Index

Abbott, A. 131, 136, 168, 195
adverse drug reaction (ADR) 41, 49
reporting systems 54, 57, 67, 87, 91
reports 7, 53, 59, 82, 91, 98, 156
side-effects 5, 8, 12, 13, 16, 17, 37,
82, 83, 89, 91, 99, 107, 139, 142,
143, 148, 152, 153, 170, 183,
194, 195, 197, 203
signal of 12, 38, 43, 67, 73, 75, 77,
82, 85, 87, 95, 154, 180, 181
spontaneous notification 55, 56, 86,
87, 90, 91, 108, 173, 194, 207
Agence Française de Sécurité Sanitaire
des Produits de Santé (AFSSAPS)
83, 85
American Medical Association (AMA)
67
Bauman, Howard 114, 124–6, 131–2,
135
Bayer 84, 85, 94
Ben-David, J. 25
boundary-organisations 34
Bovine Spongiform Encephalopathy
(BSE) 39, 44, 45, 46, 47, 70, 73,
165, 166
Boyle, Robert 29, 32, 208
Braithwaite, J. and Drahos, P. 8, 20
Brunsson, N. 10, 18, 33
Cambrosio, A. 214
Carpenter, D. 17, 73
Cerivastatin 84–6, 92–8, 106, 153, 194,
196, 205; see also Lipobay
Chipping Campden 129
circulation
as defining experts 32
as professional mobility 29
between activities of control 33
between evaluation and standard-setting 33
invisibility of 11
measurement of 28
multi-professionalism and 169–71
of drug safety experts 78, 99, 102,
107
of HACCP experts 119, 137,
139–40
of PMM experts 159, 161
transnationalisation and 177–81
clinical pharmacology
as evaluative science 12, 37
as experimental science 48–50; see
also clinical trials
cow-word analysis of 57–8
dose-response assessment and 48,
57, 58
drug regulation in the USA and
66–7
efficacy 48–50, 54, 58, 66, 67, 211,
212
history of 74
pharmacovigilance and 53
statistics and 56
clinical trials; see also marketing
authorisation
as experiment 48–50
as tool of qualification 37
clinical pharmacology and 74
for functional or novel foods 143
generalisation of 41
limits of 53–9, 77, 90, 98
safety data from 14, 102, 106
Codex Alimentarius (Codex)
as receptacle of expert work
125–30
as standard setting organisation 33
as WTO reference body 75
Codex Committee on Food Hygiene
128, 129
Codex principles for risk analysis
and EU food law 70
consensus on HACCP and 134–40
International guideline for HACCP 14, 112–22
members of ICMSF and 132
risk assessment and 69
setting of critical control points and 129–30
Committee for Proprietary Medicinal Products (CPMP) 41, 73, 88, 178; see also Committee for Human Medicinal Products (CHMP)
Committee for the Safety of Drugs (CSD) 67
Conference for the International Organization of Medical Sciences (CIOMS) 98, 101, 102–5, 108–9, 167, 177, 178, 181–3, 186–7, 193, 207; see also International Conference on Harmonisation (ICH)
consensus
consensus conferences 15, 169
consensus, manufacturing of 11, 34, 134, 135, 137, 187
conventional foods 144, 145, 151, 212
Council of Ministers of the European Union 46
co-word analysis 57, 61, 63, 213, 214
Crane, D. 29–31, 34
Crestor 153
Daemmrich, A. 73
development safety update report (DSUR) 102
Directorate General XXIV 74; see also Directorate General for Health and Consumer Protection
Directorate General for Health and Consumer Protection (DG SANCO) 45, 70, 161; see also DG XXIV
Djelic, M.-L. and Sahlin-Andersson K. (eds.) 9
drug safety
CIOMS and ICH 178, 182, 183
clinical pharmacology and 53
clinical trials and 56–9
drug safety and PVP 78–83
drug safety experts 14, 86, 89, 92–4, 98, 99, 102, 107–9, 173, 193, 196–7, 201, 202, 205
scientists’ conception of 66
Drug Safety Research Unit (DSRU) 86
drug withdrawal
as result of pharmacovigilance activities 72
Cerivastatin 84–6, 88; see also Lipobay
periodic safety update report and 196
PVP and avoidance of 12
risk management and 94–7
series of 77–8
worldwide withdrawals of Vioxx and Lipobay 43
due diligence 123, 138
European Commission
as international policy-making organisation 33
CIOMS and 182
European Medicines Evaluation Agency and 67
HACCP and 113, 118–22, 128, 137, 143
New Approach 118, 119, 128
Novel foods and 146, 147, 150, 153, 155, 161, 165
Elixir Sulfanilamide 39, 91
European Medicines Evaluation Agency (EMEA); see also regulatory agencies
creation of 41
Gabriel and meetings at 177
globalisation of pharmaceutical regulation and 209
marketing authorisation decisions 195
pharmacovigilance missions 43
risk management guidelines 78, 80, 83, 84, 193, 195
risk management strategy 95–6
Environmental Protection Agency (EPA) 16, 64
European Medicines Agency (EMA); see European Medicines Evaluation Agency (EMEA)
epidemiology
combination with toxicology 64
detection of regularities 54
epidemiological surveillance 7, 47, 69, 72, 209
epidemio-surveillance 12
imputation and 62
pharmacoepidemiology and 196
post-marketing surveillance and 68
safety specification and 80
epistemic community 11, 19–21, 24–6, 28, 35–6, 189
EudraVigilance 96
European Federation of Pharmaceutical Industries and Associations (EFPIA) 102, 178
European food law 43–7, 64, 70, 119, 121, 128, 144
European Food Safety Authority (EFSA); see also regulatory agencies
coordination of surveillance plans 60
creation of 47
data collection mission 47
International Life Science Institute and 161, 206
members of EFSA panels 159, 160, 178
production of risk assessment opinions 47
recommendation on post-market monitoring studies 150
European official guidelines on pharmacovigilance for medicinal products for human use (the ‘Volume 9’) 80
European Parliament 45, 46, 47, 73, 74, 94, 146, 165
evaluation
as science 12, 15, 32, 35, 37, 38, 48, 169, 173, 183
regulation 196, 208
standard-setting and 11, 99, 108
Evans, Stephen 86, 87, 88, 89, 90, 93, 98, 99; see also Waller, Patrick
Expert; see also scientists
coopptation 76, 125, 135, 174, 183
hybridisation of expertise 197
industry advice 33, 132, 139, 187
label of expert 171, 188
prestige 20
quasi-regulators 107, 108, 188
recruitment 131, 134, 135, 158, 182
scientific advice 4, 36, 44, 45, 73, 167, 168, 174, 175, 180, 189
occupationalisation of 174
transnationalisation of experts’ career 177, 181, 188

