

**THE EURASIAN ECONOMIC COMMISSION  
COUNCIL**

**D E C I S I O N**

January 26, 2018

**No. 15**

Moscow

**On Approval of Rules of Good Practices  
in Growing, Harvesting, Processing and Storing  
Herbal Raw Materials**

In accordance with Article 30 of the Treaty on the Eurasian Economic Union dated May 29, 2014, Article 4 of the Treaty on the Eurasian Economic Union dated May 23, 2014, paragraph 7 the List of acts of the Eurasian Economic Commission on regulatory issues of common markets of pharmaceuticals and medicinal products in the framework of the Eurasian Economic Union for the years 2017-2019 approved by the Order of the Council of the Eurasian Economic Commission No. 15 dated May 17, 2017, the Council of the Eurasian Economic Commission **decided to:**

1. Approve the Rules of good practices in growing, harvesting, processing and storing herbal raw materials attached hereto.
2. This Decision shall enter into force 6 months after the date of its official publication.

**Members of the Council of the Eurasian Economic Commission:**

**From the  
Republic of  
Armenia**

**From the  
Republic of  
Belarus**

**From the  
Republic of  
Kazakhstan**

**From the  
Kyrgyz  
Republic**

**From the  
Russian  
Federation**

**V. Gabrielyan V. Matyushevsky A. Mamin S. Mukanbetov I. Shuvalov**

**APPROVED BY**

the Decision of the Council of  
the Eurasian Economic  
Commission No. 15 dated  
January 26, 2018

**R U L E S**  
**of good practices in growing, harvesting,**  
**processing and storing herbal raw materials**

I. General provisions

1. These Rules establish the requirements to good practices in growing, harvesting (procuring), processing and storing herbal raw materials intended for medical use, and the quality assurance system for these practices. Production and processing of herbal raw materials directly affects the quality of the active pharmaceutical substance.

2. To ensure reproducible quality of herbal raw materials, due to the complexity of the compositional analysis of wild and cultivated herbal raw materials and limited efficiency of analytical techniques in characterization of their components when cultivating, an appropriate system of quality assurance is required during harvesting (procuring), processing and storing of medicinal herbs.

3. The main goal of these Rules is to establish an appropriate system of quality assurance of herbal raw materials in order to ensure the safety of consumers of herbal raw materials, as well as to avoid possible mix-up of similar plants and environmental damage due to low skilled personnel and lack of control by establishing appropriate quality standards for herbal raw materials. At the stages of cultivation, harvesting (procuring), processing and storing herbal raw materials, in order to avoid degradation in quality and to minimize microbiological load, it is necessary to ensure compliance with the legislation of the Member States of the Eurasian Economic Union (hereinafter referred to, respectively, the Member States of the Union) in the sphere of hygiene requirements and sanitary regulations, as well as careful processing of herbal raw materials.

4. These Rules apply to agricultural production of herbal raw materials, including organic production, and procuring wild herbal raw materials.

5. For the purposes of these Rules, the following terms shall be used, their meanings set forth in the respective definitions below:

«herbal raw materials» are fresh or dried plants, algae, fungi or lichens, or parts thereof, whole or crushed, morphological groups used for the production of medicinal products. Some exudates (such as gum arabic, vegetable gum), not subjected to special processing, are also considered to be herbal raw materials. Herbal raw materials are precisely determined by the part of the plant used and botanical name in accordance with the binominal system (genus, species), variety and indication of the author in the botanical name;

«organic production» is a form of agriculture that features responsible minimization of the use of synthetic fertilizers, pesticides, plant growth regulators, feed additives, genetically modified organisms. In organic production, in order to increase harvesting capacity, to provide cultural plants with mineral nutrition, to fight pests and weeds, the effect of crop rotation, organic fertilizers (manure, compost, etc.), different tillage methods, etc. is applied more actively;

6. These Rules are inseparably associated with Part II of the Rules of good manufacturing practices of the Eurasian Economic Union, approved by the Decision of the Council of the Eurasian Economic Commission No. 77 dated November 3, 2016. These Rules establish, in addition to the requirements set out in the Rules mentioned, mostly requirements to the critical stages in the production of herbal raw materials that are necessary to ensure adequate quality.

