



## News for the Federal Biorisk Management Policy Community

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Crossword Puzzle Key

## Policy Announcement: United States Government Policy for Dual Use Research of Concern

The Federal Government has released a new policy for oversight of life sciences dual use research of concern (DURC) that is funded or conducted by the USG. For the purpose of this Policy, DURC is defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences

to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. The Policy will establish regular review of this research in order to mitigate risks and collect information to inform policy updates, and aims to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

Under this Policy, review will focus on research involving one or more agents or toxins that are considered to pose the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence. The Policy includes a list of these specified agents and toxins (on pg. 8), as well as a list of categories of experiments being conducted with these agents and toxins for review.

*cont. on pg. 8*

## FBI Connects Science and Security Communities

The Biological Countermeasures Unit (BCU) within the FBI Weapons of Mass Destruction Directorate stays busy with a full schedule of events aiming to reach and connect the scientific and security communities. The BCU educates members of both communities on the importance of biosecurity and available tools to mitigate the potential security risks involved with working with biological materials and technologies. Scientists in industry, researchers in academic facilities, students, biosafety and compliance professionals, information technologists, first responders, environmental and public health officials, local law enforcement, and emergency management professionals are among those included in the FBI's target audience for education and outreach, both in the United States and with their international partners.

A long list of conferences and workshops speak to the value placed on this type of outreach by the BCU. Regional FBI Academic Biosecurity



Workshops<sup>1</sup> take place at colleges and universities across the country and aim to improve the cooperation among law enforcement agencies and research institutions to mitigate potential biosecurity issues that may affect public health and safety. The BCU offers workshops, free of charge, to interested institutions. Over 20 have been carried

<sup>1</sup>[Link to FBI Regional Academic Biosecurity Workshops](#)

*cont. on pg. 5*

## Interagency Biorisk Management Working Group is Established

The term “biorisk management” describes the development and application of practices and procedures to reduce biosafety, biocontainment, and biosecurity risks posed by working with hazardous biological agents in research laboratories.



In January 2012, the White House Office of Science and Technology Policy (OSTP) convened the first meeting of the Interagency Biorisk Management Working Group (IBMWG). Established by action of the National Science and Technology Council Committee on Homeland and National Security Subcommittee on Biodefense Research and Development, the IBMWG is tasked with examining the current framework for local and Federal research laboratory biorisk management oversight. The term “biorisk management” describes the development and application of practices and procedures to reduce biosafety, biocontainment, and biosecurity risks posed by working with hazardous biological agents in research laboratories. The IBMWG provides participating Federal agencies with a focused forum to coordinate and collaborate on mechanisms to strengthen research laboratory biorisk management and to promote outreach and education programs that inform scientists, biosafety professionals, institutional officials and the public on biorisk management. IBMWG membership includes representation from sixteen Federal departments and agencies, and three organizations within the Executive Office of the President.

The IBMWG will examine the current oversight framework and evolving oversight practices for local and Federal biorisk management of research and related activities at high- and maximum-containment (Biosafety Levels 3 and 4, respectively) laborato-



ries operated within the United States or supported by the United States Government. The IBMWG will identify gaps in Federal biorisk management policies and procedures for these research activities, develop a strategy and implementation plan to address gaps and priority recommendations, and ensure that Federal efforts in biorisk management are harmonized. Where appropriate, the IBMWG will evaluate the applicability of its findings to biorisk management oversight for non high- or maximum-containment laboratories.

In addition to strengthening research laboratory biorisk management oversight, the IBMWG will coordinate Federal outreach and educational programs designed to inform scientists, biosafety professionals, institutional officials and the public on biorisk management and relevant federal regulations and related

issues. The IBMWG will facilitate awareness among Federal and non-Federal stakeholders about ongoing outreach activities relevant to understanding and addressing biological threats, and will develop and promote the use of common terminology and consistent messages about biorisk management by Federal departments and agencies. Finally, the IBMWG will enhance international partnerships to strengthen global biorisk management and establish mechanisms to continually review and improve Federal biorisk management policies, practices, and procedures, and assess the efficacy of IBMWG outreach efforts.