Federal Food Drug and Cosmetic Act 39
Fischer, F. 206
Food and Agricultural Organization (FAO) 70, 113, 131, 132, 135, 151, 159, 178
Food and Chemical Toxicology (FCT) 142, 143, 147, 149, 155
Food and Drug Administration (FDA) 39, 40, 64, 66, 67, 68, 73, 74, 86, 89, 93, 110, 113, 125, 131, 150
food hygiene
as research area 169, 171
Codex Committee on Food Hygiene 128, 129
consultants 130
criteria 113
dead of chain control 112–14
European Directives 118
food microbiologists and 131
food microbiology and 52, 62
fragmentation of 14
large businesses and 199
liberalisation 198
local regimes 123
performance-based 139
promotion of industrial food hygiene 125
regulation of 1, 12, 201, 202
food microbiology
co-word analysis of 63–4
elite of 131, 134, 169, 170, 173, 189, 202
food regulation and 202
industry support 64, 176
journals of 126
limits of 65
microbiology and 52
Scientists and the regulation of risk

professional jurisdiction of 131
reorientation of 130
food safety; see also risk assessment
food additives 2, 5, 46, 50–51, 60, 61, 62, 68, 69, 74, 147, 151, 159, 162, 176
food surveillance 12, 60, 65
food zoonoses 47
food-borne diseases 39, 136
White Paper on Food Safety 45
functional foods 46, 144–7, 150, 152, 156, 158, 159, 162, 163, 212
functional efficacy 144, 148
Funtowicz, S. and Ravetz, J. 2

