

Guidelines for Essence Production, labelling and advertising

These guidelines for good practice for the production of flower and vibrational essences that are available to the public in the UK.

Few people would be expected to follow everything immediately they start to make essences. However this information should be acted on where possible and as soon as is practical.

By aiming at understanding of where the production of essences is controlled by the laws and regimens of the society in which we live, BAFEP works towards ensuring we all have the freedom to make and use essences in the future.

1. Setting up a dedicated workspace for making up essences

Since at the moment essences are classified as a food (other categories available are cosmetic and medicine), all rules and regulations for Food Hygiene are technically applicable. In any doubt, please visit your Public Health Office and talk it over with them before picking up your hammer or taking out a loan, just to ensure you get it right! They are very helpful and since you are not preparing food, there is flexibility.

This is what you should be aiming at in an ideal situation is a dedicated space:

- An easily cleaned area made of plastic/formica NOT wood. Cleanable cupboards, washable walls, shelves and lino flooring. Ideally worktops and floors should be sealed. This is really like a normal kitchen.
- In a dedicated space you must have two sinks, one for washing equipment and one for washing hands. These sinks need to be labelled. A bottle of antibacterial hand wash should be on hand. Double sinks have proved to be adequate.
- No animals should be allowed in the area, or outside coats or shoes. Overalls are advised as are plastic gloves and hair-coverings.
- Sterilising equipment.
- A liquid sanitiser (antibacterial surface wash), preferably biodegradable may be advisable, although alcohol is quite good!

Should you be investigated for some reason you will be advised at what you need to rectify and given time to do the work.

2. Making Essences without a Permanent Dedicated Space.

The Women's Institute Markets have built up a very responsible position in the campaign for food safety. Their guidelines are ideal for those just beginning the process of making essences for sale or for those who have a very small production with no permanent dedicated space.

These procedures would need to be followed **EVERY** time essences are prepared.

The points are as follows:

1. Environmental Health officers have the right to inspect premises without notice.
2. All involved must obtain a Basic Hygiene for Food Handlers certificate and attend the refresher course every 3 years.
3. In the room to be used there must be an overall atmosphere of cleanliness.
4. An adequate supply of hot water, detergent, nailbrush and disposable towels, clean utensils and worktops.
5. Have removed any pets and their bedding.
6. Have the room free from laundry and outerwear.
7. Have first aid materials readily available.
8. Thoroughly clean and disinfect all work surfaces using food friendly cleaners.
9. Label according to the DEFRA guidelines

Personal information:

1. Have a professional attitude to personal cleanliness, risks of contamination.
2. No smoking
3. Wear protective clothing and hair covering.
4. Do not prepare items when you or a member of the family is unwell, especially after a cold or stomach disorder.
5. Cuts or abrasions are covered with a suitable dressing.
6. Hands are thoroughly washed regularly.

Further information:

Food Hygiene (General) Regulations 1970

Food safety Act 1990

3. Bottling Guidelines

Essences that are intended or may be used internally, are treated as foods, As such they are subject to food production laws (Health & Safety: Food Hygiene) and food labelling laws (DEFRA Regulations.)

1. If you are intending to sell essences you make and maybe even if you are mixing dosage bottles for people, you should consider doing the Basic Food Hygiene Certificate. This is usually a day course, offered at most colleges, cost varies.
2. The site for bottling needs to comply with food guidelines.
3. You must ensure that the essence is bacterially inactive. This can be achieved by sterilisation, proper handling and a preservative.
4. Sterilisation of your bottles is an option even though alcohol at certain levels tends to stop bacterial growth. Alcohol content of over 25% is often needed to ensure no growths. Some producers use 37-40%.
5. Basic personal hygiene, and monitoring of the environment will ensure no contamination occurs.
6. Preservative – this has traditionally been brandy. You might opt for vodka, glycerol, or a vinegar as long as you are sure the dilutions are correct to prevent bacterial growth.
7. Tamper-evident bottles/bottle-tops are advisable when selling to the public.
8. Literature and advertising must comply to present laws and it is strongly suggested that this also complies with Medicines and Health Products Regulatory Agency Guidelines.

4. Labelling Law

Flower and vibrational essences that are for ingestion are treated as foods and are subject to food production laws (Health & Hygiene) and labelling law, (DEFRA regulations).

If you don't label you essences as 'external use only' ingestion will be assumed. However, 'external use only' suggests a cosmetic, and more regulations apply, including a need to have an independent laboratory analysis.

The Food Labelling Regulations 1996, Document 1499.