The IBMWG will review recommendations developed by, inter alia, the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, National Science Advisory Board for Biosecurity, Federal Experts Security Advisory Panel, European Committee for Standardization (Comité Européen de Normalisation [CEN]), and World Health Organization to identify those that may inform options for improvements or alternatives in Federal biorisk management oversight.

IBMWG Co-chairs:

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## Outcome of the Biological Weapons Convention 7th Review Conference



The 7th Review Conference of the Biological Weapons Convention (BWC) took place last December in Geneva, Switzerland. The Review Conference is held every five years with the goal of addressing specific issues designed to keep the treaty in a position to address the ever-changing nature of biological threats. The United States delegation entered the discussions with a focus on three critical issues, including bolstering confidence building measures, addressing developments in science and technology, and building capacity for nations to detect and respond to disease outbreaks (more information can be found [here](#)). In addition to the formal BWC Review Conference sessions, U.S. Conference on Disarmament Ambassador and BWC Representative Laura Kennedy hosted three events that provided an overview of the U.S. approach to several critical BWC areas, including U.S. biodefense programs, U.S. assistance provided under Article X of the BWC, and international preparedness and response. More information on these events can be found [here](#). The three-week session concluded with the States Parties' adoption of a Final Document related to countries' views on how the Articles of the Convention are being implemented and a series of decisions and recommendations covering the next

five years until the 8th RevCon in 2016.

It is evident that the States Parties were united in focusing on these critical issues, among other items. In its [summary](#) of the meeting, the Biological Weapons Convention Implementation Support Unit (ISU) posted the following on the United Nations Office at Geneva website: "In the decisions and recommendations, the Review Conference retains the previous structures of annual Meetings of States Parties preceded by annual Meetings of Experts; makes cooperation and assistance, a review of developments in the field of science and technology, and strengthening national implementation all Standing Agenda Items to be discussed during the intersessional period; establishes a database system to facilitate requests for and offers of exchange of assistance and cooperation among States Parties; establishes a sponsorship programme to increase the participation of developing States Parties in the meetings of the intersessional programme; adopts revised reporting forms for all Confidence Building Measure submissions; requests States Parties to promote universalization of the Convention through bilateral contacts and regional and multilateral activities; and renews the mandate of the Implementation Support Unit from 2012 to 2016." Assistant Secretary

of State Tom Countryman, during his [remarks](#) at the American Society for Microbiology Biodefense and Emerging Diseases Research Meeting in February, affirmed that the "Administration is pleased with the outcome of the 2011 Review Conference."

In the Final Document the States Parties decided to include in their 2012 – 2015 intersessional program a standing agenda item on developments in the field of science and technology related to the Convention. The three standing agenda items, as well as a two-year focus on improving the relevance of the CBMs, and another two years on preparedness and response will be guided by a new arrangement of the BWC Chairman and two Vice Chairmen. Algeria has the rotating position for Chairman for 2012 from the non-aligned movement, Switzerland and Poland will take the Vice Chair positions for the Western European and Others Group and Eastern European Group, respectively.

The Conference agreed to hold the Experts Meeting July 16-20 and Annual Meeting from December 10-14. U.S. BWC Representative and Conference on Disarmament Ambassador Laura Kennedy will continue to lead the U.S. delegation as she did for the Review Conference.

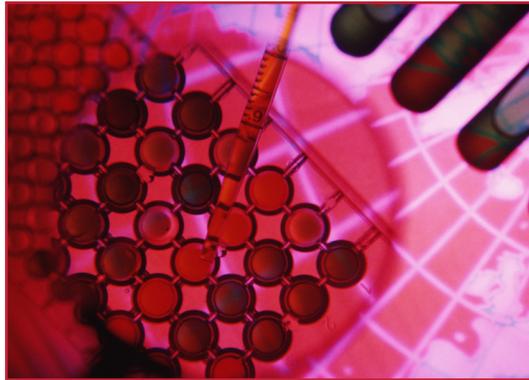
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The Review Conference is held every five years with the goal of addressing specific issues designed to keep the treaty in a position to address the ever-changing nature of biological threats.



## Deemed Exports and Licenses in Biological Research

Relevant to recent events regarding communication of dual use research of concern, technology controls may also apply to technical data transmitted in oral or written form.