Gabriel 99, 102–9, 172, 177, 178, 181, 182, 183, 190, 193, 194, 196
General Agreement on Tariff and Trade (GATT) 70
General Food Law 46, 47, 64, 70, 119, 144; see also European food law;
European Food Safety Authority (EFSA)
global knowledge network 19, 23; see also network concept
Gold, Harry 56, 74
guidance
as source 213
for HACCP 113, 114, 116, 125, 126, 128, 131
for PMM 142, 149, 156, 163, 164, 203
for PVP 83
generic guidance 120
inducement of change in industry 103
normative pyramid 150
risk management 99
soft law 18

Haas, P. 20–21, 24–26
Hazard Analysis Critical Control Point (HACCP)
audit and 120, 121
critical control points (CCP) 112, 115, 125, 131, 134–8
critical control points, determination of 127–8
critical failure areas concept and 124
decision-tree 75, 118, 126, 127, 129, 134
developing countries and 136, 209
HACCP-like approaches and systems 112, 113, 123, 139, 140
hazard analysis 115, 122, 123, 127, 136, 149
ISO and 116, 128, 138
local vs. central establishment of critical control points 121–3, 130
logic sequence 116, 117, 129, 134
manuals 35
negotiation of critical control points 123, 139
philosophy 121, 127
policy panacea 115
principles 112
quality assurance 120, 122, 130, 131, 132, 172, 180, 187, 201, 213
regulatory concept 12, 13, 14, 15
reliability 124, 199
risk analysis 199
systems thinking 124, 199
total quality management and 128
translation 136
Heads of Agencies (HOA) 73, 95, 96, 107, 110
Heads of Medicines Agencies (HMA): see heads of agencies (HOA)
Hill, Bradford 56
imputation, research programme of 12, 17, 37–8, 46–7, 52, 55–6, 60, 63–4, 71–2, 76, 202, 213; see also evaluation
Inman, William 56, 67, 86
inspectors
as actors of regulatory intervention 213
as consultants and auditors 121
as regulatory intermediaries 130
complexity of the role of 198, 199
food microbiologists and veterinarians as 202
HACCP plans and external inspectors 113, 120
National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and 126
negotiation with 123, 139
self-control and 119
sharing of information with 9
surveillance of food contaminations 7
training of food inspectors 125
interest groups 24
International Commission for the Microbiological Safety of Food (ICMSF) 69, 76, 125–9, 130, 131–5, 137, 139, 176, 177, 178, 181, 183, 186, 198, 201, 207
International Conference of Harmonisation (ICH) 33, 77, 78, 79, 81, 83, 84, 88, 97–9, 101–5, 107–10, 167, 177, 178, 181, 193, 209; see also Council for the International Organization of the Medical Sciences (CIOMS)
interstitial organisations 15, 34, 169, 181–6, 188, 189, 207, 208
invisible college as club 183, 189
benefits of using the notion of 11, 19, 31–4
big players and 139
embeddedness in regulation 103–4
frontiers 161–3, 204
HACCP principles and 114
history of the 29
junction between evaluation and standard-setting 11, 99, 108; see also evaluation
manufacturing of consensus 134
occupational diversity in 172
PMM experts as 159
scientometrics and 29–30
Jasanoff, S. 2, 171
Jean-Claude 132, 176–8, 186–8, 199
John 158, 161, 163, 178, 187
Joint Expert Committee for Food Additives (JECFA) 68, 69, 70, 178
Kefauver, Senator Carey Estes 40
Keohane, R. 21, 25

Knorr-Cetina, K. 26, 27, 27
Koch, Robert 52
Lachance, Paul 124
Lezaun, J. 7
liability 17, 43, 56
life-style medicines 86, 95
Lipobay 43, 97, 110, 153; see also cerivastatin; drug withdrawal
marketing authorisation as a type of control 47
European Union procedures for 40–43
for food products 46, 68
for novel foods 149, 150, 152
of me-too drugs 86
phytosterol esters 153
positive list and 68
pre-marketing tests 13, 56, 145, 147, 195
revision of 87, 98
submission of risk management plan and 81
Marks, H. 48, 66, 71, 73
medicines agencies blaming of 94
Medicines and Health products Regulatory Agency (MHRA) 73, 76; see also Medicines Control Agency (MCA)
Medicines Control Product Agency (MCA) 73, 86, 88, 89, 101, 107, 110, 167, 172, 177, 193, 206
organisation 82, 83, 156
Merck 96, 97
me-too medicine 5, 17, 84, 85, 86, 95
Meyer, J. 192
Michael 132, 140, 172, 176, 177, 178, 186, 199
microbiology as scientific discipline 176, 201
microbiological risk assessment 37, 65, 69, 199
Ministry of Agriculture, Food and Fisheries (MAFF) 151, 152
Modell, Walter 74
Mogoutov, Andrei 214
multi-professionalism: see scientists
Scientists and the regulation of risk

