



**University of  
Sunderland**

Dodou, Kalliopi (2020) UK and Worldwide Regulation for the Manufacture and Marketing of Cosmetic, Personal care and Fragrance products. [Teaching Resource]

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## Module Descriptor

Module Summary Information	
<b>A</b>	<b>Module Title</b> EU and Worldwide Regulation for the Manufacture and Marketing of Cosmetic, Personal care and Fragrance products
<b>B</b>	<b>Module Code:</b> CSCM01
<b>C</b>	<b>Credits:</b> 30 credits
<b>D</b>	<b>Level:</b> 7
<b>E</b>	<b>Pre-Requisites:</b> None
<b>F</b>	<b>Co-Requisites:</b> None
<b>G</b>	<b>Faculty:</b> Health Sciences and Wellbeing
<b>H</b>	<b>Module Leader:</b> Dr Kalliopi Dodou
<b>I</b>	<b>Other Teaching Staff:</b> tbc
<b>J</b>	<b>HECoS Code:</b>

<b>K</b>	<b>Content Synopsis- Web version</b>
	<p>Develop a critical understanding of the legal framework and regulatory bodies for advertising cosmetic products and perfumes and how these regulations differ among countries. Gain critical understanding of the updated regulations in relation to animal studies and alternative testing methods. Develop evaluative skills on how advertising claims are supported by the appropriate claim substantiation testing of products based on the statistical analysis of consumer and scientific data. Gain expertise and initiative to devise a process for the design of a cosmetic product taking into consideration specific regulatory requirements and dilemmas (e.g. organic, preservative-free, borderline products)</p>
<b>L</b>	<b>Module Content</b>
	<p>EU and Worldwide regulations will be explained in depth to allow a comparison and contrast of the key aspects of the legislation in each region on aspects like definitions of a cosmetic product (for example some EU cosmetics are over-the-counter (OTC) medicines in the US), labelling requirements, registration needs, restricted lists, etc.</p> <p>The regions that will be covered are:</p> <ol style="list-style-type: none"> <li>1. EU</li> <li>2. Canada</li> <li>3. United States</li> <li>4. Mercosur &amp; Andean</li> <li>5. Australia &amp; New Zealand</li> <li>6. China</li> <li>7. ASEAN</li> </ol> <p>For each region of the world, the learning outcomes will be developed through a detailed explanation of the following evolving module themes:</p>

	<p><b>Key Laws and Authorities/Enforcement Bodies</b> You will gain understanding of the authorities, frameworks, processes and protocols in each world region that regulate the manufacture and marketing of cosmetic, personal care and fragrance products.</p> <p><b>Regulatory Overview</b> You will gain insight in the working of the cosmetics industry, how it is organised and regulated, and in the structure of applicable regulations. You will be able to differentiate cosmetic products from other types, with special focus on borderline products and their marketing dilemmas. You will also gain understanding of the regulations that determine the restriction of ingredients.</p> <p><b>Documentation Requirements</b> You will gain knowledge and demonstrate professional skills in the compilation of documents such as Product Dossiers eg Product Information File (PIF) and Safety Assessments eg Cosmetic Product Safety Report (CPSR). You will also demonstrate critical understanding of the registration needs for cosmetic products and how regulations apply and are enforced throughout a product's life cycle.</p> <p><b>Packaging &amp; Labelling</b> You will gain understanding of the labelling requirements for cosmetic, personal care and fragrance products, how advertising claims are created, and what claim substantiation is needed in each region. The importance of product marketing using accurate claims will be highlighted. You will become competent in the design of claim substantiation studies within existing legal frameworks and also in the critical evaluation of product claims based on consumer and scientific data that underpin the claim.</p> <p><b>Enforcement Policies</b> You will gain understanding of the regulatory enforcement institutions and policies in each region via real-world examples on the implementation of the procedures and documentation required by the industrial sector. You will gain up-to-date knowledge of the current toxicological testing methods which have been developed as an alternative to animal testing. These will be accompanied by an overview of the updated regulations on animal studies.</p> <p><b>Transferrable skills:</b></p> <ul style="list-style-type: none"> <li>• Team working</li> <li>• Communication skills (verbal and written)</li> <li>• Compilation of industry-quality product documents and dossiers</li> </ul>
<b>M</b>	<b>Module Learning Outcomes</b>
	By the end of this module successful students will be able to do the following:
<b>1</b>	Display mastery of the legal framework and regulatory bodies for advertising cosmetic products and perfumes and how these regulations differ among countries
<b>2</b>	Display mastery of the updated regulations in relation to animal studies and alternative testing methods.
<b>3</b>	Demonstrate expertise on how advertising claims are supported by the appropriate claim substantiation testing of products based on the statistical analysis of consumer and scientific data
<b>4</b>	Demonstrate expertise and initiative to devise a process for the design of a cosmetic product taking into consideration specific regulatory requirements and dilemmas (e.g. organic, preservative-free, borderline products)

