety Criteria and Conditions of Use, which a client – owner of an Expertise Item – must review and abide by and which in future will constitute the subject matter of state sanitary and epidemiological supervision.

2. Goals, Tasks and Principles of State Sanitary and Hygienic Expertise

2.1. The goal of the state sanitary and hygienic expertise (hereinafter referred to as, the “Expertise”) shall be to preserve and protect human health through identification, prevention, reduction and elimination of harmful impact of Expertise Items thereon.

2.2. The main tasks of the Expertise shall be as follows:

- substantiation of needs to apply the requirements of sanitary legislation to a particular Expertise Item;

- organization of inspection and examination of the Expertise Items, and identification of their conformity with sanitary norms. In case of absence of sanitary norms, scientific substantiation of applicable requirements related to the Expertise Items – the Safety Criteria and Conditions of Use, with subsequent establishment of hygienic and epidemiological regulations dealing with functioning, transportation, recycling or other similar actions related to the Expertise Items, use of respective indicators and their maximum possible levels, contents, concentration, etc;

- evaluation of efficiency, rationality, sufficiency of measures with respect to protection of public health;

- evaluation of possible negative impact of hazardous factors related to activities of Expertise Items, identification of potential risks for public health;

- preparation of objective and substantiated conclusions of state sanitary and hygienic expertise (hereinafter referred to as, “Conclusions”).

2.3. The Expertise shall be based on the principles of:

- priority of preserving human health, ensuring sanitary and epidemic safety of the public;
- prevention of negative impact of Expertise Items on human health;
- scientific substantiation, objectiveness, consistency, professional competency,

without normative documents approved in accordance with Ukrainian legislation, items whose examination demands special techniques, etc.) – by commissions (hereinafter referred to as, “Commissions”) that will be formed by a chief State Sanitary Doctor and that will include leading scientists who work in the corresponding area of medicine.

4.2. Establishments (institutions, organizations, enterprises, laboratories) of the State Sanitary and Epidemiological Service of Ukraine, which are legal entities and are authorized by the Chief State Sanitary Doctor of Ukraine, subject to their accreditation for performing of works and services for needs of state sanitary and hygienic expertise (hereinafter referred to as “Work Performers”), shall be retained to perform state sanitary and epidemic expertise. If the system of the State Sanitary and Epidemiological Service of Ukraine does not have capacity to perform particular kinds of work and services for the needs of state sanitary and hygienic expertise, other establishments (institutions, organizations, enterprises, laboratories), which are authorized to perform such works and services by the Chief State Sanitary Doctor of Ukraine and accredited according to the Law of Ukraine “On Metrology and Metrological Activity”, may be retained.

4.3. Works and services specified in item 4.2 of this Procedure shall be performed in accordance with a contract entered into between a performer and a client.

5. Applicants for State Sanitary and Hygienic Expertise

5.1. Owners of Expertise Items or their authorized representatives shall be applicants for State sanitary and hygienic expertise.

5.2. The owner of an Expertise Item – a natural person or a legal entity - shall reimburse all costs connected with the performing of state sanitary and hygienic expertise, and shall observe all expertise requirements as to the Expertise Item.

6. Financing of State Sanitary and Hygienic Expertise

State sanitary and hygienic expertise shall be conducted free of charge.

7. Arrangements for and Organization of State Sanitary and Hygienic Expertise

7.1. Expertise divisions of establishments (institutions) of the State Sanitary and Epidemiological Service of Ukraine shall perform the Expertise of Items covered by sanitary regulations or normative documents that are approved according to Ukrainian legislation.

7.2. Commissions, which are formed by the Chief State Sanitary Doctor, shall perform the Expertise of Items that are not covered by sanitary regulations or approved normative documents and in other especially complex cases.

7.3. Specialists of scientific, design and other institutions and organizations, regardless of their subordination, representatives of the public, experts of international organizations may be involved into performing the Expertise subject to their own consent.

