Index

accountability
  DIY bio, in 14
  external 96
  regulatory legitimacy, in 13–14
adaptive management 133, 153,
  155–6, 159, 160, 171
  see also planned adaptation
Australia, in 160–61
  regulatory regime assessment, and
  157
Alfred P Sloan Foundation 98
Amyris 37, 53, 64
  biofene 56
  Production of Isoprenoids patent
  259
  renewable fuels 56
applications 51–2
  agricultural 57–8
  chemical production 58–9
    commodity chemicals 58
  energy 55–7
    biofuels 55, 131
    renewable fuels 56
environmental remediation 57
medicine 52–5
  engineered microorganisms as
    factories 52–4
  smart therapeutics 54
  synthetic vaccines 53
  tissue engineering 54–5
military/security 59–60, 77
  bio weapons 77
  risks 77–8
Asilomar Conference on Recombinant
DNA Molecules (1975) 101, 225
Aull, Kay 183
Baldwin, Robert 238
  benefit sharing 361
Benkler, Yochai 305
Bill and Miranda Gates Foundation
  64–5
biobanks 93
  regulatory role 333
UK Stem Cell Bank 93
  Research Use Agreement 332
BioBricks community 300–302
  see also commons; standard
    biological parts; parts agenda
  awareness of ethical and regulatory
    issues 94
  commons development 300–301,
    302–4
  norms 89
    engagement 91–2
    openness 321–2
    positive contribution 90–91
    sharing 89–90, 321–2
BioBricks Foundation 11, 36, 48,
  49–50
  see also commons; open access;
    standard biological parts
BIOFABS, and 50
  commons development 300–301,
    302–4
  emphasis on promoting biosafety
    and security 91
freedom rhetoric 307, 347
Global Roadmap 50
  goals of 48–9
    open access 49
no regulatory role 333
President’s Commission report see
  Presidential Commission
Public Agreement (BPA) 90–91,
  189, 303, 312–13
  access agreement 332
Regulation of synthetic biology

