

EHPM Guidelines for food supplement companies on the management of adverse event reports

2024



Chairman's introduction

Safety, high quality standards, clear information to consumers and transparency are the core priorities of the European Federation of Associations of Health Product Manufacturers (EHPM) for food supplements. These values are fully aligned with those of National and European decision-makers and competent authorities. EHPM strongly supports the need for a better regulatory environment for food supplements.

The General Food Law Regulation (EC) No. 178/2002, together with the Food Supplements Directive 2002/46/EC and other regulatory texts, forms the legal basis of the European food safety framework ensuring the highest level of consumer protection. In this context, the safety of food supplements is the responsibility of Food Business Operators (FBOs) who must use safe and high-quality ingredients, adopt high-quality safety and hygiene standards (HACCP) and apply appropriate and reliable labelling. Furthermore, EHPM believes that FBOs should implement a post-market vigilance system when placing products on the EU market.

Through this post-market vigilance, FBOs must collect all Adverse Events (AEs) reported by consumers, healthcare professionals, and/or competent authorities (AEs reporters), which are suspected to be related to the intake of their food supplements alone or in combination with other products.

Recently, National and European Authorities have highlighted the lack of post-market vigilance for food supplements. This contributes to questioning the safety of food supplements and fuels the scepticism of the Authorities towards the food supplement sector. In line with this, some Member States (e.g. France) have already implemented national vigilance systems and others intend to follow a similar approach. However, unlike other product categories (e.g. cosmetics and medical devices), there is no official and harmonised vigilance system at European level for food supplements.

In the framework of Article 8 of Regulation (EC) 1925/2006, when the safety of an ingredient is questioned or is under scrutiny by EFSA, or in any other case where safety data are requested by National or European Authorities, it is important to provide safety and consumer exposure data regarding the concerned ingredient. The availability of vigilance data is crucial for FBOs to be able to monitor the safety of their products once they are placed on the market.

In this context and in line with its proactive approach, EHPM has developed these Guidelines whose objective is to propose to its Members a concrete, realistic, applicable food supplement vigilance system that guarantees an even higher level of safety for products marketed in the EU.

The scope of the guidelines

This document concerns food supplements and is intended for all FBOs placing their products on the EU market. It has been developed with the objective of being easily applicable by all FBOs and in particular by small and medium enterprises (SMEs), which represent the majority of FBOs in the European food supplement sector.

This document is intended as a non-mandatory self-regulating guide, in line with the above-mentioned priorities and values of EHPM and the EU. Where specific national regulations or guidelines apply, these prevail over the Guidelines.

These Guidelines are designed as a tool to provide guidance to companies in developing and implementing procedures to ensure that AEs received from reporters are dealt with in a logical, functional and comprehensive manner.

The document is fully adaptable: although examples and templates are provided, these should be adapted as necessary to suit the wide range of food supplement products, the FBOs that produce them, as well as the specific legal framework in which the FBOs operate. In light of the above, it is possible that not all sections of the Guidelines may be applicable or appropriate for a particular company.

These Guidelines are intended as a tool for companies to consider when developing and implementing their internal vigilance system.

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ACKNOWLEDGMENTS

When drafting these EHPM guidelines, reference has been made to already available guidelines and best practices by National Authorities and food supplement companies and other Industry sectors and associations. In particular, we acknowledge the important and comprehensive IADSA “Global Guide to The Handling of Adverse Event Complaints – Guidelines for Supplement Companies”.

We also acknowledge the French ANSES “AVIS révisé¹ de l’Agence nationale de sécurité sanitaire de l’alimentation, de l’environnement et du travail”, the Italian Istituto Superiore di Sanità, and the Belgian Ministry of Health. Consideration was also given to the Platform of European market surveillance authorities for Cosmetic and Pharmaceutical vigilance guidelines and also best practices for other consumer products.