7. These Rules apply to all participants of the production process from individual entrepreneurs and business entities engaged in harvesting (procuring) and cultivation of herbal raw materials to manufacturers and distributors of herbal raw materials. Manufacturers and distributors of herbal raw materials must comply with the requirements of these Rules, record all their actions in the documents (dossiers) for the batch and require compliance with these Rules by all participants in the production process of herbal raw materials (if not justified otherwise).

8. Growing, harvesting, processing and storing herbal raw materials must be performed in compliance with the provisions of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), and without damage to the environment.

## II. Quality assurance

9. In order to ensure the quality of herbal raw materials, written agreements (contracts) are concluded between herbal raw material suppliers and buyers, tailored to the requirements of the legislation of the Member States, where quality characteristics of herbal raw materials are coordinated, including the content of the active ingredients, macroscopic and aromatic properties, microbial contamination limits, chemical residue, heavy metals, etc.

## III. Personnel and personnel training

10. All operations (procedures) of processing herbal raw materials shall be governed by the legislation of the Member States in the sphere of

application of hygiene requirements and sanitary regulations. All personnel related to processing of herbal raw materials must comply with the manufacturer's documented level of personal hygiene and undergo appropriate OH&S training.

11. The manufacturer must provide adequate sanitary conditions for the operation of all personnel involved in the stages of growing, harvesting, processing and storing herbal raw materials.

12. The personnel directly related to growing, harvesting (procuring) and/or processing herbal raw materials, should be provided with appropriate protective clothing to prevent contact with potentially toxic or allergenic herbal raw materials.

13. Employees suffering from infectious diseases with alimentary routes, including diarrhea, or their carriers must be suspended from the work with herbal raw materials until complete recovery.

14. Employees with open wounds, skin infections and inflammations must not be allowed to work with herbal raw materials, or must use suitable protective clothing (gloves) until full recovery.

15. It is necessary to conduct personnel training in the basics of Botany before performing works requiring relevant knowledge.

16. Harvesters (collectors) of herbal raw materials should have the necessary knowledge about medicinal plants to be procured (harvested), including requirements to identification, characteristics and habitats of medicinal plants. To avoid any risk to public health, the harvesters (collectors) should be able to recognize and distinguish botanically related and/or morphologically similar plants. To ensure the appropriate quality of herbal raw materials, the harvesters (collectors) must have sufficient knowledge about the best timing and methods used in collection, and also understand the importance of primary treatment.

17. If the harvesters (collectors) do not possess the knowledge referred to in paragraph 16 of these Rules, it is necessary to ensure their briefing, operation monitoring and keeping the relevant records.

18. The employees involved in cultivation and other kinds of works with herbal raw materials must be instructed on methods of cultivation, including proper application of herbicides and pesticides.

19. The harvesters (collectors) of herbal raw materials must be instructed on environmental protection, including information on the Rules for handling protected species of plants.

#### IV. Buildings, premises and industrial areas

20. The premises used for processing the collected herbal raw materials must be clean and ventilated. It is prohibited to keep farm animals in the premises used for processing the collected herbal raw materials.

21. The premises must provide adequate protection of the collected herbal raw materials from birds, insects, rodents and domestic animals. In all the areas reserved for processing and storing herbal raw materials, it is necessary to take appropriate measures to control pests (e.g., use baits (traps), electric devices to eliminate insects, etc., which must be operated and maintained by qualified personnel or contractors).

22. Packaged herbal raw materials must be stored in premises with concrete or other floors easy to clean:

- a) on pallets;
- b) apart from walls sufficient to ensure cleaning and venting distance;
- c) apart from other types of herbal raw materials to prevent cross-contamination.

23. The packaged herbal raw materials obtained by method of organic production must be stored separately from any other herbal raw materials.

24. The premises used for processing herbal raw materials must have cloakrooms and toilets that allow for hand washing, separated from the industrial premises.

## V. Equipment

25. The equipment used in the process of growing and processing plants should exclude the possibility of contamination of herbal raw materials with undesirable substances (e.g., fuel, lubricants, exhaust gases, etc.).

26. The measuring tools used to handle fertilizers and pesticides must comply with the legislation of the Member States in the sphere of ensuring the uniformity of measurements.

27. The parts of equipment that come into contact with the collected herbal raw materials should be cleaned after use to avoid the possibility of cross-contamination due to herbal remains.

28. The equipment must be manufactured from suitable materials to prevent contamination of herbal raw materials with chemical and other undesirable substances.

