

**COMMITTEE ON SUBORDINATE LEGISLATION**  
**(FOURTEENTH LOK SABHA)**

**(2008-2009)**

**TWENTY-FIRST REPORT**

**(PRESENTED IN LOK SABHA ON 22.10.2008)**

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**LOK SABHA SECRETARIAT**  
**NEW DELHI**

**OCTOBER, 2008/ASVINA, 1930 (Saka)**

**COSL No. 5**

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**(2008-2009)**

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| 3. Ms. Miranda Ingudam | - | Committee Officer   |

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## **INTRODUCTION**

I, the Chairman, Committee on Subordinate Legislation having been authorized by the Committee to submit the report on their behalf, present this Twenty-First Report.

2. The matters covered by this Report were considered by the Committee on Subordinate Legislation at their sitting held on 4<sup>th</sup> August, 2008.

3. The Committee considered and adopted this Report at their sitting held on 17<sup>th</sup> September, 2008.

4. For facility of reference and convenience, recommendations/observations of the Committee have been printed in thick type in the body of the Report and have also been reproduced in Appendix I of the Report.

5. Minutes of the Ninth sitting of the Committee (2007-08) held on 4<sup>th</sup> August, 2008 and extracts from the minutes of the Second sitting of the Committee (2008-2009) held on 17<sup>th</sup> September, 2008 relevant to this Report are included in Appendices II & III.

**NEW DELHI;  
20 OCTOBER, 2008**  
**27 ASVINA, 1930 (SAKA)**

**N.N. KRISHNADAS,  
CHAIRMAN,  
COMMITTEE ON SUBORDINATE LEGISLATION**

## **REPORT**

### **I. INORDINATE DELAY IN PUBLICATION OF THE PREVENTION OF FOOD ADULTERATION (AMENDMENT) RULES, 2005**

The Prevention of Food Adulteration (I Amendment) Rules, 2005 (GSR 184-E of 2005) and the Prevention of Food Adulteration (II Amendment) Rules, 2005 (GSR 185-E of 2005) were published in the Gazette of India, Extraordinary, Part-II, Section 3(i) dated 21 March, 2005. It was observed therefrom that there were delays in publication of the final rules after bringing them out in the draft forms, the details of which are as under:-

- (i) The draft rules of the Prevention of Food Adulteration (I Amendment) Rules, 2005 were published on 18 July, 2003 whereas the final rules were published on 21 March, 2005 after a gap of 20 months; and
- (ii) The draft rules of the Prevention of Food Adulteration (II Amendment) Rules, 2005 were published on 16 June, 2003 whereas the final rules were published on 21 March, 2005 after a gap of 21 months.

1.2 One of the oft-repeated recommendations of the Committee on Subordinate Legislation has been that in cases where no objection/suggestion on the draft rules were forthcoming, the final rules should be published within a period of three months and in cases where a large number of objections/suggestions were received, the gap should not be more than six months.

1.3 The Ministry of Health and Family Welfare (Department of Health) were requested to state the reasons for delay in publication of the final rules and also to furnish the number and nature of objections/suggestions received on the draft rules. In response, the Ministry vide their replies dated 13 January, 2006 detailed the steps taken by them from the date of notification of the draft rules to their final publication. As regards the

Prevention of Food Adulteration (I Amendment) Rules, 2005, the Ministry stated as under: -

“On the basis of recommendations of Central Committee for Food Standards (CCFS), a Statutory Committee under the PFA Act, 1954, a draft notification GSR 555 (E) related to standards for Sugar, Salt and Confectionery products was published on 18.07.2003 for inviting objections and suggestions from the public. Sixty days time (from the date on which the copies of the notification were made available to the public on 23.7.2003) was given for sending objections and suggestions on the proposed amendment. A large number of objections and suggestions were received from various stake holders, because this notification is one of the notifications in the series of harmonization of Prevention of Food Adulteration Rules, 1955 in line with Codex Standards. As these were bulky and highly technical in nature the objections and suggestions received were considered by an expert group on 29.12.2003. A table showing the objections and suggestions received on the said notification from various quarters is enclosed. On the basis of the decision of the expert group a final notification was accordingly prepared and put up on 9.3.2004 for approval of DGHS. The proposed notification was after the approval of DGHS sent to Ministry and the Hon’ble HFM on 31.3.2004. However, Hon’ble HFM directed that they should be resubmitted after 10 May, 2004, when new Hon’ble Minister assumes the charge after the new cabinet was set up. In the mean time some consequent amendments pointed out by the stake holders have been incorporated in the final notification and final (draft) notification was submitted to new Hon’ble Minister for approval on 18.10.2004. Thereafter the file was immediately sent to M/o Law for vetting on 26.10.2004. However, M/o Law took a long time and after discussion in a personal meeting with officers of Dte GHS, the file was approved by M/o Law on 5.1.2005. Since it was a bulky notification, OL Wing also took considerable amount of time for the Hindi Translation and the same was made available on 9.2.2005. The Hindi version of the notification was then compared and it was found that a number of mistakes were there. The Budget Session of Parliament was on and retyping of the whole notification and its comparison also took some time. Thereafter the notification was finally sent to GOI Press for its publication. It is however assured that efforts will be made in future to adhere to the time frame fixed for finalization of notifications”.