- a) the name of the food [to include what it is i.e. essence etc]
- b) a list of ingredients [in descending order of volume or weight]
- c) the appropriate durability indication ['use by' or 'best before' use date, batch number]
- d) any special storage conditions or conditions of use
- e) the name or business name and an address [post code is OK, telephone number is not OK]
 - the manufacturer or packer or
 - the seller established within the EC
- f) particulars of the place of origin or provenance, if failure to do could mislead
- g) instructions for use [unless label is less than 10 sq.cms – then this can be omitted]
- h) Volume of the bottle needs to be on the label in a readable size.
(This is the full list of requirements from the actual document, not the shortened version that appears on the Foods Standards Agency website)

2004: Following six months of debate with Trading Standards, the Public Analyst, food Standards Agency and the Medicines and Health Products Regulatory Agency, extra guidelines are these:

In the ingredients listing,

5. If you use the words 'spring water' you have to say which spring.
6. Brandy (or vodka) should be stated, not grape alcohol.
7. The words 'highly diluted extracts of the flowers' are fine, followed by a list of plants.
8. You can also add the percentage by volume of alcohol
9. Do not use '5x' or something similar to describe dilution

The name of the product—this complies with MHRA Guidelines

Also on the boxes is a statement that the essences are believed to “capture the positive spirit of each flower”

There then followed a **list** of each flower with a few MHRA compliant words about the emotional qualities of the spirit of the flowers.

This has become the best guidance we have from ALL agencies on how to label and describe our products.

5. An Excerpt from
**Medicines and Health Products Regulatory Agency Guidance
Note No 8**

(Previously MAL8) March 2002

**With respect to
Words and Phrases that the MHRA
associate with Medicines**

*You are strongly advised to avoid these words and phrases when describing essences as they may contribute to the MHRA determining that essences described with these words are **medicines** and need the necessary licenses.*

This list is not exhaustive

Alleviates
At the first sign of.....
Avoids
Boosts the immune system
Burns fat
Calm/calms/calming
Can benefit those who suffer from.....
Can lower cholesterol
Clears
Clinical Trials evidence
Clinically proven
Combats
Controls
Counteracts
Cure/cures
Eliminates
Fights
Heals
Helps body adjust after crossing time zones
Increases metabolic rate
Is said to help with.....
Medical research.....
Prevents/preventing
Protects against
Remedies
Removes
Repairs

Restores
Stimulates the nervous systems
Stops
Stops craving for.....
Strengthens the immune system
Strips off sun-damaged pre-cancerous cells
Traditionally used for
Treats/clears infestations
Treats/treatment/treating

Although words in themselves do not define 'medicines' bear in mind that essences come in little bottles and are usually taken by mouth. Therefore they already have a tenuous hold in the Foods category. Please don't let careless use of words or attachment to market forces endanger the future of essences.

6. **Advertising:**

The law makes it an offence to take part in the publication of any advertisement referring to any article of any description in terms which are calculated to lead to the use of that article for the purpose of treating human beings for any of the following diseases: Bright's Disease; Glaucoma; Cataract; Locomotor Ataxy; Diabetes Paralysis; Epilepsy or fits; Tuberculosis.

It is also an offence to publish any advertisement which:

- a) offers to treat or prescribe a remedy or advice for cancer, or
- b) refers to any article in terms calculated to lead to its use in the treatment of cancer.

7. HACCP Explained (courtesy of Healing Herbs)

As Flower Remedies are classified as foods in the UK a **HACCP** plan is an important measure that can be incorporated into a business to show that all necessary safety procedures are being taken to adequately meet current Food Safety Regulations.

HACCP stands for **Hazard Analysis Critical Control Point**. It is used to examine a company's system by looking at the product produced and the processes used to do this, identifying all steps in the products cycle of development which are critical to food safety. (A Hazard Analysis).

For each process used in the development of the product, three hazard types are evaluated:

- **Biological/Microbiological Hazards** - These are commonly caused by contamination of ingredients, improper cooling, poor sanitation, poor personal hygiene and cross contamination.
- **Chemical Hazards** - These include agricultural/horticultural chemicals, industrial chemicals, naturally occurring toxicants, environmental contaminants and food chemicals.
- **Physical Hazards** - These could be debris in raw materials, contamination during food processing, materials entering food during distribution and intentional tampering.

Any hazard identified is then assessed to produce a **hazard severity** and **risk** score and **Critical Control Points** are established. A **CCP** is a step at which control can be applied and is essential to prevent, eliminate or reduce a food safety hazard to an acceptable level.

Critical limits, the maximum or minimum value to which a physical, chemical or biological parameter must be controlled at a CCP, are also established. These limits need to be continually followed in work practice.

The Critical Control Points should then be monitored in the work place, with a planned sequence of observations and measurements repeatedly carried out, ensuring each CCP is adhered to, that safety controls are in place, maintained and reviewed. (HACCP assessment forms are used for this).