contributor agreement 312, 313–14, 332
model 319, 323
open access approach 315
regulatory limitations 92–3
user agreement 312, 314, 332
sharing strategy 301
bioinformatics 26
biological research
commercial 176–7
dual-use 174, 209
embryo 115–16
engineering inspired 28
life sciences 211
mapping see mapping research
military and security 221–2
biopunks 172
biological experimentation as right 200–201
biosafety 77, 172
Commerce Control List 228, 232–3
commercial research 176–7
manufacturers’ responsibilities 177
containment levels 176
definition 173–4
dual-use dilemma 174–5
DIY biology, of see DIY biosafety
General Industry Safety Orders (California) 178
institutional biosafety committees 175–6
laboratory 175
NIH Guidelines 175
compliance 175, 176
gold standard, as 176
occupational health and safety 178
Recombinant DNA Advisory Committee 175
responsibility, as 201
Select Agents and Toxins system 178
application of 178–9
criminal penalties under 179
modification 226–7
penalties for breach of 226
prescribed list of organisms and toxins 226
Responsible Officials 179
restricted experiments 226
security plans 226
university biosafety training 176
biosecurity 77, 207–9, 246–7
see also regulation
as regulatory challenge 209–12
arms control approach 211
bioterrorism see bioterrorism
criminalisation of activities relating to bioweapons 211–12
definition 173–4
increasing availability of pathogenic organisms 218
insider threat 209
new issues 208
customer screening 218–19
de-skilling of biology 221
DNA synthesis and assembly 216–20
military and security research 221–2
new capabilities 212–15
rogue actors 212, 214
scale of capacity 215–16
sharing and openness 220
regulation
proposed rule of law framework 243–5
tiered model for 92
regulatory challenges of competing considerations 210
control of biological materials 211
life sciences research 211
rapid advances in bio science 209–10
self-regulation 222–4
screening of orders for synthetic DNA
US National Science Advisory Board for Biosecurity 215
bioterrorism 3, 129, 215
increasing danger of 209
potential consequences 210
uncertainty of 132
WMD 192, 208
Black, Julia 238
Blue Heron Bio 64
Bobe, Jason 186, 187, 192, 193, 195, 197
code of ethics 194
DIY bio founder 180
Boyle, James 259–60, 277, 304–5, 307, 310, 319
definition of commons 306
The Public Domain (2008) 315–16
well-run commons 308, 309
Carlson, Robert 195, 196–7, 200, 217–18
chromosomes
designer yeast 47
eukaryotic 47
Church, George 3, 27, 28, 167, 236
Amyris 37
Codon Devices 37
community responsibility, on 199–200
CRISPR-Cas 9 46
engineering principles 32
funding 37
Gen9 37
Human Genome Project 37
Joule Unlimited 37, 64
LS9 37
regulatory approach 220
screening proposal 218–19
codes of conduct 101, 245
IASB Code of Conduct for Best Practices in Gene Synthesis 231
Codon Devices 36, 37, 259
commons 301, 304, 315–18, 339–40
see also BioBricks Foundation;
open source; public domain
access mechanisms 312–15
access agreements 332
defence of experimental use 338–9
patent pools 337–8
public sector licensing 335–7
anti- 308–9
common pool resource management 307–8, 310
design principles 308, 309, 313
dispute resolution, lacking 334
monitoring/enforcing compliance 333–4
problems 309
community building 311–12
contributions 331–2
motivation 327–9
creative commons licenses 307
defining 305, 306
deposit agreements 332
developing 302–4
obligations to funders 329–31
operation of 310–12
BPA and 312–13
patent issues 325–7
practical issues 332–4
public domain distinction 307
sharing mechanisms 301–2
standard biological parts see standard biological parts commons
tragedy of 304–5, 306, 308
usage 332
user agreements 332
well-run 308, 309–10
comparative genomics 33
construction approach 29–30
building a chassis 45
building synthetic genome 41–3, 46
creating minimal bacterial genome 41, 44–7, 76
designer yeast chromosomes 47
genome transplantation 43
producing synthetic cell 43–4
traditional recombinant DNA
 technology 38–40
Regulation of synthetic biology

Convention on the Prohibition of the Development, Production and Stockpiling of Bacterial (Biological) and Toxin Weapons and on their Destruction (1975) 211