7.4. The Expertise includes the following stages:

7.8. Before commencement of work, an expertise division, a Commission or a Work Performer shall establish a program for performing measurements, examinations of Expertise Items, scientific substantiation of the Safety Criteria and Conditions of Use of an Expertise Item, relevant rules, regulations, etc.

The volume of works and services shall be determined by needs of the Expertise to perform examinations, inspection, tests or measurement of an Expertise Item in order to identify conformity of the Expertise Items with the requirements of sanitary legislation applicable to this Expertise Item.

7.9. The Committee for Issues of Hygienic Regulation under the Ministry of Health Protection of Ukraine shall establish hygienic regulations and state registration of dangerous factors, which are obligatory precondition for performing the State sanitary and hygienic expertise.

7.10. The Expertise shall be performed within 30 days following the receipt by Expertise performers of documents specified in this Procedure. This term will not include time during which an Item undergoes additional examination, as well as time necessary for an applicant to deal with comments. The performer shall provide written notice to the applicant of a need for additional examinations. A letter shall be a ground for prolongation of the time period which the Expertise should be completed.

7.11. An act on examination of an Item, findings of examinations, tests, measurements, scientific substantiation of relevant Safety Criteria and Conditions of Use of the Expertise Item, corresponding rules, regulations, etc. shall be finalized in separate reports. The performer shall provide the reports, together with a draft Conc

7.16. The first copy of the Conclusion shall be handed out to the applicant after it has been approved and recorded in the Register.

7.17. The second copy of the Conclusion and minutes on the Expertise shall be kept at the Chief Sanitary and Epidemiological Department of the Ministry of Health Protection of Ukraine. Copies of minutes on the Expertise and copies of the Conclusion shall be kept at expertise divisions or Commissions for the entire validity term of the Conclusion. Work reports, as well as documents and materials that were provided for the Expertise shall be kept by Work Performers for such a period as is specified in the corresponding category of documents in accordance with legislation.

7.18. The Expertise Conclusion shall be effective for the term of effect of a normative document adopted under established procedures for this

Column 7 – sphere of sale (through retail, a drugstore network, for industrial use, without a right of sale through a retain network);

Column 8 – name of a performer of the expertise, a number of minutes;

Column 9 – the validity term of the Conclusion;

Column 10 – a person responsible for compliance with the requirements of the Conclusion;

Column 11 – notes.

8.7. In the event that corrections or changes are made to the Register, they shall be certified by the personal signature and seal of the Chief State Sanitary Doctor of Ukraine or his authorized deputy.

9. Invalidation of the State Sanitary and Hygienic Expertise Conclusion

Conclusions of state sanitary and hygienic expertise shall be invalidated:

- in connection with the expiry of their validity term;

- on the basis of findings resulting from the second State sanitary and hygienic expertise of an item, which expertise has been appointed by the Chief State Sanitary Doctor of Ukraine and invalidates the previous.

10. Appeal against the Conclusion of State Sanitary and Hygienic Expertise

Appeals against Conclusions of State sanitary and hygienic expertise shall be filed in accordance with the procedures stipulated in Article 43 of the Law of Ukraine ” Ensuring of Sanitary and Epidemic Safety of Population”.

11. Responsibilities of Applicants for and Performers of State Sanitary and Hygienic Expertise

11.1. An applicant shall be liable for inauthenticity of provided documents, materials, samples, and the failure to comply with the requirements of an Expertise Conclusion.

11.2. Performers of the Expertise and works for Expertise needs shall be liable for inauthenticity, partiality, incompleteness, impropriety of performed of works, and for disclosure of confidential information.

11.3. The Chief Sanitary and Hygienic Department of the Ministry of Health Protection of Ukraine shall supervise procedures for performing the Expertise, fulfillment of works for Expertise needs and all Expertise-related documentation.