Export control regulations are federal laws that restrict the passage of certain materials, devices and technical information outside of the United States or to foreign nationals within the United States. These regulations apply to research activities that are not considered “fundamental” research, or that which “is defined to mean basic and applied research in science and engineering where the resulting information is ordinarily published and shared broadly within the scientific community.” Biological research, including the agents studied, the equipment used, and the technology applied may be regulated by export controls. Relevant to recent events regarding communication of dual use research of concern, technology controls may also apply to technical data transmitted in oral or written form. Discussion of export-controlled technology at conferences or even in laboratory settings should be evaluated for possible requirements for export control.

Export controls also apply to the release of controlled technology to a foreign national inside the United States. The term for such a release of technology is “deemed export”. Any foreign national is subject to the “deemed export” rule except a foreign na-

tional who (1) is granted permanent residence, as demonstrated by the issuance of a permanent resident visa (i.e., “Green Card”); or (2) is granted U.S. citizenship; or (3) is granted status as a “protected person” under 8 U.S.C. 1324b(a)(3). Much more information is available on the Bureau of Industry and Security [website](#).

Many people have questions on what triggers a requirement for a deemed export license for biological research. There are several factors and Export Control Classification Numbers (ECCNs) to consider. The ECCNs that cover pathogens of concern are 1C351, 1C352, 1C353, 1C354, and 1C360. These agents are Australia Group listed or are Select Agents. However, it is not the pathogen itself that is the subject of control for a deemed export license, but the technology association with that pathogen. If the pathogen were to be shipped from the US to the foreign national, that would be a regular export license. A deemed export license is for a foreign worker in the US. If technology is to be exported to a foreign country, that is considered a technology export – the difference is where the technology is imparted.

ECCN 1E001 is technology for the development or production (definitions below) of controlled biological agents. The key question is if the foreign national is learning how to “grow” a con-

trolled pathogen using techniques that are not in the public domain or are not fundamental research. There are also exclusions from licensure based on publications (please review 734.8 through 734.12 and the appendix to 734 of the Export Administration Regulations (EAR)). Release of controlled 1E001 technology would necessitate a deemed export license if the scientist was learning “development” or production” of a controlled organism. When you look at the EAR definition of these terms, it would mean the researcher would be licensed for how to grow, maintain, quality check, etc a pathogen. Most of this technology is in the public domain. If the researcher was working on a sensitive project where they were working on biodefense or some other type of research that would not be allowed to be published and involved a controlled listed pathogen being grown in non-standard conditions (not in the scientific literature), then 1E001 might apply. There is also 1E351 disposal technology but it doesn’t really apply because biological agents are destroyed through autoclave, chemicals, etc, in standard universal techniques.

Another area of concern is 2E001 and 2E002 technology controls for development and production - these would only apply if the researcher was developing 2B352 controlled biological equipment (fermenters, cross flow filtration equipment, class 3 glove boxes, for example). The third area to look at is 2B301 which is “use” of biological equipment. (see below). All six parts of the components of use as defined in the EAR must be met. Of course the technology might be public

*Cont. on pg. 5*



## ***FBI Connects Science and Security Communities cont. from pg. 1***

out since Jan 2011. The 2011 FBI Synthetic Biology III Workshop *Safe and Secure Science: Partners of Today and Tomorrow* and the February 2012 meeting *Bridging Science and Security for Biological Research: A Dialogue Between Universities and the FBI*, jointly sponsored by AAAS, APLU, AAU, and FBI<sup>1</sup>, are examples of the effort to engage the science and security communities and foster a dialogue leading to mutual benefit and understanding.