Convention for the Protection of Biological Diversity (1993) 134, 143

Cowell, Mac 180, 181–2, 187, 189
democratisation 186, 348
innovation, of 323–4
desirable innovation
promoting 125, 220, 252, 321, 346, 351
commons, through 340
development 35
see also construction approach;
parts agenda
commons 300–301, 302–4
construction approach, of 38–47
key scientists in 35–8, 69
parts agenda, of 48–9
DIY biology 3, 172, 175, 177, 178, 179
biosafety see DIY biosafety
Bioweathermap 183
BosLab 180, 184
community biology labs 180
connection with synthetic biology 182–3
constructive biology 184
culture 181
DIYbio.org 180, 181, 186–7
exploratory biology 183–4
external accountability, and 14
GenSpace 180
key tools 182
LavaAmp 184, 188–9
mapping 68
Open PCR 182
open source approach 189–90
origins 180–81
reasons for 185
accessibility 186–7, 189, 190
democratisation 186
frustration 187–8
studying neglected diseases 188
DIY biosafety 179–83
addressing 193
advisory board 194
concerns 192–3
DIYbio community engagement 192–5, 202, 204
draft codes of ethics 194
Presidential Commission
adaptive approach to risk assessment 196–7
creation of novel pathogens 195–6
intellectual freedom 198–9, 234
not sufficiently cautious 203
recommendations 197–8, 233–5
regulatory challenges 191–2, 194–5
civil approach 204–5
criminal approach 204
customer screening 218–19
misapplication 204
secrecy 203–4
responsibility, as 201–2, 205
risks 192, 202
education, openness and engagement approach 199, 200
oversight approach 199–200
safety promotion 200
DNA 2.0 64
DNA synthesis technology see also genetic engineering;
recombinant DNA technology
building new organisms 166
outsourcing of lab work 182
oversight 95
potential for biosecurity risk 92, 216–20
rapid increase in 217–18, 245
dual-use research 174, 209
dual-use dilemma 174–5
easy to engineer 4, 25
E. coli 34–5, 52, 58
enabling technologies 29, 35, 38, 69
patent issues 254
standardised DNA assembly 40
synthetic biology 99, 343–4
Endy, Drew 8, 25, 26, 30, 36–7, 48, 219–20, 316
see also BioBricks community; BioBricks Foundation; parts agenda
BioBricks Foundation 36, 88
BIOFAB 36, 49
biological risk landscape 87–8
biosafety, on 191, 213
Codon Devices 37
communal norms approach 87–9
critique of 92–5
engagement 91–2
positive contribution 90–91
sharing 89–90
strengths of 95
Foundations for Engineering Biology (2005) 87
GEN9 36
open science champion 300, 310–11, 315
open source biology 90
parts agenda 48, 274
Registry of Standard Biological Parts 36
regulatory approach 220
safety and security regulation, on 92, 218, 227
environmental damage 3, 129
potential for synthetic biology to cause 22–3, 112, 130, 131
remediation 130–31
environmental risk
see also risk; precautionary principle
application of precaution and adaptation to 162–3
Presidential Commission approach 117, 120, 163
downplaying 168
photosynthetic bacteria 169
regulation in US 151–2
ETC Group 26–7, 71
against self-regulation of synthetic bio community 223–4, 243
anti-technology 26
‘Concentration’ 97
‘Erosion’ 97
‘microbesoft’ 98
moratorium approach 97
bioeconomy 98–99
bioweapons 100
critique of 102–3
objections to synthetic biology 98–101
risk 99
‘pandora’s bug’ 98
precautionary principle 101
ethical, legal and social issues (ELSI)
8–9, 50–51, 76, 84, 91
conducting experiments 216
dual-use dilemma 174–5
embryo research 115–16
ethical appropriateness of regulatory action 12–13
Ethical Considerations in Synthesizing a Minimal Genome (1999) 76–7
ethical principles 107, 113
need to foster debate on 21
iGEM program, in 88
monitoring 93
research 63–4, 84
funding 62
SYNBIOSAFE project 65–6
ethics
DIY bio draft codes of 194
European Group on Ethics in Science and New Technologies 65
Group on Ethics in Science and New Technologies 65
research 62, 67
European Union
ban on genetically modified foods 144–5
case law
Alphapharm Inc v Council of the European Union 140–41
Commission on the Precautionary Principle 140
ERASynBio program 66
Regulation of synthetic biology

European Group on Ethics in Science and New Technologies 65
Framework Programmes for Research and Technological Development 65
Group on Ethics in Science and New Technologies 65
MGR-Grammar initiative 66
New and emerging Science and Technology (NEST) 65
precautionary principle, and 140
research in 65–6
SYNBIOCOMM project 65–6
SYNBIOSAFE 65
evolution 28

Fidler, David P 239, 243, 244
funding 36, 37, 336
ELSI research 62
government 62
philanthropic 64–5

Geist, Michael 237
GEN 9 36, 37, 64
genes
flow of 130
suicide 164
genetic engineering 6
see also DNA synthesis technology;
recombinant DNA technology
extreme 26
genome engineering distinction 167
large-scale 166
synthetic biology
differentiation 166
whole genome 166
genome editing 46
CRISPR-Cas 9 46–7
genome engineering 28
genetic engineering distinction 167
genomes
designing 217
Human Genome Project 37
minimal bacteria 4–5, 76
modification of 4
synthetic 4