V. I. Velykiy
Head of the Department on
Sanitary and Epidemiological
Standardization, Regulation,
Expertise and Registers

Addendum 1 to Item 7.5
of the Temporary Procedure for State
Sanitary and Hygienic Expertise

Application

" ___ " _____ 20__

To: Chief State Sanitary Doctor

I request to conduct the State sanitary and hygienic expertise, and to issue your Conclusion:

Name of the Expertise Item _____

Sphere of application and sale of the Expertise Item _____

SCPS code, UCP FA code, marking of product _____

Country of origin of the Expertise
Item _____

Producer, designer of documentation (its/his representative in Ukraine) _____

Details of the producer,
designer _____

(address, telephone, fax, e-mail, WWW-site)

Information on the contract on for the supply of the Item in
Ukraine _____

Applicant (owner) _____

Country of the applicant's registration _____

Details of the applicant _____

(address, telephone, fax, e-mail, WWW)

EDRPOU code or the national number of the applicant for the Expertise

Document on authorities of the applicant to represent the producer (owner) (agreement, contract,
assignment) _____

I confirm that the presented Expertise Item (products, raw materials, technology, normative document, etc.) meet the indicators for quality and safety criteria as are specified in the accompanying documentation.

Applicant's Signature _____

stamp place

Addendum 2 to Item 7.5
of the Temporary Procedure for State
Sanitary and Hygienic Expertise

List of Documents and Materials necessary
for Performing of Works and Services for needs
of State Sanitary and hygienic
Expertise (Products, Raw Materials, etc.)

1. An application for performing of work for needs of State sanitary and hygienic expertise.
2. Specifications (a certificate on the full composition of an Expertise Item and its identification indexes).
3. An owner's document that certifies the Expertise Item's compliance with requirements for their quality and safety for human health as established in Ukraine (a document confirming products' quality, containing information on indicators of safety, contents, features, shelf life, storage conditions, etc.).
4. Information on the registration of the Expertise Item in a producer's country (for foreign products), and a list of countries, in which the Expertise Item has been registered.
5. Application recommendations and the user's manual.
6. Labeling.
7. Documents from the supplier's (producer's country) certifying the safety of the Expertise Item.
8. A letter from the producer (owner) of the Expertise Item on furnishing of samples or an act on selection of samples for performing of examinations.
9. Samples of the Expertise Item.
10. A normative document and technical documentation, according to which the Expertise Item has been manufactured (if available).
11. An act on examination of the enterprise that is a manufacturer of products (if available); industry Expertise Conclusions or conclusions of experts and other materials that characterize the process of manufacture by indicators for quality and Safety Criteria.
12. Veterinary permission for products of animal origin and quarantine permission for vegetable products, provided that their availability is required by Ukrainian legislation.

13. Minutes on examinations of the Expertise Item by indicators for quality and Safety Criteria – if examinations were performed earlier in another laboratory (institution), or abroad (if available).

14. A toxicology dossier (for the main active agents, as well as for special ingredients) by the following classifications: high toxicity, average toxicity, chronic toxicity, allergenic, sensibilizing, immune-toxic, teratogenic, embrio-toxic, carcinogenic, mutagenic effects, etc., with the reference to the performer of examinations (in cases as are envisaged by Ukrainian legislation). The toxicology dossier may be made in Ukrainian, English or Russian and its annotated part has to be translated into Ukrainian.

15. Results of clinical and on-site tests, epidemiological and population studies, etc. or scientifically grounded evidence.001wgsodd.39 etc., [idem)10i10.0 TDrainian

identification, methods of utilization of materials upon the lapse of their warranty period, if they are not specified in the document, etc.;

- results of respective measurements, tests, researches, examinations, regulations, etc. (if available);

- draft marking, instructions, etc.;

- a description of the technological process, regulations (technological instructions) of manufacture and application of products;

- other information necessary for evaluation of impact of products upon human health.

The draft normative document shall not be returned.

Addendum 4 to Item 7.5
of the Temporary Procedure for State
Sanitary and Hygienic Expertise

List of Documents and Materials necessary
for Performance of Works and Services for Needs
of State Sanitary and Hygienic
Expertise (Technology, Operating Object, etc.)

