



History of safe use of herbs - Approaches for documenting evidence

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ABSTRACT

Approval by regulatory authorities for commerce of herbs to different nations is lengthy process involving quality, safety, and efficacy data submission for the herbs under different category. Submission of documented history of use of herbs in such steps has gained momentum in the last decade globally. EU Directives and Food Regulations, India, specifically describes this requirement. However, authors have not seen any broad guidelines on how to document such evidence. This paper attempts to provide inputs for wider consultations to lead to guideline development.

1. Introduction

Use of plant species for medicinal and healthcare purposes, has been an age-old practice. The primitive societies naturally acquired the art of utilizing locally growing plants for their healthcare needs. The knowledge about the healing powers of plants-accumulated by indigenous people subsequently shaped the evolution of codified systems of medicine, medicine including Chinese, Ayurvedic, Middle Eastern, European, African and American (Shankar & Liao, 2004, Mamedov, 2012) [1,2].

The codified healthcare systems are supported by vast battery of treatises like Charaka Samhita, Sushruta Samhita, Ashthanga Hridayam, etc (Jaiswal and Williams, 2017) [3]. While these examples pertain to Ayurveda, the historical, scientific literary credentials of other traditional systems of medicine like Arabic, TCM, Egyptian, etc are widely described in few other publications (Gurib-Fakim, 2006) also [4].

Though the importance of traditional systems of medicine is well recognised in general, there are few cultural, scientific, and regulatory constraints in accepting the medicinal herbs discovered, described, and utilized in the countries of their origin. One of the effective approaches to overcome these constraints is to consider the history of use (HoU) and History of Safe Use (HoSU). This kind of approach is being closely considered for introduction of novel foods obtained from GMOs (Constable et al., 2007) [5], herbal teas (Wise and Santander, 2018) [6], prebiotics (Ojansivu et al., 2007) etc. [7].

In countries like India, traditional systems of medicine are assigned with a regulatory status. Taking a rational approach, the Drugs and

Cosmetics Act of India enlisted only selected treatises compiled during different centuries. While there exists a vast battery of treatises/texts documenting the use of medicinal plants and their formulations-only 57 of such documented authoritative texts are recognised legally under the Indian Drug Regulations (Drugs and Cosmetics Act, 1940, The First Schedule) for purposes of review and issue of licences to manufacture and market the herbs or recipes listed therein [8]. Similarly traditional Chinese Materia Medica, texts that document Kampo medicine in Japan exist. Herbs listed in these texts (*the term 'herb' used in this paper includes botanicals and their parts, other ingredients such as processed minerals, metals, materials of animal origin, ingredients sourced from sea and insects, and wherever applicable to recipes/formulations*) have now been recognised for their documented long history of use. Such a recognition is due to the ability to extrapolate their safety profile when used as described in these texts.

Need for Introduction of Herbs and Herbal Products: Generally, use of herbs for nutritional, healthcare and therapeutic purposes is confined largely to, the countries of origin. However, global healthcare scenario has been dynamic during last few decades. Promotion of positive health has gained greater priority to reduce the healthcare costs while increasing social productivity. In this direction, herbs offer a greater potential, and this social value is considered important (Srivastava et al.) [9]. Access to herbs and herbal products provides wider healthcare choices to the citizens. Therefore, transnational trade with herbs needs to be augmented with realistic and flexible regulatory systems.

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HoU/HoSU: In fact, the descriptions about medicinal plants in ancient and medieval literature constitute foundational evidence of the safety/safety profile of the herb, and also the efficacy for the disease conditions for which it is indicated. Documented usage for extended periods provides confidence about the safety profile of the herb and hence history of use, length of usage history can serve as a regulatory consideration. History of Use (HoU) and History of Safe Use (HoSU) are terms used interchangeably and gained significance in the context of regulatory processes. Term HoSU is used in this paper for uniformity in the expression.