National Advisory Committee on Microbiological Criteria for Foods (NACMCF) 126, 129, 131, 132, 135
National Aeronautics and Space Administration (NASA) 112, 124, 131, 186, 198, 199
National Research Council (NRC) 3, 64, 70, 126, 166, 199
Nestlé 126, 129, 132, 145, 176

network concept
- embedded knowledge network 23
- global knowledge network 19, 23
- global public policy networks 22
- network of professionals 20, 21, 24
- transnational policy networks 22
- Nicolas 159, 161, 163, 175, 176, 187, 189
- non-governmental organisations 20, 161, 210

novel foods
- as regulatory domain 1
- European novel food regulation 146, 147, 150, 153, 165, 166
- experience of 15
- pre-market regulation and 46, 68
- post-market monitoring and 142, 158–66
- regulatory definition 144–52
- regulatory terminology 146
- research interest 156
- researchers in 169
- side-effects of 8, 13, 14

Olestra 154
Organisation for Economic Cooperation and Development (OECD) 159, 161, 178
Parmar, I. 23
Pasteur, Louis 52
Patrick 159, 161, 163, 176, 178, 190
Periodic Safety Update Report (PSUR) 98, 99, 102, 195, 196
pharmaceutical industry 41, 49, 67, 102, 179, 182, 207, 211