patent application for 5
Gentry, Eri 184, 190
Gostin, Lawrence O 239, 243, 244
Henkel, Joachim 276
Hippel, Eric von 323–4
Democratizing Innovation (2005) 323, 327–8
innovation community 324
Homebrew Computer Club 181
Human Genome Project 37

incentivising innovation 16, 252
Industry Association for Synthetic Biology (IASB)
Code of Conduct for Best Practices in Gene Synthesis 231
information-genomics revolution 4
Institute on Science for Global Policy 241
intellectual freedom 198, 234
responsibility, and 109–11
intellectual property
commercialisation 35, 64, 77, 274, 277
commons see commons
DIYbio community open source approach 189–90
patents see patents
International Gene Synthesis Consortium (IGSC)
screening protocol 229–30
Regulated Pathogen Database 230, 232–3
International Genetically Engineered Machine (iGEM) 88, 92, 182, 191, 224, 317, 324
Competition 36, 50, 182, 311
Foundation 50, 302, 309, 310
jamboree 311–12
International Open Facility Advancing Biotechnology (BIOFAB) 36, 49, 50
commons development 301
intersectional issues 359
biosecurity/IP interactions 360
Index

enhancing innovation 359–60
Ivins, Bruce 209
Jackson, Joseph 188
LavaAmp 184, 188–9
Jankowski, Tito 182
Joly, Jan 322
Jorgensen, Ellen 181–2
Joule Unlimited 37, 64
Keasling, Jay 33–4, 52, 60–61, 298
Amyris 37, 56
Codon Devices 37
kill switches 164
Knight, Tom 36, 48, 181
parts agenda 316
Lessig, Lawrence 306, 309, 310
licensing 199–200, 236
complex 257, 261
creative commons licenses 307
cross- 316
equipment 246
exclusive 253
general public licences 318–19
march-in rights 336
patent-based 315
patent trolls 253–4
public sector 335–7
reach-through licenses 274
Research Use License 332
restrictive 190
user license 32
Litman, Jessica 305
LS9 37, 57
mapping research 60
see also European Union; United
Kingdom; United States
DIY 68
European Union 65–6
United States 60–65
United Kingdom 66–8
Marris, Claire 95–6, 104, 158, 162
material transfer agreements 316, 320, 333
Maurer, Stephen 238, 240, 276
metabolic engineering 29, 33–5
definition 33
metabolic pathways 33, 34
monopoly property rights 16
see also intellectual property
moral panics 4–5
Mycobacterium mycoides 43, 44, 45, 270
Mycoplasma capricolum 43
Mycoplasma genitalium 41–2, 44–5, 280–81, 293
nanotechnology 10, 97
regulatory shortcomings 15
Novartis 54
novel communities 346–7
Nunez-Mujica, Guido 188
LavaAmp 184, 188–9
O’Malley, Maureen 28
open access 194, 257, 335
BioBricks Foundation 49, 50, 92, 315,
BPA 340
facilitating collaboration 322–3
licences 319
motivation behind 315–16
rationale 315
self-perpetuating terms of 318–19
strategic disclosure 319–20
open/closed research 347–9
tension 17, 347
open source
biology 90
DIY biology approach 189–90
model 316, 319
BPA model, distinguishing 319–20
OpenPCR 182
software 181, 301, 316, 327,
openness in 329
technology 318–21
general public licences 318–19
Ostrom, Elinor 307–8, 309
definition of common pool 307
design principles 308, 333–4
overview 341–2
Regulation of synthetic biology