Category of Approval: Presently, regulatory approvals are sought for introduction and marketing of herbs under different categories - like foods, food ingredients, dietary supplements, healthcare products, cosmeceuticals etc. It is the intent of use which determines the category and not the herb *per se* - since each herb can be used for diverse usage applications. For example, Amla (*Emblica officinalis* Gaertn.) fruit – may be considered as food or food ingredient for its nutritional benefits. In this case, it may be used as in Pickles, preserves (murabba), Condiments (chutney), rice mixtures (in biryani/Chitranna) or candies. Dried amla, its powders, its extracts intended for use to give health benefits-makes it ‘supplements of nutraceuticals,’ processed amla products as described in TK recipes makes it ‘herbal medicinal preparations,’ while its use in herbal amla hair oils or creams make it ‘cosmetics.’ Each of such category needs different types of data sets for approval. HoSU concept may reduce such complexity of data requirements.

Traditional Use of Herbs: The experiences with traditional use of herbs in countries like India have been positive. The regulatory approach relied on documented evidence for this purpose.

The usage of medicinal plants described in various textbooks is elaborate. Monographs in different Ayurvedic Nighantus (Lexicon) specify the plant part for use and suggested dosage range. The recommended plant part is specific to the species. Indirectly, it is imposed that the other plant parts are not acceptable for medicinal and healthcare purposes. For example, Bhavaprakasha is a medieval text compiled during 16th century by Bhavamishra. This book contains descriptions for over 600 medicinal plants and is recognised by Drugs and Cosmetics Act-assigning regulatory credentials to it. Table- 1 enumerates few examples in terms of the plant part used suggested for few medicinal plants (Sitaram, 2018) [10].

The information shown in the table establishes the long history of usage as recorded in the Ayurvedic books at the first place due to their antiquity. Secondly, it shows that using medicinal plants was not random but followed a rational approach-using species specific plant part. The plant parts are diverse, covering galls, fixed oils and volatile oils etc. Over above current regulatory systems assigned due credits to the approach in the country of origin. Similar kind of approaches and opportunities can also be explored in Traditional Chinese System, Kempo of Japan or Unani from Middle east countries and India etc.

Regulatory needs: Traditional medicine health directive of EU (Traditional use registration application for a herbal medicinal product (Article 16c of Directive No. 2001/83/EC) states that documented evidence of 30 years of use globally, including documented evidence of at least 15 years of evidence of use in the specific European nation would be considered while reviewing and for approval under abbreviated requirements of safety and efficacy [11]. The Indian Food Safety and Standards regulations related to supplements and nutraceuticals also has provision that states need for documented evidence of 30 years of use globally, or 15 years of use within India (Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022. [FSSAI (Nutra) Regulations, 2022]) [12].

Advantages of providing HoSU data: Any attempt to register and get regulatory approval for a herb in other nations’ is a time consuming and costly exercise, especially if the herb’s safety data is required. Generation of safety data as per OECD guidelines (involving traditional repeat dose administration toxicology on two species of animals, AME’s

Table 1

Examples of plant part recommended for each medicinal plant.

S. No.	Botanical Name	Name in Sanskrit	Plant Part Recommended	Chapter & (Section)
01	<i>Abelmoschus moschatus</i> Linn.	Lata Kasturi	Seeds	6 (III)
02	<i>Abies webbiana</i> Lindl.	Talisapatri	Leaves	6 (III)
03	<i>Aquillaria agallocha</i> Roxb.	Agaru	Heartwood or Resin	6(III)
04	<i>Celastrus paniculatus</i> Willd.	Jyotishmati	Fixed oil	6(II)
05	<i>Centella asiatica</i> (Linn.), Urban	Mandukaparni	Whole Plant	6(IV)
06	<i>Pinus longifolia</i> Roxb.	Saraladaru	Volatile Oils	6(III)
07	<i>Pistacia integerrima</i> Stew ex. Brandi	Karkatashringi	Galls	6(II)
08	<i>Pueraria tuberosa</i> DC	Vidarikanda	Tuber	6(IV)
09	<i>Rauwolfia serpentina</i> Benth ex Hooker	Sarpagandha	Roots	6(II)
10	<i>Soyimida febrifuga</i> A. Juss	Mamsarohini	Bark	6(IV)
11	<i>Terminalia chebula</i> Retz.	Hareetaki	De-seeded fruit rind	6(II)
12	<i>Tinospora cordifolia</i> (Willd) Miers	Guduchi	Stems	6(IV)
13	<i>Woodfordia floribunda</i> Salisb.	Dhataki	Flowers	6(II)