## VI. Documentation

29. It is necessary to document:

a) all operations and procedures carried out with herbal raw materials which may affect the quality of the herbal medicinal preparation;

b) extraordinary circumstances throughout the vegetation period and especially during harvesting (for example, extreme weather conditions, pests, etc.) that can affect the chemical composition of herbal raw materials;



c) all stages of processing cultivated herbal raw materials, including the habitat. All manufacturers must maintain field records describing the cultivated medicinal plant and characteristics of its cultivation, as well as field records on the cultures grown on this site before describing the agents used for plant protection, in the form according to the Annex hereto;

d) the use of fumigants.

30. In the documentation on the cultivated herbal raw material it is necessary to specify the method, the amount and date of collection, as well as chemical and other substances used in the production process (e.g. fertilizers, pesticides, herbicides, growth stimulators, etc.).

31. The geographical location of harvesting (collection) and the period of harvesting herbal raw materials must be indicated as precisely as possible, allowing to define them clearly.

32. It is necessary to ensure traceability of each batch of herbal raw materials down to the source. The assignment of batch number and labelling must be carried out in the early stages of production. Herbal raw materials made of wild and cultivated herbs should have different batch numbers.

33. Batches of herbal raw materials from different habitats may only be mixed if the test results confirm the homogeneity of the mixture obtained. Such operations must be documented in detail.

34. All agreements and treaties between the manufacturer or harvester (collector) and the buyer of herbal raw materials must be executed in writing. You must document that cultivation, collection and processing were performed pursuant to such agreements.

The documentation must specify geographical location, country of origin, manufacturer, the person responsible for the quality, etc.

35. The results of internal and external quality audits conducted on the basis of agreements (contracts) (in case they are conducted) must be

documented (copies of all documents, audit reports, analytical reports) and stored for at least 10 years.

## VII. Seeds and planting material

36. The seeds must be obtained from plants with identified and traceable attributes, such as genus, species, cultural variety (cultivar, chemotype, origin).

37. The requirements referred to in paragraph 36 of these Rules also apply to cloned plants. The compliance of seeds and cloned plants used in organic production to the requirements of this production must be documented by the requirements established by the statutory power of the Union and the legislation of the Member States. The source material must be as free of pests and diseases as to ensure growth of healthy plants. It is advisable to use species (cultivars) of plants with natural resistance to diseases.

38. Throughout the entire production process, it is necessary to monitor the absence of other species and varieties of plants, as well as other plant parts, and prevent them from getting into the production process.

39. The use of genetically modified plants and seeds must conform to the requirements established by the statutory power of the Union or the legislation of the Member States.

## VIII. Cultivation

40. Depending on the method of cultivation used (standard or organic), various standard operating procedures may be applied, while it is necessary to avoid impact on the environment not involved in the cultivation process.

It is necessary to observe the principles characteristic of effective agriculture and plant cultivation, including appropriate crop rotation.

### 1. Soil and fertilizer application

41. Medicinal plants should not be grown on soil contaminated with sludge, heavy metals, waste, plant protection agents, and/or other chemicals. The use of any chemicals for growth and protection of cultures should be minimized.

42. Before use, the manure must be thoroughly composted, it should not contain human feces.

43. Fertilizers should be applied moderately and in accordance with the needs of specific types of medicinal plants. Fertilizers must be applied in such a way as to minimize leaching of soil.

### 2. Watering

44. Watering must be performed and controlled taking into account the conditions necessary for the growth and development of specific medicinal plants.

45. The quality of water used for irrigation must comply with the requirements of the legislation of the Member States.

### 3. Maintenance of culture and protection of medicinal plants

46. The soil must be treated taking into account the conditions necessary for the growth and development of specific medicinal plants.

47. The use of pesticides and herbicides should be avoided. If necessary, the plant protection agents permitted for use must be used in a minimally effective amount, in accordance with the manufacturer's recommendations and the requirements of the legislation of the Member States. Plant protection agents should only be applied by qualified personnel, using the equipment dedicated for this purpose. The minimum time interval between such processing and collection must be established in accordance with the recommendations of the manufacturer of the plant protection agent or negotiated with the buyer of the herbal raw materials. The maximum allowable residual content of plant protection agents in the herbal raw materials shall comply with the Pharmacopoeia of the Union, and if not represented in it - with the pharmacopoeias of the Member States or with the provisions of the Codex Alimentarius.

## IX. Procurement

48. It is necessary to assign the personnel to perform identification and validation of the collected herbal raw materials, as well as supervision of the harvesters.