Although individual companies need to devise their own safety procedures relating exclusively to themselves, at Healing Herbs we have found the following CCPs and recommend our findings as a guide.

- **CCP1 – Personal hygiene** (a biological/microbiological and physical hazard). To eliminate this we wash hands on starting work in a new area, wear protective personal awareness, aided by staff completion of a basic hygiene course.
- **CCP2 – Receipt and store of raw materials and packaging** (a physical hazard). To overcome this we check all goods on arrival for damage and dirt and return any breached materials to the supplier. We continually monitor our goods throughout production for glass breakages or contamination, disposing of any that are not adequate.
- **CCP3 – Setting up labelling machine, printing and labelling** (a physical hazard). To avoid any problems here we observe for glass shards, use clean bags and trays, routinely clean machinery and handle bottles with care.
- **CCP4 – Preparation of filling room and adding mother tincture to brandy** (a biological/microbiological, chemical and physical hazard). To prevent hazards here we observe for any glass shards, use 40% Abv brandy which kills any biological contaminants, practice good personal hygiene and use eco friendly cleaning agents.
- **CCP5 – Assembly of 40 bottles into sets and alcohol awareness.** All bottles are sleeved to safeguard against intentional tampering and we label our product showing that it contains brandy.

Thus, the main safety issue at Healing Herbs is contamination of our product. This is controlled by the use of 40% Abv. Brandy, which would kill anything of this nature. All other safety issues concern glass, which is controlled for at every step in our product production.

HACCP was initially developed in America, in the 1960's, in a quest for quality and safety in the Food and Drink Industry. It has been constantly developed and was last amended and approved by UN/FAO in 1997.

Hazard Analysis is a requirement under the **Food Safety (General Food Hygiene) Regulations (1995)**, which came into force out of the EU **Directive 93/43/EEC**, to identify all steps in production activities which are critical to food safety, and then, to ensure adequate safety controls are in place, maintained and reviewed. This applies to anyone who sells or processes food (except those in primary food production) and **HACCP** is a recommended way in which to meet the requirements of these current regulations, helping to ensure business success, profitability and growth.

8. How are you going to put HACCP in place?

You make your own, review it yourself, control the hazards and keep a full record of any problems. That's it.

1. Make a full list of every process involved in manufacture.
2. List all possible hazards throughout all processes.
3. Determine what are the hazards
 - a. Physical: for instance broken glass in product
 - b. Biological: for instance bacteria growing in product
 - c. Chemical: for instance contamination of the product
4. Evaluate the degree of possibility that any hazard will occur
 - 0 for no possibility
 - 1 for possible but unlikely
 - 2 for likely
 - 3 for almost certain
5. Evaluate the degree of danger to the end user should any hazard occur. This involves assigning a value to the risk:
 - 0 for no danger
 - 1 for mild
 - 2 for medium
 - 3 for severe
6. For each risk allocate a points score like this:

Critical Control Point No 1: Incoming Goods

Process: incoming supply of glass bottles.

Hazard: that there is contamination from the transport vehicle (eg oil) which may transfer to the product.

Risk: assessed as 2

Hazard: assessed as 1

Overall point score of 3 out of a possible 6 but anything which scores above 0 still needs to be considered.

Action: examine all incoming goods and determine if packaging is damaged and if goods are dirty.

Deviation Report: if goods are damaged or dirty record the delivery date, consignment etc and the action taken:

- a. to remedy the problem and zero the risks/hazard
- b. to ensure that future supplies are better

As you work through the whole production process it will emerge that there are a number of Critical Control Points:

- delivery of goods

- labelling bottles
- filling bottles
- storage of materials etc etc

Where these HACCP occur you need to have an active plan in place to analyse the problem and record, using a 'deviation report form', when it occurs and what was done to make good.

A couple of obvious pointers are:

- the risk of bacterial contamination is high if you fill bottles in your kitchen on the same table as cutting up meat for the dog. The stage of production therefore becomes a Hazard Analysis Critical Control Point. What you decide to do to reduce the hazard and the degree of risk is up to you but your HACCP plan should look at the problem and record how you propose to limit the risk.
- the chemical contamination of your essence making bowls is probably low but if you wash them in detergent is there a possibility of that creeping into the mother essence? Or is there a degree of risk associated with the water used?
- in food production the biggest risk is microbiological and if we use alcohol as a preservative then that is sorted. But what strength of alcohol is required for the finished product to be certainly safe?

HACCP planning is not difficult to do but requires some thought and time to make your plan. Once it is done keep the folder with your active files and use it as a constant record for all actions taken that refer to control of good manufacturing practice.