test, carcinogenicity test, teratology data where required) would involve a testing time of about 9–12 months and at current approximate rates charged by accredited GLP approved laboratories would be upwards of 1.25 crores Indian Rupees (≈153000 USD). Hence writing a document that provides documentary evidence of HoU/HoSU would be of great advantage. Describing availability of HoSU also provides a higher level of acceptability and comfort to the end user, **and regulators, and saves time, energy, cost of generating safety, efficacy data. If the herb is not approved, while “commerce suffers, the availability and access of herbs to the citizens of the nation for health maintenance with HoSU also is deprived”**. While these regulations specify the need for such evidence, in what form and what kind of such data is required or acceptable is not specified. HoSU of the herb may be as a food ingredient, as a prepared food, as a herbal medicine, as a traditional recipe/medicine, and even as a potent medicine to treat chronic or life-threatening diseases.

The authors having decades of working experience in this area, in this paper suggest some potential methods/approaches.

2. Suggested approaches

2.1. Textual reference

In this approach, detailed textual reference of the herb would be from HoSU document. The reference should consist of:

- Copy of the cover page of the text, page providing publisher, edition, year of publication, ISBN/ISSN number.
- Copy of the specific page/pages, verse/verses that describes and lists the herb.
- Copy of the regulations if any, documenting the regulatory provisions recognising the text.
- Since the language in which these texts in Ayurveda, appear is not English (like oriental language of Sanskrit or Mandarin or Japanese, etc.) an official certified translation of these pages to languages such as English, French, German, Spanish etc. depending on the country in which recognition is sought.

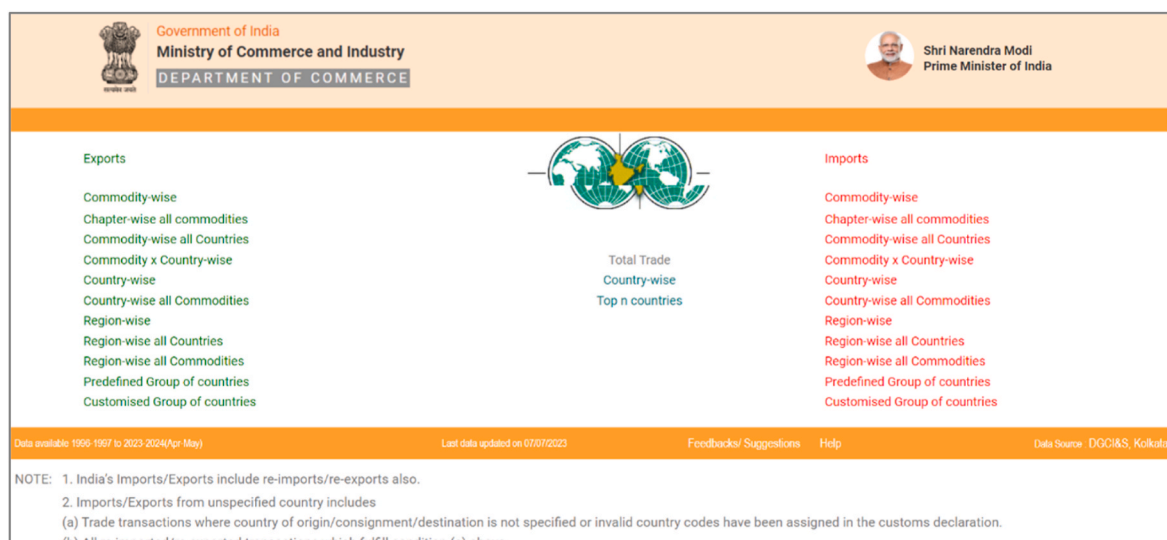


Fig. 1. Screen shot of DGFT site.

