

IFRA Consortium Formation Protocol

Aim of the Document

The aim of this document is to set out the basic principles of Consortium formation, management and operation for Consortia with IFRA involvement, as have been approved by the Board after consultation with the Executive Technical Committee (ETC).

Ingredient Defense Group (IDG)

IFRA Board will nominate an Ingredient Defense Group (IDG) responsible for the activation, support and oversight of potential Consortia. The IDG will be composed of IFRA staff members involved in ingredient defense, [the Chair of the CMR Working Group] and representatives of IFRA members (direct members and members of the European national associations).

Creation of Ingredient Defense Consortium (IDC)

When an ingredient issue requires specific work such as the preparation of a risk assessment or a complete safety dossier for submission to the EU Commission or other regulatory body, an Ingredient Defense Consortium (IDC) can be created.

The basic rules and criteria for the formation of an IDC are specified in Annex I.

Role of the IDG

The role of the IDG will include ensuring that the criteria for the formation of IDC are fulfilled, calling for the formation of such IDC, handling horizontal issue relating to IDC, providing the necessary support to IDC, liaising with IFRA legal Counsel when needed in connection with the formation or management of the IDC.

Pre-Consortium Phase

The formation of an IDC will consist in the following Pre-Consortium steps:

- Through the IFRA monitoring system (including CMR WG), or members' notification, the IDG is identifying and assessing issues which would require the formation of a Consortium. An announcement will be made by IFRA of the proposal to form an IDC to all parties that could have an interest to join through the following means: e-mail to IFRA membership and IFRA partner organizations such as customers, suppliers and other sector groups, notification in IFRA public website. The call for participation in the Consortium will be open for a certain number of weeks;
- The issue will be discussed and evaluated by the IDG to verify whether the criteria for the formation of an IDC are fulfilled. If so, IFRA will start with the organization of a dedicated IDC and nominate a Consortium Manager who will work on the formation of the Consortium and start its activities.

Consortium Agreement

A template Consortium Agreement will be drafted by IFRA. The template Agreement can be adjusted to match the specificity of each IDC but subject to any competition or other legal constraints. The Consortium Agreement will need to be signed by all the parties that intend to be part of the Consortium.

Entry fee

A total entry fee will be set up to be shared between all the companies willing to be part of the Consortium, including IFRA members.

Budget

The cost will depend on the specificities of the case and the gaps to be addressed, but will be determined based on objective criteria. From experience based on previous work, the budget (not including the costs of additional specific studies) could be in the range of 50000 Euros.

IFRA commitment on project management and initial activities

IFRA is prepared to manage Consortia in an efficient and cost-effective way. This involves the following activities to initiate Consortia formation:

- Create a SharePoint page for the Consortium members;
- Prepare a Consortium agreement to be signed by all Consortium participants;
- Create a system to secure the confidentiality of all the documents shared in the Consortium and prevent disclosure of confidential business information.

Cost Sharing

The rule of the cost sharing would be equal sharing, unless decided differently by the Consortium members, based on objective and non-discriminatory criteria. Any cost sharing mechanisms agreed between the Consortium members should be objective and subject to compliance with principles of competition law.

Membership

Membership of the Consortium should be based on objective criteria, and open to both IFRA and non- IFRA members. Membership should remain open for the life of the Consortium, provided a fair contribution to accumulated costs is made. Any decision to exclude a company from joining the Consortium needs to be objectively justified. There is no obligation for companies to join a Consortium.

Competition Law

Members of the Consortium are provided with detailed information concerning competition law rules before the Consortium starts to work. A reminder of competition law rules is provided at the beginning of each meeting (face-to-face and conference call). All exchanges of data are performed in compliance with competition law rules.

Group Leader

The members of the Consortium need to nominate a Group Leader between them. The position of Group Leader is best fulfilled by either the Lead Registrant, or the company that has registered the substance under REACH.

Activities

The activities in Table 1 will need to be performed respectively.



Table 1

	TASKS	BY WHOM?		
		CONSORTIUM MEMBERS	IFRA	TECHNICAL/LEGAL CONSULTANT
	Communication with IFRA membership on Consortium formation		X	
Preparatory work and Consortium formation	Make announcement that IFRA creates a Consortium (email and website)		X	
	Organize a call for participation in the Consortium		X	
	Draft template Consortium agreement			IFRA Legal Counsel
	Negotiate the formation of the Consortium			X
Consortium management	Maintain Roles and Responsibilities of Group Leader & other members	(X) (Group Leader)	X (?)	X
	Maintain Membership and Agreement records		X (?)	X
	Administer Finances, invoices, membership fees			X
	Organize Platform for Communication and Record Keeping (SharePoint page)		X	
	Maintain Platform for Communication and Record Keeping		X	
	Meeting minutes			X
	Meeting Rooms	(X) As decided by the members	X	X
	Monitoring of progress & deadlines	X (Group Leader)	(X)	(X)
Operations	Data summarization			X
	Preparation of dossier for defense			X
	Submission of dossier to EU authorities		X	

ANNEX 1 IFRA Consortium criteria and rules

IFRA is empowered by the Board to get actively involved in and/or remain involved in a defense ingredient Consortium as long as the following criteria are fulfilled:

- ✓ The ingredient defense has a significant benefit for the IFRA membership, thus justifying IFRA involvement.
 - ✓ The Consortia formation is always triggered by Regulation;
 - ✓ The Consortia formation needs to fulfil all relevant requirements in its creation and functioning to ensure full compliance with antitrust laws;
 - ✓ The concept is aligned with Cosmetic Europe;
 - ✓ The Consortium comprises at least 3 IFRA members (Regular or members of national and regional associations);
 - ✓ The Consortium is self-financed.
- The Consortium agrees that:
 - any scientific dossier is prepared using templates which are acceptable to respective authorities;
 - such dossier is submitted to the EU agency or scientific bodies by IFRA on behalf of the Consortium Members;
 - IFRA is the main contact to the authorities on all issues relating to this dossier, unless decided otherwise by the Consortium, and that the negotiation of appropriate risk management measures with the EU authorities (based on the dossier and ensuing SCCS opinion) is carried out by IFRA or by the person designed by the Consortium on behalf of the Consortium Members.
 - The Consortium members agree the following:
 - (i) to participate in a deposit fund at the onset to cover Consortium expenses to avoid any financial burden on IFRA budget;
 - (ii) to contribute financially to the administrative overhead costs incurred by IFRA to ensure Consortium daily management;
 - (iii) to follow the rules of the Consortium agreement.

The information generated or acquired by a Consortium is owned by the Consortium members and is in principle not accessible for non-Consortium members.