The FBI is also actively involved in policy discussions and activities dealing with biosecurity, particularly regarding biological select agents and toxins. During the Select Agent Program Workshop Series, sponsored by the CDC and USDA-APHIS and held in Knoxville, TN in November 2011, leadership and personnel at entities registered with the Select Agent Program were encouraged to participate in the Regional Biosecurity Workshops and connect with their local WMD Coordinator, of which

<sup>1</sup>Meeting report

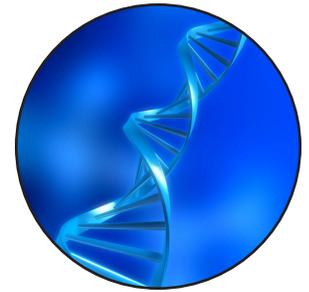
there is at least one in each of the 56 FBI Field Offices. WMD Coordinators are Special Agents that are trained and experienced in dealing with chemical, biological, radiological, and nuclear threats and incidents. They have established partnerships with Federal regional counterparts, state, county, and local response agencies and entities in their jurisdiction, as well as having the reach-back capabilities to FBI and other Federal Department and Agency headquarters. By establishing relationships with the WMD Coordinators SAP entities have access to an array of resources and expertise to mitigate potential biosecurity risks.

The BCU pursues other innovative avenues of outreach to the scientific community by sponsoring the annual International Genetically Engineered Machine (iGEM) Competition. Starting at the undergraduate level, iGEM exemplifies the tremendous benefits and rapid advances in the field of synthetic biology with projects ranging from environ-

mental remediation to potential new medical therapeutics. Sponsorship of iGEM has allowed the FBI to raise awareness and inculcate the culture of security in the next generation of researchers and entrepreneurs. This has been accomplished through workshops promoting responsible research and working with iGEM to incorporate security in the judging process. At the same time, the FBI developed the Synthetic Biology Tripwire Initiative, in partnership with the U.S. synthetic biology industry, to facilitate and encourage the reporting of suspicious requests for genetic sequences mitigating risks for abuse and ensuring advances in science and technology remain open and accessible.

The FBI Biological Countermeasures Unit will continue its prevention activities in a way that strikes a balance between security and supporting advances in scientific research and protecting public safety.

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The FBI is also actively involved in policy discussions and activities dealing with biosecurity, particularly regarding biological select agents and toxins.

## ***Deemed Exports and Licenses in Biological Research cont. from pg. 4***

domain depending on what type of item they were learning to use. If someone from a CB2 country on the CCL country list (supplement 1 to part 738) country comes to the United States to learn how to operate, install, maintain, repair, overhaul, and refurbish 2B352 equipment then they should get a deemed export license. This is not the normal activity of researchers. In conclusion, a deemed export license is only required for a foreign national in the United States learning technology controlled by the Export Administration Regulations.

### **Definitions**

**Production:** (General Technology Note) (All Categories)—Means all production stages, such as: product engineering, manufacture, integration, assembly (mounting), inspection, testing, quality assurance.

**Development:** (General Technology Note)—“Development” is related to all stages prior to serial production, such as: design, design research, design analyses, design concepts, assembly and testing of prototypes, pilot production schemes, design data, process of transforming design data into a product, configuration design, integration design, layouts.

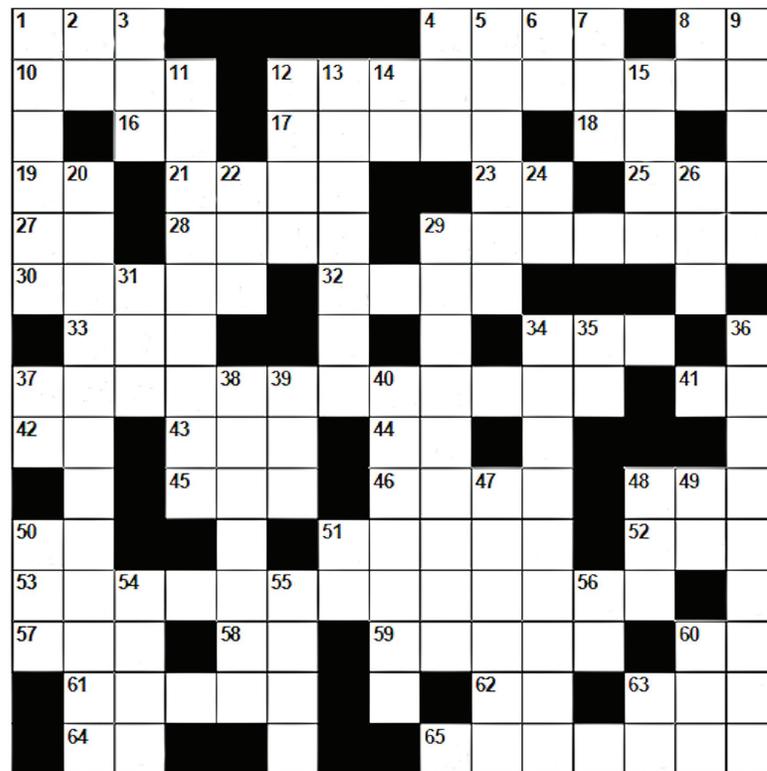
**Use:** (All categories and General Technology Note)—Operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing.