Source: <https://tradestat.commerce.gov.in/eidb/default.asp>

Textual Data to be given: Care should be taken to specify the correct identity of the herb, part of the plant to be used, process/processes described, usage levels, indications, and any advisory/caution if mentioned. Specifying the part of the plant and the process is particularly important as the documented text says to use them. If other parts of the same plant or a different process is involved in the application, extrapolating the HoU is neither scientifically rational nor would be justifiable. A simple example like – tomato fruits come with HoSU while tomato leaves are not edible and are considered unsafe. The contents of Table-1 provide a clear direction as to which plant part can be used for respective plant species.

Published Scientific data: There would be a large number of published scientific books or books that document traditional usage which are not recognised under the national regulations. While these documents may also provide additional HoSU references, whether the reviewing official in the offices would provide the same level of acceptance to a non-listed text is not clear. Depending on the type of such evidence, considerations would vary. The regulations cited above, consider 30 years of global usage as recognition of HoU, most of the texts in traditional usage have much longer dates of publication/origin. If published review of the herb in standard scientific literature dating back to 20–30 years are available, they may provide additional evidence. In case of multiple herb-based recipes or formulations, reference to the whole formulation or references for each of the herbs would be necessary.

2.2. Commerce data

2.2.1. Own data

Applicant may give own data in support of commerce of supply of the herb in either the same nation or neighbouring nations in support of earlier usage for consideration regulators. Acceptability of such data is not clearly known.

2.2.2. Official data based on HS/HSN codes

Each nation has systems to define and collect Goods and Services Tax/Customs Duty, with different nomenclature for all commerce done in that country. Such system also has taxation on goods and services exported and imported into any nation. In India currently, Goods and Services Tax is in operation. Similarly, there are specific import duties (custom duty, countervailing duty, any Cess/surcharge as applicable). In order to track and trace as well as facilitate international trade, a Global

Harmonised System Code (HS code) or a Harmonised System Number Code (HSN code) is used and are in operation. HS or HSN code is given as an identity to specific ingredients, materials, parts of equipment, types of services, finished food products, finished pharmaceuticals as well as active pharmaceutical ingredients, excipients, fruits and vegetables and preparation thereof, animal products and for that matter anything that is produced and traded internationally. In India, Directorate General of Foreign Trade (DGFT), Ministry of Commerce and Industry, Govt. of India, regulate, operate, and facilitate this system. HS codes or HSN codes are available even for herbs, medicinal plants, fruits, and vegetables, ayurvedic medicines as well as pharmaceutical products. All items imported or exported need to mention applicable and relevant HS or HSN code and data related to quantity of that item gets recorded in the relevant database. One can search for HSN code (HSN code finder) or how to locate a HSN code and harmonised system codes (Reference: [HSN Code for Pharmaceutical products](#), [HSN Code Finder](#), [How to locate an HS code?](#), and [Harmonized System \(HS\) Codes](#)). Directorate General of Foreign Trade in their database/site access to HS code and the data related to quantum of import or quantum exported can be searched. Advanced commercial information search on such sites can provide quantum of a herb exported if the relevant HS code is known for current year as well as preceding years. Such data can also be suitably searched for the herb with specific HS code exported globally, and exported to specific nation/nations like United Kingdom or other nations e.g., Germany, Europe, Australia etc. (See Fig. 1). This data search would need some expertise similar to expertise of scientist to search relevant scientific published data from various search engines/databases. Data for herbs imported into India from different nations can also be searched (See Fig. 1).