LINKS TO THE MENTIONED DOCUMENTS

IADSA
<https://www.iadsa.org/global-guide-to-the-handling-of-adverse-event-complaints>

ANSES
<https://www.anses.fr/fr/system/files/NUT2010sa0195.pdf> (2011)
<https://www.anses.fr/fr/system/files/NUT2018SA0026.pdf> (2019)

ISTITUTO SUPERIORE DI SANITÀ
<https://www.epicentro.iss.it/fitosorveglianza/vigierbe>

BELGIAN MINISTRY OF HEALTH
<https://www.health.belgium.be/en/general-information-0>
<https://www.health.belgium.be/en/types-foodstuffs-concerned>
<https://www.health.belgium.be/en/es-operateurs>
<https://www.health.belgium.be/en/citizens>
<https://www.health.belgium.be/en/healthcare-professionals>
<https://www.health.belgium.be/en/reporting-adverse-reactions-online>

“All due diligence has been observed in writing this document so as to provide complete and accurate information at the time of its publication. However, EHPM expressly excludes any warranty as to the reliability of this document in terms of completeness and correctness, and rejects any liability whatsoever resulting from its use.”

TABLE OF CONTENTS

Chapter One	6
Definitions and Responsibilities	6
1.1 Definitions	6
Chapter Two	8
Adverse event reports (AERs)	8
2.1 General Overview	8
2.2 Contract Manufacturing	8
2.3 Standard Operating Procedures (SOPs)	8
2.4 AER Types and Sources	9
2.5 Receipt of AERs	9
2.6 Causality	9
2.7 Confounding factors when assessing causality	9
Chapter Three	10
Procedures for managing AERs	10
3.1 AER management responsibility – the Accountable Person (AP)	10
3.2 Training of personnel	10
3.3 Receiving and recording AERs	11
3.4 AER information requirements	11

3.5 Recording of responses to questions	12
3.6 Questions to AER reporters	12
3.7 Recording of AER question response details	13
3.8 Assessing AERs	13
3.9 Classifying AERs	13
3.10 External Reporting requirements	13
Chapter Four	14
The AER Central Records System	14
4.1 General Overview	14
4.2 Operating a Central Records System	14
4.3 Function of an AER Central Record System	15
4.4 Retention of AER records	16
4.5 Reviewing AERs	16
4.6 Frequency patterns and action to be taken	16
4.7 External advice	16
4.8 Scheduling regular reviews	16
4.9 Review and analysis of the AER data	17
4.10 The review results	17
Chapter Five	18
AER Causality Assessment	18
5.1 Definition	18
5.2 Management of causality assessments	18
5.3 Procedure for an FBO AER causality assessment	18
5.4 Assessment criteria for causality assessment	18
5.5 Product withdrawal or recall	19
5.6 Periodic review of AERs	19
ANNEX I	20
Food Supplements Adverse Event Report Form	21



Chapter One

Definitions and Responsibilities

1.1 DEFINITIONS

Food Supplements are defined by European Union (EU) Directive 2002/46/EC as a specific category within the vast family of food products, as “[...] foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect”. Food supplements must comply with the general quality and safety requirements applicable to all foodstuffs. The quality and safety of food supplements are covered by harmonised EU legislation, and compliance is mandatory for all operators within the EU. As with all other foodstuffs, food supplements must be safe to use and truthful regarding the benefits they claim to deliver.



- **Food Business Operator (FBO)**

Article 3 of Regulation (EC) No 178/2002 defines “‘food business operators’ as the ‘natural or legal persons’ responsible for ensuring that the requirements of food law are met within the food business under their control”.

- **Adverse Event (AE)**

Any untoward health-related event following the ingestion of a supplement alone or in combination with other products.

- **Serious Adverse Event (SAE)**

An adverse event reported to have resulted in death, life-threatening experience, in-patient hospitalisation, persistent disability or significant incapacity, congenital anomaly or birth defect, or, a medical or surgical intervention required to prevent one of these outcomes.

- **Adverse Event Report/Serious Adverse Event Report (SAER)**

A Report of an Adverse Event/Serious Adverse Event from consumers, reporters on behalf of consumers, healthcare professionals or Competent Authorities

- **Accountable Person (AP)**

The accountable person, appropriately qualified and expressly appointed by an FBO, for the receipt, analysis and management of Adverse Event Reports (AERs) and Serious Adverse Event Reports (SAERs); the AP can be an employee of the FBO, or an external consultant.