1. An application for performing of works for needs of State sanitary and hygienic expertise.
2. Specifications (a certificate on the full composition of an Expertise Item and its identification indicators).
3. An owner's document that certifies the Expertise Item's compliance with requirements for their safety for human health as established in Ukraine (a document confirming products' quality, which document contains information on safety indicators).
4. Information on the registration of the Expertise Item in a producer's country (for foreign products), and a list of countries, in which the Expertise Item has been registered.
5. Application recommendations and the user's technological manual.
6. Certificates on safety of Expertise Item from the supplier's (producer's) country.
7. A letter from the owner (producer) of the Expertise Item on furnishing of samples or an act on selection of samples for performing of examinations.
8. Samples of the Expertise Item.
9. A normative document and technical documentation, according to which Expertise Item has been manufactured, as well as technological documentation (process, regulations, instruction, etc.) (if available).
10. Minutes on examinations of the Expertise Item by indicators for quality and Safety Criteria – if examinations were performed earlier in another laboratory (institution), or abroad (if available).
11. An act on examination of the enterprise (if available); industry Expertise Conclusions or conclusions of experts and other materials that characterize the process of manufacture by indicators for quality and Safety Criteria.

No materials shall be returned after the Expertise is completed.

Addendum 5 to Item 7.12
of the Temporary Procedure for State
Sanitary and Hygienic Expertise

MINISTRY OF HEALTH PROTECTION OF UKRAINE

Address, telephone,
fax, e-mail, WWW

Approved by:

Chief State Sanitary Doctor (Deputy Chief State
Sanitary Doctor

(last name, first name and patronymics)

(signature) _____

stamp place

Conclusion of State Sanitary and Hygienic Expertise

"__" _____ 20__ N _____

(name of the Expertise Item)

1. _____
(sphere of application and sale of the Expertise Item)

2. _____
(SCPS code, UCP FA code, marking of products)

3. _____
(country of origin of the Expertise Item)

4. _____
(name and details of producer, designer, owner or his representative in Ukraine, address, telephone,

fax, e-mail, WWW, country of registration,

EDRPOU code or national number)

5. _____
(information about the contract for the supply of the Item into Ukraine)

6. _____
(name and details of the client, address, telephone,

fax, e-mail, WWW, country of registration, EDRPOU code

Expertise division (Commission) _____
(address, telephone, fax, e-mail, WWW)

Expertise Minutes _____
(number of the minutes, date of approval)

Director of the expertise division (Commission) _____
(last name, first name and patronymics)

(

Addendum 6 to Item 7.12
of the Temporary Procedure for State
Sanitary and Hygienic Expertise

MINISTRY OF HEALTH PROTECTION OF UKRAINE

Address, telephone,
fax, e-mail, WWW

Approved by:

Chief State Sanitary Doctor
(Deputy Chief State Sanitary
Doctor)

(full name)

(signature)

stamp place

Conclusion of State Sanitary and Hygienic Expertise

"__" _____ 20__ No. _____

(name of the Expertise Item)

1. _____

(sphere of application and sale of the Expertise Item)

2. _____

(SCPS code, UCP FA code, marking of products)

3. _____

(country of origin of the Expertise Item)

4. _____

(name and details of the producer, designer, owner or

his representative in Ukraine, address, telephone,

7. _____
(if necessary, name and details of the intermediary,

supplier, etc., address, telephone, fax, e-mail, WWW,

country of registration, EDRPOU code or national number)

8. According to the findings of the state sanitary and hygienic expertise

(name of the Expertise Item)

is safe for human health subject to compliance with the requirements of this Conclusion, and may be used as designated in the sphere of application or - for normative documents may be approved (confirmed) by _____

Liability for compliance with the requirements of this Conclusion is borne by

(owner, customer, producer)

The original of the Conclusion may not be transferred to a third party.

Reverse side of the Conclusion

Expertise division (Commission) _____
(address, telephone, fax, e-mail, WWW)

Expertise Minutes _____
(number of the minutes, date of approval)

Director of the expertise division (Commission) _____
(last name, first name and patronymics)

(signature)