Example: Various HS codes related to amla and its products, along with global export values for last 10 years are given in Table 2.

Such data of commerce can substantiate and provide documented evidence of a herb, or a recipe having been commercially exported and having entered the market of the nation in which the document is been provided. This data also demonstrates authentic information of an herb, or its products having been locally sold, traded, or distributed in that country for a number of years for which the data has been provided, under different categories. Some sections of pharmaceutical industry and traditional knowledge industry are known to have used such data in support of their applications for registration of the herb.

Table 2
Exports of Amla and Products thereof from India since last 10 years (figures in US\$ million).

Common Name	HS Code ^a	Description ^a	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22
Amla	080590	Other Citrus Fruits Fresh Or Dried	1.76	2.40	2.15	3.35	6.53	2.91	0.50	2.85	6.82	3.49
Amla arjun/karela juice	200990	Mixture Of Juices Unfrmtid Not Contng Spirit	0.59	0.85	0.88	1.02	0.98	1.19	0.76	1.61	0.68	0.59
Amla candy	300490	Other Medicine Put Up For Retail Sale	7004.54	7912.21	8256.46	9650.41	9725.19	9926.35	11206.56	12321.99	14811.53	14629.60
Amla juice	200989	Other Juices	0.00	4.01	3.44	3.45	4.34	8.87	6.29	5.59	6.19	7.15
Amla murabba	200600	Vegetables Fruits Nuts Fruit Peel & Other Parts Of Plants prsrd by	2.80	1.80	2.71	1.81	1.81	2.63	3.24	3.39	3.56	4.60
		Sugar										
Amla paste	200799	Others	84.70	108.74	117.54	131.60	135.52	150.11	152.61	159.74	148.35	199.30
Amla pickle	210390	Other Sauces & Preparations Therfor Mixed Condiments & Mixed seasonings	20.14	30.96	33.43	38.70	47.90	50.49	57.67	64.22	72.55	70.66
Amla powder	121190	Other: Seeds	208.85	194.14	242.00	254.45	274.01	311.14	302.51	283.48	377.55	423.12
		Total	7323.38	8255.11	8658.61	10084.79	10196.29	10453.69	11730.12	12842.89	15427.23	15338.52

ITC HS classification: India Trade Portal.

Note: The code for Amla Candy includes various traditional medicines such as ayurvedic, unani etc.

^a See detailed description under reference.

Data source: DGCI&S. and specially supplied by SHEFEXCIL.

2.2.3. Need for government support

The Finance Ministry of Govt. of India in its budget speech and The Finance Bill 2022, introduced a section 135 AA subsection (1), (2) amending the customs act that such publication of data, reproducing the information in printed or electronic format making it available for the public, a punishable offence (The Finance Bill 2022, Govt. of India) [13]. However, authors have not seen subsequent notifications implementing this proposal of the Finance Bill 2022. A number of export promotion councils, namely, Pharmaxil - Pharmaceuticals Export Promotion Council, Chemexcil - Chemicals Export Promotion Council, Shefexil - Shellac and Forest Products Export Promotion Council, who are Govt. of India undertaking councils can help to provide such data. Authors recommend that the government should consider notifying a system where such export data for specific herbs may be made available to bonafide industry/sector on payment of a prescribed fee. This would support export of 'Made in India', 'Produced in India', herbs and recipes in their registration process in different nations.

In addition to, or in absence of such data from Export-Import data sites, providing tabulated summary of exports or imports done by any applicant for that herb year-wise would also provide documented proof. Such a Table should consist of details of customs documents giving Serial No. of Bill of lading, Bill of import, date of export or date of clearing in the country to which exported, description of item along with HS/HSN code and quantity with copies of those custom documents could be another approach.