- **Food Supplement Vigilance**

The system to detect and analyse any AER and SAER of food supplements. Similar national systems may be already in place in some Member States, and may be referred to as “Post-Marketing Surveillance” or “Nutrivigilance”.

The above definitions are intended to capture the language most commonly used to define what constitutes an Adverse Event and a Serious Adverse Event and who, within an FBO, should be responsible for their management. However, the language and definitions themselves can vary, and, where applicable, all companies should operate in compliance with any and all current national and European legal definitions.



1.2 RESPONSIBILITIES

FBOs are responsible for ensuring that they have appropriate systems in place to capture, record, evaluate and address adverse events with their products, including appointing an Accountable Person (AP), to manage such events and, where appropriate, to report them to regulators in accordance with national regulations.

The AP is responsible for establishing the AER system, for training of staff, for reviewing any AERs received and deciding on the corrective and or preventative action that should be taken, including communicating the AER or SAER requirements to other FBO's across the supply chain and ensuring the effective management of AERs in this supply chain context.



Chapter Two

Adverse event reports (AERs)

If used according to the product instructions, adverse events to food supplements are typically rare, and most AERs received by an FBO are likely to be minor, non-serious and reversible. A full AER procedure can help determine if the reports are serious in nature (SAERs) and if a causal relationship exists between use of a food supplement and the reported adverse events. An effective AER review process should be in place, enabling the AP to take swift and appropriate actions within timelines defined by the FBO's AER procedure, or according to any national requirements.

2.1 GENERAL OVERVIEW

All food supplement manufacturers, distributors or marketers whose names appear on product labels should have adequate procedures in place that enable them to receive, assess and manage adverse event reports (AERs). Not all FBOs will necessarily operate a full AER procedure as outlined in these Guidelines, but every FBO should have a coherent procedure that sets out the appropriate level of control applicable to their role in the supplement supply chain and that also creates transparency in communication within the different levels of AER management. It is the responsibility of the FBO that places the food supplement on the market to define the specific procedure(s) to be applied, including agreeing and defining the role(s) of other parties in the supply and distribution chain.

2.2 CONTRACT MANUFACTURING

Technical agreements with Contract Manufacturers or with Distributors, or with Product Marketers/Promoters should specify:

- i. who is taking on the responsibility for handling AERs (this is usually the FBO named on the label, but may be designated by the FBO to another party)
- ii. the process, requirements and timescale for promptly forwarding AERs to the designated responsible entity

2.3 STANDARD OPERATING PROCEDURES (SOPS)

It is strongly advised that FBOs have Standard Operating Procedures (SOPs) in place that set out detailed internal procedures regarding receiving, reviewing and evaluating AERs, as well as procedures for corrective and preventative action reporting, product withdrawal or recall, should this become necessary. The procedure described in Section 3 below offers a comprehensive method for recording, evaluating and where required, reporting AERs to national competent authorities.



2.4 AER TYPES AND SOURCES

Types and sources of AERs can vary widely - from unlinked events that coincide with intake of the food supplement, to the underlying medical or physiological condition of the consumer; through to misuse of products by the consumer, unintended use, i.e. during pregnancy, breastfeeding or by children, or known mild to moderate side effects of certain ingredients.

2.5 RECEIPT OF AERS

Consumers or their representatives should be able to contact the FBOs shown on the product label via the postal, email or website address or by calling the telephone number printed on the product label/leaflet, if any. AERs may be received directly from consumers, or indirectly from representatives – family, friends, healthcare professionals, legal representatives, etc. – or via other sources such as retailers, wholesalers, government officials, or, where applicable, contract manufacturers or distributors. Thus, AERs may be received in electronic form, by mail or telephone, or in person; in these two last cases the AER must be recorded in writing by the FBO. In all cases, the AER Questionnaire (see Annex I) should be filled out.

2.6 CAUSALITY

AERs are voluntarily reported from a variety of sources and are usually not verified by medical investigation. Thus, an AER received by an FBO does not necessarily establish a causal relationship between ingestion of the food supplement and the reported adverse event. The Accountable Person AP nominated by the FBO must carefully scrutinise such AERs and, if necessary, collect additional information from the source of the AER, in order to try to establish a causality relationship between the AER and the ingestion of the food supplement, considering possible confounding factors (see 2.7 below). Therefore, caution must be exercised when evaluating causality.