pharmacoepidemiology 57, 67, 69, 74, 86, 89, 91, 196
pharmacovigilance
- additional pharmacovigilance activities 80
- audit 82, 87, 96, 196
- centralised procedure and 40, 41
- definition of 17
- drug monitoring 57, 59, 73, 101
- French school of pharmacovigilance 43
- industrial pharmacovigilance 177, 194, 195, 197
- national pharmacovigilance systems 42, 43, 67, 90, 108
- pharmacovigilance responsible person 82, 102, 170, 172
- public health and 86–8, 92, 93, 97, 98, 99, 103, 107, 196
- regulatory philosophy 93
- safety databases 35, 64, 65, 75, 83, 90, 194
- terminology 102
- phase IV studies 43, 81
- phocomelia 42, 59, 90; see also adverse drug reaction
- phytosterol esters 152–5, 159, 163, 166
- Pillsbury 14, 112, 114, 124, 125, 126, 131, 139, 140, 186, 198, 199
- post-market monitoring (PMM)
- consumer targeting 155
- dose exposure 153
- exposure assessment guidance for 142–3
- International Life Science Institute (ILSI) and 158–63
- post-launch monitoring (PLM) and 152, 153, 154–5, 156, 157, 163
- post-marketing surveillance (PMS) and 156, 157
- reassurance 8, 148
- regulatory concept 12, 13, 14, 15, 150–57
- risk analysis principle 199–200
- risk assessment 143–9, 153, 157, 158
- scope 143, 148, 153, 164, 165, 202, 203
- policy enterprise 20, 24, 39
- Porter, T. 7, 18
<table>
<thead>
<tr>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>post-normal science 2</td>
</tr>
<tr>
<td>practolol 55, 91</td>
</tr>
<tr>
<td>Price, D. J. de S. 29–31, 34</td>
</tr>
<tr>
<td>Procter &amp; Gamble 154</td>
</tr>
<tr>
<td>Prodi, Romano 45</td>
</tr>
<tr>
<td>pharmaceutical risk management 83, 84, 96, 97, 194, 196</td>
</tr>
<tr>
<td>blame avoidance and 94, 96, 99, 106</td>
</tr>
<tr>
<td>FDA risk management 95–6</td>
</tr>
<tr>
<td>pharmacovigilance planning (PVP)</td>
</tr>
<tr>
<td>agencies’ reorganisation and 79, 82, 83</td>
</tr>
<tr>
<td>as research area 169</td>
</tr>
<tr>
<td>changes linked to the introduction of 79, 83</td>
</tr>
<tr>
<td>data requirements and 80</td>
</tr>
<tr>
<td>European Union guideline 81</td>
</tr>
<tr>
<td>ICH guideline 79, 80, 81</td>
</tr>
<tr>
<td>pre-/post-marketing division 82, 83</td>
</tr>
<tr>
<td>pharmaceutical companies’ reorganisation and 83, 191</td>
</tr>
<tr>
<td>pharmacovigilance specification 12, 78, 79, 81, 88–90, 92, 94, 99,</td>
</tr>
<tr>
<td>101, 109, 193, 194</td>
</tr>
<tr>
<td>public health and 196</td>
</tr>
<tr>
<td>regulatory concept 12, 14, 77–9, 89, 90</td>
</tr>
<tr>
<td>risk management and 97, 98, 167</td>
</tr>
<tr>
<td>risk management plans 78, 79, 81, 103, 194</td>
</tr>
<tr>
<td>risk minimisation 77, 78, 81, 95, 106, 183</td>
</tr>
<tr>
<td>risk reduction 196</td>
</tr>
<tr>
<td>safety specification 80, 124, 203</td>
</tr>
<tr>
<td>physicians</td>
</tr>
<tr>
<td>hospital physicians 172, 173</td>
</tr>
<tr>
<td>physicians and national pharmacovigilance systems 53–6</td>
</tr>
<tr>
<td>physicians and reporting of adverse drug reactions 67, 69, 77, 82,</td>
</tr>
<tr>
<td>156, 205</td>
</tr>
<tr>
<td>qualification, research programme of 12, 47–53; see also evaluation; imputation</td>
</tr>
<tr>
<td>Quorn 151, 152</td>
</tr>
<tr>
<td>Rank Hovis McDougall (RHM) 151</td>
</tr>
<tr>
<td>Red Book 64</td>
</tr>
<tr>
<td>regulatory agencies</td>
</tr>
<tr>
<td>agenciﬁcation 206</td>
</tr>
<tr>
<td>as nodal point of invisible colleges 205</td>
</tr>
<tr>
<td>as risk assessment agencies 6</td>
</tr>
<tr>
<td>circulation of scientists and 11</td>
</tr>
<tr>
<td>creation of the European Food Safety Authority 47</td>
</tr>
<tr>
<td>creation of the European Medicines Evaluation Agency 41</td>
</tr>
<tr>
<td>democratic record of regulatory agencies 209–10</td>
</tr>
<tr>
<td>sharing of information 9</td>
</tr>
<tr>
<td>regulatory authority 157, 181</td>
</tr>
<tr>
<td>regulatory concepts 1, 8, 10</td>
</tr>
<tr>
<td>as typifications 5–7</td>
</tr>
<tr>
<td>conceptual power 17; see also Carpenter, D.</td>
</tr>
<tr>
<td>impact of 191–204</td>
</tr>
<tr>
<td>regulatory concepts as objects of research 178, 179</td>
</tr>
<tr>
<td>regulatory concepts as standards 11, 35, 189</td>
</tr>
<tr>
<td>regulatory space 8, 29</td>
</tr>
<tr>
<td>risk 1–8, 16, 75</td>
</tr>
<tr>
<td>hazard 2, 46, 60, 63, 64, 65, 75</td>
</tr>
<tr>
<td>quantitative dose–response assessment 65</td>
</tr>
<tr>
<td>risk analysis as science 2, 3, 16, 17, 60, 64</td>
</tr>
<tr>
<td>risk analysis principle 45, 47, 70</td>
</tr>
<tr>
<td>risk assessment 2–6, 10, 12, 16, 17, 27, 45, 47, 61, 64–5, 70</td>
</tr>
<tr>
<td>risk assessment/risk management terminology 164</td>
</tr>
<tr>
<td>risk perception 3</td>
</tr>
<tr>
<td>risk regulation</td>
</tr>
<tr>
<td>approaches of 17</td>
</tr>
<tr>
<td>as set of activities of control 6–7</td>
</tr>
<tr>
<td>prioritising risks 3</td>
</tr>
<tr>
<td>regulatory failure 15, 84, 98, 192, 196, 197, 206, 207</td>
</tr>
<tr>
<td>regulatory rationalisation 212</td>
</tr>
<tr>
<td>risk regulation regimes 211</td>
</tr>
<tr>
<td>as systems of control 191, 193, 205, 206, 207</td>
</tr>
<tr>
<td>Royal Society of London for the improvement of natural knowledge 29, 36</td>
</tr>
</tbody>
</table>
Scientists and the regulation of risk