49. Procurement should be performed in accordance with the existing environmental legislation of the Member States. The procuring methods must not cause damage to the environment and prevent the recovery of the collected herbal raw materials.

50. It is not allowed to procure endangered species of herbal raw materials without the permission of the authorized bodies of the Member States in accordance with the provisions of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

## X. Harvesting

51. Herbal raw materials should be collected during the period of its best quality, taking into account the intended purpose.

52. Damaged plants or parts thereof should be removed, or their content limited in accordance with the permissible limits established by the Pharmacopoeia of the Union, and in their absence - those established by the Pharmacopoeias of the Member States.

53. Herbal raw material should be harvested under appropriate weather conditions, avoiding damp soil, in the absence of dew, rain and high humidity (taking into account the climatic zone). If harvesting occurs in humid conditions, measures must be taken to prevent the possible adverse effects of moisture on the herbal raw materials.

54. Tools and harvesting machines designed for cutting and collecting herbal raw materials must be adjusted in such a way as to minimize the possible contamination of herbal raw materials with particles of soil.

55. The collected herbal raw material must not come into contact with the soil, it must be transported to a secure place protected from moisture.

56. At the time of harvesting, precautions must be taken to prevent the toxic weed plants from entering the collected herbal raw material.

57. The containers used when harvesting herbal raw materials must be clean and should not contain remains of plants from the previous harvests. Unused containers should be stored in a place protected from moisture, not affected by pests and away from rodents, farm animals and pets.

58. You should avoid mechanical damage and packing of the collected herbal raw material (for example, as a result of an overflow or stockpiling bags or packages) that can lead to undesirable changes in its quality.

59. To avoid thermal degradation, the collected herbal raw materials must be delivered to the production site for processing in the shortest possible time.

60. The collected herbal raw material must be protected from pests, rodents, farm animals and pets. The measures taken to combat pests should be documented.

## XI. Primary treatment

61. Primary treatment includes washing, slicing before drying, fumigation, freezing, distillation, drying, etc. All stages of primary treatment should be carried out immediately after collecting the herbal raw material and in accordance with the requirements of the laws of the Member States.

62. After entering the production site for processing, the collected herbal raw material should be immediately unloaded and unpacked. Before processing the material should not be exposed to direct sunlight (except when required), it must also be protected from precipitation, insect attack, etc.

63. When drying outdoors, the herbal raw material must be distributed in a thin layer. To ensure air circulation, drying devices must be situated at a sufficient distance from the ground. It is only allowed to dry directly on the ground or in direct sunlight if required by the procurement conditions of the raw material. To prevent formation of mold it is necessary to ensure uniform drying of herbal raw materials.

64. Drying conditions must be selected carefully (except when drying outdoors): temperature, duration, air circulation, etc., depending on the part of the medicinal plant (roots, leaves, flowers) and characteristics of the active ingredient (for example, essential oil). The drying conditions selected must be documented.

65. All material must be checked and, if necessary, sieved to remove poor-quality products and foreign bodies. The sieves must be kept clean and regularly maintained.

66. Clearly marked containers are required for wastes, that should be regularly emptied and cleaned in accordance with the periods established by the manufacturer.

## XII. Packaging

67. After processing and in-process control, in order to protect and reduce the risk of being damaged by pests, the processed herbal raw materials must be immediately packaged into clean and dry, preferably new packages, bags or boxes. The labelling must be clear, applied reliably and using non-toxic materials, the information must conform to the Requirements to labelling of medicinal products for medical use and veterinary medicinal products approved by the Decision of the Board of the Eurasian Economic Commission No. 76 dated November 3, 2016.

68. Reusable packaging material should be thoroughly cleaned and dried before it is used again. The repeated use of packaging materials should not lead to cross-contamination.

69. The packaging materials must be stored in a clean and dry place and be out of reach for pests, farm animals and pets. It is necessary to eliminate the possibility of contamination of the herbal raw materials when using packaging materials, especially bags made of textile materials.

## XIII. Storage and transportation

70. The packaged dried herbal raw materials, including essential oil dried raw materials, should be stored in a dry, well-ventilated place, with low daily fluctuations in temperature and good air circulation.

71. Fresh herbal raw materials must be stored at a temperature of 1° C to 5° C, frozen herbal raw materials - at a temperature below minus 18° C (or below minus 20° C in case of prolonged storage).