2.7 CONFOUNDING FACTORS WHEN ASSESSING CAUSALITY

The investigation of reports of adverse events can be confounded by a number of factors:

- the concomitant use of medications or other supplements, whether prescription or over the counter
- accompanying disease states, abnormalities or other factors
- other foods in the diet
- lifestyle factors e.g. lack of exercise or heavy sport activities, poor diet or sleep
- life stages – children, pregnancy, breastfeeding, the elderly

A further difficulty is that such confounding factors may not be fully known to or declared by the reporters.

A significant number of adverse events may simply be due to chance or coincidence and therefore conclusions about causation or risk from supplement use should not and cannot be based solely upon any single AER. However, while not all AERs that are notified to FBOs may have an apparent causal relationship with a supplement, **all AERs received should be properly recorded, analysed, and stored, regardless of the initially perceived level of causality or seriousness.**





Chapter Three

Procedures for managing AERs

3.1 AER MANAGEMENT RESPONSIBILITY – THE ACCOUNTABLE PERSON (AP)

The FBO should nominate a suitably experienced and qualified Accountable Person (AP) to be responsible for implementing and monitoring the AER procedure and for reviewing the records of all AERs received by the Company. The AP should have decision-making authority, excellent analytical, assessment and communication skills, plus a detailed knowledge of the product range, together with the ability to record and process AERs appropriately and accurately, and rapidly identify possible trends in the data, and to delegate as necessary. Additionally, the AP should have robust knowledge of and access to the applicable legal framework.

The AP can be an employee of the FBO or an external consultant. If the AP is not medically qualified, it is recommended that the AP has readily available access to an internal or external medically qualified person on an 'as needed' basis.

The appointed AP may also have other role(s) in the company: for example, technical or regulatory officer, quality control manager, senior executive or other roles, depending on the size of the Company, but the essential requirement is that the AP's tasks and responsibilities regarding the AER procedure be clearly defined. The AP should preferably not hold a commercial position, in order to avoid conflicts of interest.

Depending on the size of the FBO and the number and type of products it markets, the nominated AP may delegate specific tasks, under supervision, (for example, the day-to-day recording and reviewing of incoming AERs) to appropriately experienced and trained individuals. Any such delegation must be documented and supervised and the AP must maintain overview and oversight of AERs.

3.2 TRAINING OF PERSONNEL

A mandatory training programme should be implemented for all relevant employees and consultants to ensure a comprehensive and company-wide understanding of AER handling procedures. This will also allow adequate recognition and communication of AERs to the AP/ delegate in a systematic and timely manner. Employees must know who their AP/ delegate(s) are, their responsibilities, and their contact details. Completed training records, including details of the competencies, should be documented, maintained and regularly reviewed in order to schedule regular refresher training. This provides a clear demonstration of the FBO's continuous compliance with its AER handling procedures.



3.3 RECEIVING AND RECORDING AERS

Any AER information submitted to the FBO by a consumer or reported on their behalf should be forwarded to the AP/their delegate as quickly as possible with all available details, within the FBO-agreed timescale for AERs and SAERs, and any relevant national requirements.

3.4 AER INFORMATION REQUIREMENTS

A standardised questionnaire should be used to obtain all relevant information as soon as possible.

The minimum information gathered should include:

- the basic nature of the AE, including symptoms/injury/illness
- the product name
- the batch/lot number (if available)
- the name of the consumer and his or her representative (if applicable)
- relevant contact telephone numbers and/or email addresses

An example of the type of Questionnaire/Response format that could be used by the FBO is given in Annex I. Due to the wide range of food supplement products and FBOs, not all the questions listed will necessarily be applicable or appropriate for all products and FBOs, and the questionnaire should be adapted as necessary to suit the FBO's own situation and products and any national requirements. Where relevant, it is recommended that a regulatory and legal review of the FBO's standardised questionnaire be carried out to ensure that it is consistent with the requirements of the national competent authorities.