Royer, René-Jean 58, 93, 105, 173, 174, 183
Sanitary and Phytosanitary Measures (SPS) 70, 116, 129, 140
Santer, Jacques 73, 74, 165
Sauer, Fernand 73, 209
scientific committee for food (SCF) 76, 153, 154, 158, 159, 163, 178
scientific community, concepts of; see also epistemic community;
invisible college
community of thought 20
core-sets 26, 27
research networks 26
scientific communities 5, 23, 24, 25, 27
thought collectives 25
trans-epistemic arenas 26
scientific disciplines 20, 24, 32, 48
history of scientific disciplines 213
experiments
industry experiments 1, 13, 30, 33, 142, 150, 158, 192, 203, 205
scientific experiments 48, 50, 52, 54, 56, 58, 64, 66, 71, 72
scientists
accumulation of positions 143, 159, 171–2, 178, 180
disciplines and professionalisation of scientists 170, 171, 173, 174, 181
medical scientists 53, 99, 104, 105, 106, 107, 109, 163; see also drug safety scientists
multi-professionalism 11, 169, 191
physicians and 1, 7, 17, 33, 41, 42, 49
professional jurisdiction 168, 195, 196
professional rationalisation 175
professional trajectories of 31, 179
scientific elite 1, 11, 14, 19, 29, 32, 35, 39
social authority 11, 15, 20, 23, 27, 32, 34
training as physicians 172, 173
scientisation 10
rationalisation and 192, 204, 212
Scott, J. 5–7
Selznick, P. 8, 17
Slaughter, A.-M. 21
Society for Risk Analysis (SRA) 16
standardisation
as emergent action 204
boundaries of 158, 164
invisible colleges of 29–34
science-driven 10
standard-setting and 18
standard-setting organisations
as sites of scientists’ circulation 11, 176, 177
drug safety experts and 14, 99, 102, 109
International Life Science Institute (ILSI) as 161
New Approach and 119, 147
statins 17, 84, 85, 86, 92, 93, 98, 153, 195
Stockholm Centre for Organizational Research (SCORE) 10
Stone, D. 23, 28
thalidomide 39–42, 49, 54, 58, 59, 81, 87, 90, 91
theorisation 13, 15
abstraction 13, 158, 201
lesson drawing 13, 89, 96, 107, 109
regulatory modelling 13, 112, 113, 138, 199, 200
toxicology 12, 37, 48–52
allowable daily intake (ADI) 51, 74
doie-response and toxicology 61, 64, 65
food toxicology 50, 52, 64, 65, 68, 69
reference dose 69
relations with industry 64
transboundary risk management 9
transnational
transnational and the global 9
transnational policy networks 22; see also network concept
transnational regulation 10, 11, 19, 22, 123, 134, 181, 188, 208
transnational risk regulation 8, 167
transnationalisation of experts’ career 177, 181, 188
trans-science 2, 37
Truhaut, René 51, 59, 68, 69, 74
uncertainty 2, 3, 12, 20, 26, 27, 37, 48, 52, 54, 59, 64, 71
Unilever 152–6, 158, 159, 163, 166, 187, 203
Uppsala Monitoring Centre (UMC) 92, 101

veterinarians 7, 51, 69, 121, 131, 136, 137, 201, 202
vioxx 43, 96, 110

Weinberg, A. 2
World Health Organization (WHO) contribution to pharmacovigilance planning 86, 89
Council of International Organisation of Medical Sciences and 102, 182

endorsement of HACCP 113, 114, 125, 186
food safety department 136
global food safety challenges 116
International Commission for the Microbiological Safety of Foods and 129, 131, 132, 134, 135
national pharmacovigilance systems and 42, 104, 107
Patrick and 178
quantitative dose-response assessment and 65
risk analysis and 70

World Trade Organization (WTO) 75, 113, 116
Worsley, Benjamin 29