72. When transporting unpackaged herbal raw materials, its protection from moisture must be ensured. To reduce the risk of fermentation and mold formation, it is advisable to use ventilated containers, ventilated vehicles and other ventilated devices. Transportation of essential oils is governed by the relevant safety rules and should be carried out in accordance with the legislation of the Member States.

73. Fumigation of herbal raw materials and (or) storage facilities against pests should only be carried out in case of a justified need and only by specially trained personnel. Only registered fumigants may be used. The information on any fumigation against pests performed should be indicated in the accounting records.

74. For fumigation of warehouses, only fumigants allowed for use in accordance with the laws of the Member States may be applied.

75. If pest control is performed using frost operations or saturated steam, it is necessary to control the humidity of the herbal raw material after processing is completed.

76. Storage conditions must ensure preservation of the necessary medicinal properties of the herbal raw material.



ANNEX  
to the Rules of good practices in  
growing, harvesting, processing and  
storing herbal raw materials  
(form)

**DESCRIPTION**  
**of the cultivated medicinal plant**  
**and the characteristics of its cultivation**

Cultivated medicinal plant:

Scientific (Latin) name (genus, species, subspecies (variety), cultivar,  
author) \_\_\_\_\_

The adopted name in Russian (if available) \_\_\_\_\_

The part of the plant collected \_\_\_\_\_

Culture code \_\_\_\_\_

Place of cultivation:

area/region/country \_\_\_\_\_

Location of the field \_\_\_\_\_

Manufacturer:

Name \_\_\_\_\_

Location (address of a legal entity), place of residence (for a natural person  
registered as an individual entrepreneur) \_\_\_\_\_

Seeds and planting material:

Type \_\_\_\_\_

Description \_\_\_\_\_

Commercially available:

yes (indicate the name of the manufacturer and the seller) \_\_\_\_\_

no

Cultivation:

The use of planting material (underline): planting in soil/grafting

Date (day/month/year) of the first planting (seeding)/grafting \_\_\_\_\_

Date (day/month/year) of re-planting/re-grafting \_\_\_\_\_

Distance between the rows (cm): \_\_\_\_\_

Area of cultivation (m<sup>2</sup>) \_\_\_\_\_

The percentage of sprouted plants \_\_\_\_\_

The percentage of surviving plants \_\_\_\_\_

The distance between plants (cm) \_\_\_\_\_

Planting density (pcs/m<sup>2</sup>) \_\_\_\_\_

Crop rotation \_\_\_\_\_

Soil type: % clay \_\_\_\_\_ % sand \_\_\_\_\_

% silt \_\_\_\_\_ % organics \_\_\_\_\_

% other (describe) \_\_\_\_\_

soil pH \_\_\_\_\_

Soil moisture retention (underline): good/bad

Irrigation

yes

no

Soil fertility (underline): good/poor

Soil drainage (underline): good/bad

Terrain (underline): flat/slope

Type of irrigation (underline): subsoil/channels/sprinkling/aerosol

Water source (underline): water supply line/lake/river/well/

other (specify) \_\_\_\_\_

Water hardness (underline): high/low

The names of close-growing plants \_\_\_\_\_

Insects on close-growing plants (underline):  
aphids/parlatoria/caterpillars/locusts/other (specify)

Agrochemistry:

Fertilizers applied before planting (underline): organic (composted animal manure)/chemical

Name \_\_\_\_\_ Method \_\_\_\_\_

Date (d/m/y) \_\_\_\_\_ Standard \_\_\_\_\_

Herbicides applied before planting:

Name \_\_\_\_\_ Method \_\_\_\_\_

Date (d/m/y) \_\_\_\_\_ Standard \_\_\_\_\_

Herbicides applied after planting:

Name \_\_\_\_\_ Method \_\_\_\_\_

Date (d/m/y) \_\_\_\_\_ Standard \_\_\_\_\_

Pesticides used:

Name \_\_\_\_\_ Method \_\_\_\_\_

Date (d/m/y) \_\_\_\_\_ Standard \_\_\_\_\_

Harvesting/collection:

Date (day/month/year) of collection \_\_\_\_\_

Conditions \_\_\_\_\_

Time of day \_\_\_\_\_

Method

Harvesting capacity \_\_\_\_\_

Circumstances that may affect the quality (extreme weather conditions, the action of harmful substances, pest attacks, etc.) \_\_\_\_\_