3.5 RECORDING OF RESPONSES TO QUESTIONS

Responses should be recorded verbatim, if possible, so as to assist the accuracy of later interpretation and analysis. If the answer to a question is not known or the consumer/his or her representative does not answer a question, a relevant note such as 'stated unknown' or 'declined to answer' should be written in the space provided and the consumer/his or her representative should be informed of the note that has been made.

3.6 QUESTIONS TO AER REPORTERS

The AP/delegate should ensure that sufficient information is obtained to confirm authenticity of the AER and, where necessary, to enable an investigation of the AER. Questions to the consumer or their representative should include:

- Reporter's name, initials, and contact details
- Consumer's name, (if not the Reporter), initials and contact details
- Consumer's age, gender, race, weight and height;
- If consumer is female, whether she is pregnant or breastfeeding
- Product name, batch/lot number and best before/expiry date (if available)



- As much detail of the symptoms of the adverse reaction, illness or effect on the consumer as possible (the adverse event). Multiple reports may be given during the call and, if possible, information should be collected about each report as follows:

- Frequency of symptom(s) - intermittent or constant;
- Duration to onset of symptoms/illness in regard to product use
- Aggravation, specifics of de-challenge (the effect of stopping the supplement suspected of causing the AER) and re-challenge (the effect of resuming intake of the supplement causing the AER)
- History of any similar event prior to product use and associated diagnoses if applicable
- Other products or medicines (over the counter or prescription) taken during the same period (with dose and frequency)
- Name and address of medical practitioner or hospital consulted (if relevant)
- If hospital consultation/admission, specify if in-patient or out-patient, duration of stay and treatments or recommendations received;
- Follow-up care and/or referrals to specialists;
- Are medical records related to the reported event available for review (may include other actions relative to maintaining patient confidentiality etc. pursuant to national or EU regulations)?
- Permission to request a copy of the medical documentation?

- Any existing illnesses, conditions or recent operations
- Permission to contact again if necessary.
- When the product was taken (time of day; whether before, during or after a meal)
- Indication/use of the product
- Where and when the product was purchased (name, address and telephone number of retailer or practitioner or URL of internet website)
- Dose, frequency and duration of taking the product - was the product consumed and stored as recommended on the label?
- Any observations or issues that the consumer noticed that were different with regards to quality of the product (compromised packaging, changes in colour, smell, taste etc.)

3.7 RECORDING OF AER QUESTION RESPONSE DETAILS

The details relating to the AER should be recorded in the AE Questionnaire (see Annex I) and assigned a specific and unique tracking identifier by the AP/delegate. The data should then be entered in the Central Records system (see Chapter 4).

The reporter should be contacted in cases where additional information or clarification may be needed by the AP for the assessing of the AER.

For completeness, an FBO's AER recording system should also include the recording of any AERs of their products that are brought to their attention through channels such as direct contact from or by way of print media, social media etc.



3.8 ASSESSING AERS

Within its general AE-handling procedure, the FBO should ensure that all product AEs are specifically assessed by the AP/delegate for potential health-related impact. If the report includes a manufacturing/quality issue it should be forwarded to the Quality department for further investigation as required under Good Manufacturing Practices (GMP)

3.9 CLASSIFYING AERS

Each AER should be classified as either a serious or a non-serious adverse event complaint by the AP/delegate, as per the applicable definitions for AE/SAE (see Chapter 1).

3.10 EXTERNAL REPORTING REQUIREMENTS

It is important to be aware of any national legislative requirements with regards to the mandatory reporting of AEs or SAEs. This is to ensure that the reporting of the required information can be submitted within the specified time frame required. Attention should be paid to the report format and conditions under which such reporting is required, as the perceived authenticity or causality of an AE or SAE may or may not affect the obligation to report the AER (for example, depending on the requirements of the national competent authority, an AE that is internally determined to be fraudulent may still need to be reported).



Chapter Four

The AER Central Records System

4.1 GENERAL OVERVIEW

The FBO should maintain a Central Records system of all AERs received. This may consist of a paper filing system or an electronic database system, e.g. Excel, or dedicated software. The Central Records system should be located at the site where the AP/ delegate is based or be easily accessible if the Central Records system is stored electronically.