More information is available [here](#).

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# Treaties and Weapons of Mass Destruction

by Dr. Dana Perkins, [dana.perkins@hhs.gov](mailto:dana.perkins@hhs.gov)



## ACROSS

- 1 Not processed or refined
- 4 Confidence Building Measure A Part I refers to this biosafety level
- 8 Third person singular present indicative of be
- 10 Exposure Assessment and Management Program; process of assessing and controlling worker's risk of exposure to hazardous substances
- 12 Dissuading a potential adversary from initiating an attack
- 16 Yes, in Romanian
- 17 United Nations Office of Disarmament Affairs-promotes nonproliferation and disarmament
- 18 The 12th letter of the Greek alphabet
- 19 Abbreviation for ibidem
- 21 Network behavior anomaly detection; continuous monitoring to detect unusual events or trends
- 23 The symbol for the element tantalum
- 25 City in Papua New Guinea that is home of to the University of Technology
- 27 Emotional Intelligence; ability to identify, assess and control the emotions of oneself or others
- 28 Anaphylaxis reaction carried out in vitro with excised tissue, also known as Schultz-\_\_\_\_\_ Reaction

## DOWN

- 1 This type of conference occurs every 5 years
- 2 Anti-aircraft warfare
- 3 Weapons that are capable of a high order of destruction and lethality
- 4 G-man
- 5 An eloquent public speaker
- 6 Basque word for "water"
- 7 Unit of radiation dose equivalence
- 8 Collective abbreviation for the CIA, DIA, FBI, ODNI, NSA and others
- 9 The number of Confidence-Building Measure forms under the BWC
- 11 Epidemics that cover a wide geographical area or affect a large number of people
- 12 Referring the good and bad uses of life sciences
- 13 Disease that is naturally present in an area
- 14 Tonga, abbreviated
- 15 Something that has no force or meaning
- 20 The intentional use or threat of use of biological agents against humans, animals, or plants
- 22 Proscribe
- 24 Adenine and thymine

**ACROSS**

- 29 Biological toxin which affects the nervous system, made by *Clostridium botulinum*
- 30 Forty of them have been awarded the Nobel Prize between 1901 and 2009
- 32 Net-speak for “more” generally found on lolcats
- 33 Toxic Industrial Materials; toxic or radioactive substances that may be used for industrial, medical, or commercial purposes
- 34 Confidence-Building Measure
- 37 A process to demonstrate compliance with an agreement or treaty requirements
- 41 Cyanide
- 42 Area of a hospital for the acute care of patients
- 43 Simian fibroblasts immortalized with SV40 virus
- 44 Chemical symbol for neon
- 45 \_\_\_\_ Lawquane “We want no trouble here” (“Star Wars: War of the Clones” character)
- 46 Snare, ambush, stratagem
- 48 Man on a five
- 50 Nitric oxide
- 51 A prodromal symptom of an infectious disease
- 52 Biological Weapons Convention (a.k.a. Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological and Toxin Weapons and on their Destruction).
- 53 The spread of weapons of mass destruction and related technologies and materials
- 57 Apex in anatomy
- 58 Babylonian water-deity
- 59 “ \_\_\_\_ jacta est”- The dice has been cast (Latin, plural)
- 60 Chemical symbol for titanium
- 61 Cicatrices
- 62 Chemical symbol for a radioactive gas formed by the decay of radium
- 63 Acronym for the United Nations organization coordinating international public health response
- 64 Scientific abbreviation for molecular weight
- 65 It triggers antibody production