N Teaching and Learning Methods																															
	<table border="1"> <thead> <tr> <th>Scheduled Activities</th> <th>Hours</th> </tr> </thead> <tbody> <tr> <td><i>Lectures</i></td> <td>18</td> </tr> <tr> <td><i>Seminars – feed to Assessment 1</i></td> <td>12</td> </tr> <tr> <td><i>Workshops (looking at products and claims and deciding whether this makes them cosmetics or other products in certain regions, what substantiation would be needed in each region etc) – formative assessment</i></td> <td>9</td> </tr> <tr> <td><i>PBL – feeds to assessment 2</i></td> <td>9</td> </tr> <tr> <td></td> <td></td> </tr> <tr> <td><b>Independent Study</b></td> <td></td> </tr> <tr> <td><i>Directed reading on lectures and workshops</i></td> <td>212</td> </tr> <tr> <td><i>Preparation for group PBL presentation</i></td> <td>20</td> </tr> <tr> <td><i>Compilation of dossiers</i></td> <td>20</td> </tr> <tr> <td></td> <td></td> </tr> <tr> <td><b>Placement</b></td> <td>-</td> </tr> <tr> <td></td> <td></td> </tr> <tr> <td></td> <td></td> </tr> <tr> <td><b>Total Hours</b></td> <td>300</td> </tr> </tbody> </table>	Scheduled Activities	Hours	<i>Lectures</i>	18	<i>Seminars – feed to Assessment 1</i>	12	<i>Workshops (looking at products and claims and deciding whether this makes them cosmetics or other products in certain regions, what substantiation would be needed in each region etc) – formative assessment</i>	9	<i>PBL – feeds to assessment 2</i>	9			<b>Independent Study</b>		<i>Directed reading on lectures and workshops</i>	212	<i>Preparation for group PBL presentation</i>	20	<i>Compilation of dossiers</i>	20			<b>Placement</b>	-					<b>Total Hours</b>	300
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O Assessment Methods
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#	Title	Exam Length or Word length	Central or Local Exam	%	Summary	Module Mark
1	Product Dossier	3000 word	-	60	Product Dossier on safety and claims to comply with country-specific requirements. Product Dossier will be compiled and submitted as a group report. Assesses learning outcomes 1, 2, 3. Word limit for guidance only.	*
2	Problem-based learning group presentation	30 min	-	40	Group ppt presentation on design of cosmetic products abiding to specific regulatory briefs such as organic certification etc will assess learning outcome 4.	*
Overall Mark				100		**
Are there Programme Specific regulations that are applicable to this module?						Yes/No
If Yes please give details:						
Are programme Specific regulations applicable on every programme that the module is delivered on						Yes/No

If No please give details:	
<a href="https://my.sunderland.ac.uk/display/AQH/Academic+Regulations">https://my.sunderland.ac.uk/display/AQH/Academic+Regulations</a>	

<b>P</b>	<b>Reading List</b>
1	Callaghan T. (2019) Help! I'm covered in adjectives!: cosmetic claims and the consumer.
2	Casanova, EM (2011) Making up the difference: women, beauty, and direct selling in Ecuador, 1st ed., Austin : University of Texas Press
3	Maibach HI., Merk HF, Elsner P. (1999) Cosmetics: controlled efficacy studies and regulation. Springer: Berlin, London.
4	Pacifici E, Bain S. (2018) An overview of FDA regulated products: from drugs and cosmetics to food and tobacco. Academic Press: London, England
5	Sahota A. (2014) Sustainability: how the cosmetics industry is greening up. Wiley

<b>Q</b>	<b>Programmes using the module as Core/Option:</b>
i	MSc Cosmetic Science (Core)
ii	
iii	

<b>R</b>	<b>Module Delivery</b>
i	<b>On-Campus Yes/No</b>
ii	<b>Off-Campus Yes/No</b>
iii	<b>Distance Learning Yes/No</b>
iv	<b>Apprenticeship Yes/No</b>
v	<b>Available for incoming Study Abroad students Yes/No</b>
vi	<b>Professional Accreditation: Yes/ No</b> <i>(If yes, by whom and what conditions if any are specific to the module?)</i>

### S. Version Control

Module Descriptors are checked annually and updated when changes are made to the Module.

<b>Version No</b>		<b>Date</b>	<b>Details of change</b>	<b>Author</b>
<b>V1</b>	<b>Document created</b>	19/06/2020	New module	Dr Kalliopi Dodou
<b>V2</b>	<b>Document changed</b>			