4.2 OPERATING A CENTRAL RECORDS SYSTEM

Each individual AER record should be entered in the Central Records system by the AP/ delegate. The entry should include the AER's specific tracking identifier and date of receipt, together with the name of the person who added the entry to track the system. All information obtained should be included in the record. This information is important, particularly if further similar complaints are received.

If information is missing, the AP/ delegate should re-contact the consumer or the consumer's representative in a timely manner. Ideally a specified timeframe should be included in the FBO's procedure to obtain the necessary information and any relevant documentation. The AP/ delegate should also work within any timeframe for reporting requirements required by the national competent authority.

The following data, when available, should be added to the record:

- The completed AER Questionnaire
- Medical records or other objective data and assessments collected from the consumer, his or her representative, physician or other healthcare professional
- All communications received from the consumer or on his or her behalf (letters, emails, phone communications etc.), together with, where relevant, any correspondence with any local authorities
- Actions taken by the FBO with dates and persons involved, including formal responses to the consumer and/or his or her representative
- Information on any assessment and determined causality of the AE, where applicable.
- Information on any action taken related product quality reports, withdrawals or recalls or reporting



If sufficient information is obtained for the AP/delegate to complete the Record, this should be clearly stated on the record and filed as complete. If insufficient information is received and there are no replies to at least two reminder requests for further information, the record can be closed.

GDPR: FBOs must take account of the **General Data Protection Regulation (EU) 2016/679** (GDPR) on data protection and privacy in the European Union (EU) and the European Economic Area (EEA) and the transfer of personal data outside the EU and EEA. As regards records containing personal information, Data Protection legislation must be considered when collecting, sharing and storing these data and strict confidentiality of personal information should always be maintained in the central records system. Access to such personal information should be strictly limited to those who need it to handle the AERs. (Where possible, Questionnaires and records can be anonymised by using initials rather than the full name of the consumer.)

4.3 FUNCTION OF AN AER CENTRAL RECORD SYSTEM

Central Record systems for AERs should act as a safety and surveillance tool to monitor and identify any trends, increase in known and expected AEs or occurrence of new and unexpected AEs associated with a specific product or ingredient or combination of ingredients. It is important, therefore, to use standardised nomenclature, e.g. MedDRA (Medical Dictionary for Regulatory Activities), within the central records system to classify the AE type, severity, region or market affected and suspect products or ingredients.

Care should be taken within the Central Records System to avoid duplication of AER records and to ensure that all AER records are filed correctly, particularly once the record has been finalised.



4.4 RETENTION OF AER RECORDS

Retention of AER records must comply with any relevant national legislation. In the absence of such legislation, it is recommended that complete AER records be retained for **at least 6 years** following the date of receipt and thereafter, a summary for historic purposes

4.5 REVIEWING AERS

The AP/delegate should remain alert to any significant change in the frequency of AERs associated with a particular product, ingredient or blend of ingredients. The AP/ delegate should also be alert to any significant increase in frequency of any particular type of AER associated with various products within a product range, including other products in the range which may have similar ingredients.

4.6 FREQUENCY PATTERNS AND ACTION TO BE TAKEN

If patterns appear to emerge based on frequency, then the AP/delegate should initiate an immediate investigation into potential causes for the change in reporting frequency.

4.7 EXTERNAL ADVICE

If the AP/delegate is not medically qualified, it is recommended where appropriate and feasible that the FBO has access to a medically qualified person on an 'as needed' basis. This can be particularly helpful when, for example, a medical opinion on the cause of symptoms may be helpful and to determine if it could be related to product use or when a consumer's physician needs to be contacted. Similarly, there may be occasions when the FBO needs to seek external advice on drug epidemiology or safety from a pharmacologically qualified person. Access to such specially qualified persons is not compulsory but is recommended for cases where investigation of the AER requires specific knowledge outside the scope of the AP/delegate or other relevant FBO employees.