2.3. Products in the market

Another approach that can be considered could be to provide photographs, copies of advertisements in reputed journals or magazines, trade brochures in the country of registration attempted. If these data are from undisputable publications and issues of yesteryears, showing details of volume number, date of publication and other relevant information can provide additional data. Just downloading product writeups with photographs from the net may not serve the purpose as it would be difficult to give such data of yesteryears. Also, many of the commerce sites showing such product containing the herb may not meet authenticity of such data in the eyes of reviewers. Photographs of labels/back of pack or front of pack information of products containing the herb in the country of origin, specifically highlighting the regulatory approval granted (license, address of manufacture, etc.) can provide data of current availability of the product.

2.3.1. Exposure data

Such data may cover herbs, food products, traditional knowledge-based medicine products. Providing some of the market information – like, how many units of specific pack sizes are sold in the country of origin, data of preceding years of the same, approximate no. of consumers who would have consumed this quantum, calculated value of consumption per day, how long consumed as per directions of use – can provide useful data on population exposure. Similar data on herb or product in the country of application, would also be of greater value. Authors recommend careful self-review and selection of relevant data only, so that the reviewer gets an opinion of fairness of data provider. Practise of 'padding up such a section' with information that can be doubted is not recommended. Data covered under this approach would help to enhance the confidence on the safety profile of the herb. Additionally, documents that show the registration, Free Sale Certificates issued by relevant bodies, authorities, approval status in any of the Global nations, and such supporting documents add value to HoU data.

2.4. Consideration to ethnomedicinal data

As mentioned in the introductory part- Ethnomedicinal practices are at the root of codified medical knowledge systems. They are not documented. However, researchers collate these practices and analyse them

in multiple directions and perspectives. These studies are widely published in peer reviewed journals and as books and focused reports as well. This kind of historical knowledge carries two dimensions. Lengthwise, they are older practices in relation to codified works. But extent wise, they are mostly localized. Hence, we suggest that any published work covering the ethnomedicinal uses for the subject species may be assigned with a “supplementary score or weightage.” Only published research communications may be considered as evidence for historical use.

Future work: Based on long years of working in the area of herbs, food products, traditional medicine, authors have attempted to provide these approaches along with their observations and views. More discussion and debates are required to build on these ideas and eventually a broad guideline may emerge. Professional associations and governmental bodies are suggested to take up such a work. Keeping brevity in mind, in this strategy paper, we have avoided giving too many examples or supporting data.

^a HS Code detailed description	
080590	Citrus Fruits Fresh Or Dried: Other
200990	Fruit juices (including grape must) and vegetable juices, unfermented and not containing added spirit, whether or not containing added sugar or other sweetening matter
300490	Medicaments (Excluding Goods Of Heading 3002, 3005 Or 3006) Consisting Of Mixed Or Unmixed Products For Therapeutic Or Prophylactic Uses, Put Up In Measured Doses (Including Those In The Form Of Transdermal Administration Systems) Or In Forms Or Packings For Retail Sale Other: Anticancer Drugs: Other
200989	Fruit juices, incl. grape must, and vegetable juices, unfermented, not containing added spirit, whether or not containing added sugar or other sweetening matter
200600	Vegetables, Fruits, Nuts, Fruit Peel And Other Parts Of Plants preserved By Sugar (Drained Glace/Crystallised), Products include: Amla Murabba
200799	Jams, jellies, marmalades, purees or pastes of fruit, obtained by cooking, whether or not containing added sugar or other sweetening matter (excluding citrus fruit and homogenised preparations of subheading 2007.10)
210390	Sauces And Preparations Therefor, Mixed condiments And Mixed Seasonings; Mustard Flour And Meal And Prepared Mustard - Other: Curry Paste
121190	Other Plants And Parts Of Plants Used In Perfumery, Pharmacy, Insecticidal Fungicidal Purpose, Fresh Dried

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Author Contributions

D. B. Anantha Narayana: Conceptualization, Methodology, Resources, Writing – original draft, Visualization, Supervision. N B. Brindavanam: Resources, Writing – review and editing, Visualization, Supervision. Sabina Shirsekar: Formal analysis, Data curation, Writing – review and editing, Visualization.

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