**DOWN**

- 26 Dot on the Rhine
- 29 Relating to or caused by bacteria
- 31 It docked with “Atlantis”
- 34 The state of being in accordance with established agreements or treaty requirements
- 35 Brunei, abbreviated
- 36 Body invasion by pathogenic microorganisms
- 37 Venezuela, abbreviated
- 38 Mathematical analysis of data based on frequencies
- 39 Acronym for the organization established at the BWC 6th Review Conference
- 40 An infectious disease caused by *Bacillus anthracis*
- 47 Second base in mathematics
- 48 Airborne, abbreviated
- 49 Biological Weapon
- 50 Common abbreviation for the Treaty on the Non-Proliferation of Nuclear Weapons
- 51 Chemical symbol for cerium
- 54 Based in The Hague, The Netherlands, this organization monitors compliance with the CWC
- 55 Join a hunger strike
- 56 Chemical symbol for osmium
- 60 Ubiquitous article
- 63 Working group, abbreviated

**CROSSWORD  
PUZZLE KEY  
ON PG. 8**

## Call for Submissions

We want to hear from you! Please contact Laura Kwinn with news ideas for future editions of S3 Quarterly. Feel free to submit general information for inclusion or drafted articles. If you have an idea, we are happy to work with you in drafting a piece. Articles should be in MS Word format, fewer than 1000 words, with author/contact name and email address. Pictures and diagrams in jpg format are encouraged and welcome. Thank you!

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## Policy Announcement: United States Government Policy for Dual Use Research of Concern *cont. from pg. 1*



Based on this risk assessment, and in collaboration with the institution or researcher, the D/A should develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures.

The Policy outlines the responsibilities of Federal departments and agencies (D/A) that conduct or fund life sciences research. Following a review of all research projects, the D/A should identify any that meet the definition of DURC and assess the risks and benefits of such projects. Based on this risk assessment, and in collaboration with the institution or researcher, the D/A should develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures. Within 60 days of issuance of the Policy Federal D/A are requested to report those projects that include work with one or more of the listed agents or toxins and produce, aim to produce, or are reasonably anticipated to produce one or more of the effects in the listed categories to John Brennan, the Assistant to the President for Homeland Security and Counterterrorism. Within 90 days, D/A are requested to identify those projects that are identified as DURC, as well as a summary of risks and mitigation measures already in place or proposed. D/A are additionally requested to submit biannual reports on these items.

As necessary and appropriate, the USG will continue to consult with the NSABB or convene the Countering Biological Threats Interagency Policy Committee for guidance on matters relating to DURC. The Policy will be updated, as needed, following discussions with domestic and international partners, including members of the scientific and security communities.

The full Policy can be found [here](#).

### DURC Policy List of Agents and Toxins

- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- Botulinum neurotoxin
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola virus
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Marburg virus
- Reconstructed 1918 Influenza virus
- Rinderpest virus
- Toxin-producing strains of *Clostridium botulinum*
- Variola major virus
- Variola minor virus
- *Yersinia pestis*

### CROSSWORD PUZZLE KEY

from pgs. 6-7

1	R	2	A	3	W					4	F	5	O	6	U	7	R	8	I	9	S	
10	E	A	M	11	P			12	D	13	E	14	T	E	R	R	E	15	N	C	E	
	V		16	D	A			17	U	N	O	D	A		18	M	19	U		V		
19	I	20	B		21	N	22	B	A	D			23	T	24	A	25	L	26	A	E	
27	E	I		28	D	A	L	E				29	B	O	T	U	L	I	N			
30	W	31	O	M	E	N			32	M	O	A	R								T	
		33	T	I	M									34	C	35	B	36	M		I	
37	V	E	R	I	38	F	39	I	C	40	A	T	I	O	N			41	C	N		
42	E	R			43	C	O	S			44	N	E	M							F	
					45	S	U	U			46	T	R	A	P			48	A	49	B	E
50	N	O								51	C	H	I	L	L			52	B	53	W	C
53	P	R	O	L	I	F	E	R	A	T	I	O	N									T
57	T	I	P		58	E	A			59	A	L	E	A	S			60	T	I		
		61	S	C	A	R	S			X		62	R	N			63	W	H	O		
	64	M	W											65	A	N	T	I	G	E	N	