4.8 SCHEDULING REGULAR REVIEWS

The FBO's AER management system should include a schedule requiring the AP/delegate to regularly review the data in the Central Records system for any trends or frequent re-occurrences of AERs to a particular product or ingredient – regularity of review as defined in the schedule by the AP. For example, line graphs (whether hand-produced from hard copy data or produced electronically from computer databases) are a useful tool, if not the starting point, for observing trends in AERs. It is recommended that regular monitoring for trends is carried out, and that quarterly or annual trend reports are generated by comparing trend data at least over the past year/previous year.



4.9 REVIEW AND ANALYSIS OF THE AER DATA

May provide an indication of:

- The increased rate of occurrence or severity for a specific type of event or the more frequent correlation of an event to the use of a specific product or ingredient(s)
- The possibility of new food supplement/ food supplement, food supplement/food interaction (assuming appropriate questions have been asked about the consumer's diet), or food supplement/ medication interactions;
- Consumer confusion over a product's name, labelling, packaging or intended use and dosage;
- A need for revisions to directions for use instructions, contraindications or product label warnings, or the intended users.

Trends identified from reviewing the data should be used to:

- Facilitate adverse event (AE) resolution and support the response
- Potentially initiate label changes and other product information changes if necessary and/or initiate change to product formulation.
- Prompt other risk management activities, such as corrective and preventive actions, withdrawals and recalls
- Enhance safety surveillance within the FBO.
- Provide valuable safety information to address national and EU safety concerns about ingredients.



4.10 THE REVIEW RESULTS

The AP/delegate should communicate the results of the review or any trends detected internally within the FBO, for information or potentially for further action. In addition, the AP/delegate should have at all times good communication with the quality and technical personnel, as some AERs may be indicators of a product quality or technical issue. Senior management within the company should periodically review the AERs and related assessments and/or trends, together with the agreed corrective and preventive actions.

Any untoward review results or trends should be communicated by the AP/delegate in a timely manner within the FBO, and to other relevant parties in the supply chain such as Contract Manufacturers and/or Distributors – they may have additional data or information that could be relevant to the review.



Chapter Five

AER Causality Assessment

5.1 DEFINITION

AER Causality Assessment is the evaluation of the likelihood of whether a causal relationship exists between an AER and the use of a product.

5.2 MANAGEMENT OF CAUSALITY ASSESSMENTS

National regulations related to the monitoring of AERs generally do not require FBO-initiated causality assessments. However, FBOs typically will carry out a causality assessment in order to meet the expectation of the complainant or other purposes, such as evaluating a product liability claim or in communications with government authorities (including investigative requests) who may, in turn, base their actions on a causality assessment.

5.3 PROCEDURE FOR AN FBO AER CAUSALITY ASSESSMENT

If an FBO decides to instigate a causality assessment it should be on a case-by-case basis, and in relation to a specific individual and an identified product, for those AERs for which sufficient relevant information has been obtained. If insufficient information is available after reasonable follow-ups of the AERs, then causality cannot be assessed.

When a causality assessment is performed, the AP/delegate should consider the fact that additional information obtained at a later date could alter the results of an initial assessment. In the event that additional information is received, any effect on the causality assessment should be considered.

5.4 ASSESSMENT CRITERIA FOR CAUSALITY ASSESSMENT

Criteria to be considered in a causality assessment system include:

- the time sequence of events,
- the likelihood or exclusion of other causes,
- the claimed symptoms, the plausibility of the claimed symptoms and, where necessary and feasible, a medical investigation and/or a controlled re-intake of the product

A causality assessment system generally classifies the likelihood of causality, using terms such as unclassifiable, unlikely, possible, likely, very likely, certain. Different causality assessment systems are available for other industries, and these could potentially be adapted by the FBO to suit its particular products.

5.5 PRODUCT WITHDRAWAL OR RECALL

The AP/delegate and relevant personnel should have a clear understanding of when the procedure for product withdrawal or recall should be initiated if a product safety concern is highlighted by a review of the AERs

The decision to initiate a product withdrawal or recall is usually a company decision, but FBOs must at all times adhere to any national legislation related to necessary product withdrawals/recalls and any other safety legislation and applicable guidance that may be in place.

In the event of a major concern with a particular ingredient source, wider notification of the problem to other supplement companies and local or national authorities, (who may in turn decide to contact other supplement companies), may have to be considered.