parts agenda 30, 300, 302
see also commons; BioBricks community; BioBricks Foundation; standard biological parts; systematic design abstraction 31–2
Minimal Bacterial Genome (2006) 280–81
rejected 287
Synthetic Genomes (2006) 281
Patterson, Meredith, The Biopunk Manifesto (2010) 186, 187, 200
planned adaptation 152, 154, 156
see also adaptive management approach to public policy 153, 155
concept of 153–7
importance of 158
review processes, and 159
strengths 156–7
logical appeal 158
promoting regulatory effectiveness 159, 161
US, in 154–5
weaknesses 155–6, 161
policy environment 207–8
Posner, Richard A 209, 245–6
Prather, Kristala 191, 195, 202
precautionary principle 20–21, 145
see also prudent vigilance;
scientific uncertainty
criticism of 137, 159–60
defining 134
downplaying of in US 146
European idea, as 146–9
impact on decision-making 135–7
probability neglect 136
international leadership 149–50
legitimacy of 134–5, 137
necessity of 170–71
Presidential Commission misconception 141–4, 170
prudent vigilance distinction 146, 160
scientific progress, and 144–6
triggering/implementing 133–4,
135, 144
burden shifting mechanism, as 135
cost benefit analysis and 143
procedural requirement, as 135
proportionality and 144
uncertainty, and 133–7
workability of 137
Presidential Commission 5–6, 71, 106, 124–5
assessment principles 107–8, 118, 169–70
democratic deliberation 111–12
intellectual freedom and responsibility 109–11, 234, 348–9
justice and fairness 112–13
public benefit 108, 335
regulatory parsimony 119–20, 234–5
responsibility 108–9
DIY biology, on
adaptive approach to risk assessment 196–7
creation of novel pathogens 195–6
intellectual freedom 198–9, 234
not sufficiently cautious 203
recommendations 197–8, 233–5
failure to make policy recommendations 114–17
functions 113–14
international leadership, on 149–50
International Research Panel 116
misconception of precaution 141–4
New Directions: The Ethics of Synthetic Biology and Emerging Technologies report (2010) 105
open sharing, on 335
patents discussion 297–8
recommendations see Presidential Commission recommendations review of synthetic biology 106–7, 234
risk approach 117, 120, 163
precautionary principle, rejecting 165–6, 170–71
prudent vigilance 163–4, 170
responsible stewardship 164, 234
risk assessment 164, 170
technical safety measures 164–5
strengths of 121
adaptation 121–2
coordination 122–3
democratic deliberation 123–4
techno optimism of 165
Presidential Commission recommendations 233–5
critique of 163–70
over-reliance on technological containment measures 164–5
marginalising synthetic biology’s differences 166–8, 169–70
neglecting potential environmental impact 168, 170
not adopting precautionary principle 163–4, 165–6
problematic use of risk assessment 164
protocell creation 28
prudent vigilance 170
see also precautionary principle
critique of 138–9
precautionary principle distinction 146, 160
untested concept, as 139–41
public benefit 61, 83, 121
BioBricks Foundation see BioBricks Foundation
contested term, as 12
maximising 108
Presidential Commission focus on 124, 335
public domain 305
see also commons; intellectual property
commons distinction 307
defining 306–7
enclosed domain differentiation 305–6
public interest 48–9, 91
contested term, as 11–12
Rai, Arti 259–60, 261, 275, 326
recombinant DNA technology see also DNA synthesis technology;
genetic engineering
applied to metabolic engineering 28
classical 26
construction approach
development, in 38–40
construction of devices from DNA components 28
modern 39–40
Recombinant DNA Advisory Committee 175
regulation of 224–5
synthetic biology differentiation 166
Registry of Standard Biological Parts 36, 48, 50, 317–18
commons development 300–301
gate and give philosophy 304, 314
open repository, as 303–4
sharing strategy 301, 314–15
regulation 12, 71, 103–4
bespoke 6
biosafety see biosafety
biosecurity see biosecurity
 communal norms approach 87–95
DNA sales 218
effective 94
external accountability 96
government/industry guidelines comparison 231–3, 240
non-interventionism 72–87
recombinant DNA research, of 224–5
regulatory challenges see regulatory challenges
regulatory connection see regulatory connection
regulatory cosmopolitanism 22
regulatory effectiveness see regulatory effectiveness
regulatory legitimacy see regulatory legitimacy
responsive model 18, 238
Really Responsive Regulation framework 240
role of 9–12
maximising benefits 9–11
minimising harms 9
security 95
Select Agents see biosafety, Select Agents and Toxins system
self-222–4, 237–8
enforced 238
insufficient, as 235–7
International Gene Synthesis
Consortium Harmonized
Screening Protocol 229–30
lacking legitimacy 242
smart 18–19, 238–9
sociological approaches 95–7
art of governance 96
limitations 96–7
reflexiveness 96
US, in
coordinated biotechnology
framework 150–51, 356
environmental risk 151–2
voluntary screening guidelines see
voluntary screening guidelines
regulatory challenges 3–4, 6–7, 23–4,
28, 77, 17
see also risk; uncertainty
fragmentation of social authorities
96
insider threat 209
managing scientific uncertainty 20,
96
risk of deliberate misapplication 92,
218
uncertainty 129
US, in 81
regulatory connection 21, 159
adaptation and 245–6
problems 169–70
regulatory effectiveness 14–15,
237–40
adaptation and 245–6
failure of 15–16
industry buy-in 240–41
planned adaptation promoting 159
regulate resistance 17–19
regulatory prudence 19–21
sequence screening 241–2
unintended consequences 16–17
US, in 81
regulatory legitimacy 12–14, 242–5
external accountability 13–14
procedural 13, 14, 86, 242
public participation 13, 86–7
promoting 242
purpose 12–13
regulatory needs 350–53, 357
adaptive review mechanisms 353
encouraging sharing 350–51
enforceable oversight 353
greater control of DIY biology
352–3
precautionary regulation 351–2,
356–7
Synthetic Biology Agency 353–7
address ‘patchwork’ regulatory
field 356
biosecurity 354–5
engage with communities 354
foster professional cooperation
356
generate institutional expertise
356
promote adaptive governance
355–6
promote procedural legitimacy
355
provide enhanced regulation 354,
356
regulatory policy making 356
regulatory parsimony 119–20, 234–5
Reinhoff, Hugh 188
Relman, David 197
Renewable Energy Group 37, 64
responsibility 108–9
biosafety as 201–2, 205
intellectual freedom and 109–11,
234, 348–9
Rettberg, Randy 36, 38, 48, 181,
316–17, 331
parts agenda 316
revolutionary, synthetic biology as
342–5
risk 345–6
see also biosafety; biosecurity;
regulatory challenges;
uncertainty
accidental environmental harm
129–30
environmental remediation
130–31
uncertainty of 132–3
bioterrorism 129, 132
closing down of discussion 117–18
Regulation of synthetic biology