5.6 PERIODIC REVIEW OF AERS

As part of the FBO's policy for the proper management of adverse event reports, the AP should institute a periodic review (e.g. every one, two or three years), of the AER data by post-marketing and clinical experience, if any, as well as bibliography. Any relevant safety data from any subsequent clinical studies carried out by the FBO should be included. The periodic review should also include sales data for that period in order to normalise the data and enable a better comparison of the frequency of the AE data.



ANNEX I



Food Supplements Adverse Event Report Form

For an AER form to be considered valid the following information should be completed:

- the basic nature of the AE, including symptoms/injury/illness
- the product name
- the batch/lot number (if available)
- the name of the consumer and his or her representative (if applicable)
- relevant contact telephone numbers and/or email addresses

INTRO

Unique Reference Number

Name of Employee completing the form

INITIAL REPORTER

Name of Reporter, if different from affected person *(Initials only)*

Qualification of Reporter
(e.g. physician, pharmacist)

How was it reported?

Letter

Email

Telephone

Other *(Please specify)*

Date reported *(DD/MM/YYYY)*

Is this a follow up?

No

Yes

If yes, date received *(DD/MM/YYYY)*

Outline discussion / Outcome of followup call

USER / AFFECTED PERSON DETAILS

Initials

Sex

F M

Age / DOB (DD/MM/YYYY)

Height

Weight

Location where the adverse event occurred (Country of incidence)

Concurrent conditions

Pregnancy
(Please specify the week)

Breastfeeding

Other
(Please specify)

Is there any existing food allergy/intolerance or contact allergy?

No Yes (Please list)

Former food intolerance known?

No Yes (Please list)

SUSPECTED FOOD SUPPLEMENT PRODUCT

Product name

Packaging size

Dose/Intake

Lot number

Best before date (DD/MM/YYYY)

Has the product been returned?

No Yes

Has the product been verified by a quality investigation?

No Yes

CONDITION OF USE / SUSPECTED EVENT

Outline the reaction

Nature of event <i>(e.g. overdose, reported lack of efficacy, misuse)</i>	When started taking the product? <i>(DD/MM/YYYY)</i>	Number of intakes <i>(Total per day/week)</i>	When did the reaction start? <i>(DD/MM/YYYY)</i>

Was the product used for the first time?

Yes

No

Was the product used before without occurrence of the described intolerance event?

Yes

No

How long after the first use of the product did the reaction occur?	What part of the body was affected?	When stopped using the product? <i>(DD/MM/YYYY)</i>

Did the adverse reaction stop when the product was stopped?

No

Yes

How soon after stopping the product did the reaction stop?

Was use of the stopped product re-started?

No

Yes

For how long?

Did the symptoms reoccur?

Yes

No

OTHER CIRCUMSTANCES

Has medical advice been received?

- No Yes

What was the medical diagnosis?

Has the affected person received medical treatment for the reported event?

- No Yes

Does the affected person have any medical condition/disease?

- No Yes (*Please list*)

Any other medication being taken?

- No Yes (*Please list*)

Frequency

Any other food supplement being taken in addition to the suspected product?

- No Yes (*Please list*)

Product

Intake

Frequency

Has the affected person experienced any recent change in daily nutrition?

No

Yes *(Please list)*

What is the average daily alcohol consumption of the affected person?

Does the affected person have any history of drug abuse?

No Yes

What is the average coffee consumption of the affected person?

Does the affected person smoke tobacco, if so how many a day?

DATE PASSED FOR INTERNAL EVALUATION

The Accountable Person (AP) to assess if Serious / Non-Serious (DD/MM/YYYY)

Report to National Authority if required (DD/MM/YYYY)



About the EHPM

The European Federation of Associations of Health Product Manufacturers (EHPM) was created in 1975. With its 15 National Associations and its Member Companies, EHPM represents product manufacturers and distributors, the majority of whom are small and medium-sized enterprises (SMEs), in 17 European countries.

EHPM proactively cooperates with the European Institutions and stakeholders to strengthen the overarching strategy for a healthier Europe enshrined in the Farm to Fork and the European Green Deal.