definition 132
deliberate misapplication 92, 218
DNA synthesis technology 92
environmental see environmental risk
minimising 131
Presidential Commission approach 117, 120
prudent vigilance see prudent vigilance
regulatory action posing 136
uncertainty, and 131–3
distinction 132
unmanaged 239
Rose, Nikolas 95–6, 104, 158, 162
Rutz, Berthold 27
Schloendorn, John 184
science, key role of 11
scientific knowledge, imperfect objectivity of 85
scientific uncertainty 132
see also precautionary principle;
uncertainty
acknowledgment of 133
burden shifting 133
managing 20, 96, 129, 162
adaptive management see adaptive management
planned adaptation see planned adaptation
not a temporary state of affairs 161–2
precaution and 20–21, 133–7
self-replicating synthetic bacterial cell 5, 72–4
SGI-DNA BioXP 3200 246
Silver, Pamela 36, 38, 169
Smithson, Amy 237
standard biological parts see also BioBricks community;
parts agenda
BioBrick 302
commons see standard biological parts commons
community 302–3
community building 311
patentability 273–6
Registry of 36, 48, 50, 317–18
standard biological parts commons 301, 304, 339–40
see also commons; open source
democratising innovation 323–4
developing 302–4
innovation communities 324–5
user innovation 324
open biotechnology 321–3
defining characteristics 322–3
medical research, in 321–2
open source technology 318–21
sharing mechanisms 301–2, 322
standardisation 30
suicide genes 164
synthetic biology
scientific uncertainty in see scientific uncertainty
advantages of 26
altering existing organisms 27
applications of see applications as continuation of existing research 85
combining existing sciences 25–6
construction approach see construction approach
creating organisms 26
cross-borderness of 96
defining 25, 27, 28, 69
deleting superfluous genes 28
development of see development
divergence in 28
drivers 26, 69
dual-use research area, as 174, 209
emergence as new field 49–51
genome engineering 28
large scale of 167–8
metabolic engineering see metabolic engineering
multifaceted nature of 28
objectives 4, 25
patentable subject matter, and 28
parts agenda see parts agenda
protocell creation 28
rapid developments in 167
recombinant DNA see recombinant DNA technology
regulation see regulation
risks of 3, 4, 75–7
synthesising genes or genomes 28
synthetic genomics distinction
166–7
transformative, as 3, 4
umbrella term, as 28–9
Synthetic Biology X.0 conferences 49, 64, 87, 91, 101, 311, 323
synthetic genomics
key features 217
synthetic biology distinction 166–7
Synthetic Genomics Inc. 35, 53, 54
Agradis 58
biofuels projects 55–6
patents approach 277–8
photosynthetic algae 55–6
Production of Branched-Chain
Alcohols by Photosynthetic
Microorganisms patent 259
SG-DNA 64
Synthetic Genomics: Options for
Governance report (2007) 76, 77, 82, 98, 213–14
limitations 82
Synthetic Genomic Vaccines Inc. 53–4
systematic design 31
Systems and Synthetic Biology 49
transnational regulation 357–9
Tucker, Jonathon B 238
uncertainty 129, 170, 346
see also regulatory challenges; risk
definition 132
impact of synthetic organisms in
environment, over 168–9
risk and 131–3
distinction 132
scientific see scientific uncertainty
United Kingdom
Biotechnology and Biosciences
Research Council (BBSRC) 66
Centre for Synthetic Biology and
Innovation 67–8
Engineering and Physical Sciences
Research Council (EPSRC) 67
ethics research 67
interdisciplinary networks 67, 68
Royal Society 66
Stem Cell Bank 93
Research Use License 332
Synthetic Biology for Growth
Programme 67
United Nations
Convention on Biological Diversity
(1992) 134, 168, 358
Educational, Scientific and Cultural
Organization (UNESCO) 358
Framework Convention on Climate
Change (1994) 134
Rio Declaration on Environment
and Development 134, 143
United States 60–65
Administrative Procedure Act 155
APHIS 81
Biomedical Advanced Research and
Development Authority 54
Biosafety in Microbiological and
Biomedical Laboratories
manual 173–4
case law
Reserve Mining Co v
Environmental Protection
Agency 148–9
Clean Air Act 148, 154
Clean Water Act 148
DARPA 63
Department of Agriculture (USDA)
150–51
Forestry Planning Rule 154
ELSI funding 62
Engineering Biology Research
Consortium (EBRC) 37, 62, 88
Environmental Protection Agency
(EPA) 81, 150
discretion 152
margin of safety 147–8
responsibilities 176–7
FBI Weapons of Mass Destruction
Directorate Bioterrorism
Prevention Program 192
Food and Drug Administration
(FDA) 150
Joint Bioenergy Institute 62
Index

compliance 240

WIPO 358

World Health Organization 358

Laboratory Biosafety Manual 173

World Trade Organization 141

Agreement on the Application of

Sanitary and Phytosanitary

Measures (1995) 135, 161

litigation 145

Wyss Institute 64

Wang, Norm 190

Zhang, Joy Y 95–6, 104, 117, 158, 161–2

Weiss, Ron 38, 54–5

sequence screening 228

black list (BLiSS) 228–9

insufficient, as 235–7, 238

necessity of enforcement 239

recommended procedures 228

red flags 228, 229

follow-up screening 228, 233