1.4 As regards the Prevention of Food Adulteration (II Amendment) Rules, 2005, the Ministry stated as under :-

“On the basis of recommendations of Central Committee for Food Standards (CCFS), a Statutory Committee under the PFA Act, 1954, a draft notification GSR 489 (E) related to harmonization of standards of fruits and vegetables under PFA Rules, 1955 in line with Codex standards was published on 16.6.2003 for

inviting objections and suggestions from the public. Sixty days time (from the date on which the copies of the notification were made available to the public) was given for sending objections and suggestions on the proposed amendment. The said notification consisted of 106 pages in English and Hindi and a large number of objections/suggestions were received from various stake holders. A table consisting of 71 pages showing the objections and suggestions which were received on the said notification from various quarters is enclosed. As the comments etc. were bulky and highly technical in nature the objections and suggestions received, were considered by an expert group on 29.9.2003. The minutes of the meeting of expert group was then circulated to all its members on 19.11.2003. On the basis of the decision of the expert group a final notification was accordingly prepared by the Directorate General of Health Services and was submitted to the approval of DGHS. The proposed notification was thereafter submitted to this Ministry. Since the notification consisted of various issues, several rounds of discussions took place between various senior officers of this Ministry as well as DGHS. Finally the notification was submitted for the approval of the Hon'ble HFM on 12.7.2004. Thereafter the file was immediately sent to M/o Law for vetting on 28.7.2004. However, M/o Law took a long time for vetting the notification and officers from DGHS were deputed to discuss the matter with M/o Law. The file was finally vetted by M/o Law on 23.9.2004. Since it was a bulky notification, OL Wing directed this Ministry to have the notification translated in this Ministry, although translation of statutory notification is the duty of M/o Law. OL Wing. Thereafter, after translation of bulky notification, the file was sent to OL Wing for vetting of translation. Thereafter the file was submitted to competent authority for administrative approval for sending the notification GOI Press. Finally the notification was sent to GOI Press for publication. It is however assured that efforts will be made in future to adhere to the time frame fixed for finalization of notifications."

**1.5 The Committee regret to note that the Ministry of Health & Family Welfare (Department of Health) have taken as long as over 20 months to publish the final rules after publication of the draft Prevention of Food Adulteration (Amendment) Rules, 2005. The Ministry have stated that more time was taken in examination of the comments received on the draft rules which were bulky and technical in nature. It has further been stated that due to the same reasons, the Ministry of Law also took a long time in vetting the rules and also in getting the same translated in Hindi. A scrutiny of the chronology of events leading to the delay in final publication of the**



rules (Annexure) reveals that in the case of the Prevention of Food Adulteration (I Amendment) Rules, 2005, the final draft notification was put up for approval of the Directorate General of Health Services after being considered by the Expert Group in about 2 ½ months, in case of the Prevention of Food Adulteration (II Amendment) Rules, 2005, it took more than 9 months for similar action. Further, in the case of the 1<sup>st</sup> Amendment Rules, it took more than 6 months to get final approval leading to considerable delay in the processing of the final rules. Undue long time has also been taken by the Ministry of Law for vetting the notifications and also for translation into Hindi, which have added to the delay in publication of final rules in both the cases.

(Recommendation Sl.No.1)

1.6 The Committee on Subordinate Legislation have fixed a period of six months for publishing final rules, after taking into consideration all relevant aspects. The Committee feel that there is no reason why the Ministry of Health & Family Welfare (Department of Health) should take over 20 months for publishing the final rules. While deploring the delay, the Committee would expect the Ministry, as assured to take necessary steps to streamline their administrative machinery to adhere to the time frame of six months for publication of final rules so that the intended benefits of the rules are available to the public in time. Where it is not possible to adhere to the time limit of six months, the Committee should be approached for extension of time.

(Recommendation Sl.No.2)

# ANNEXURE

**(Please see para 1.6 of Report)**

## CHRONOLOGY OF EVENTS LEADING TO DELAY IN PUBLICATION OF FINAL RULES.

1. **The Prevention of Food Adulteration (Ist Amendment) Rules, 2005 (GSR 184-E of 2005)**

- |    |            |  |
|----|------------|--|
| 1. | 18.7.2003  | Draft notification published giving 60 days time for processing objections/suggestions from the public.                |
|    |            | [Large number of comments received which were bulky and technical in nature. Expert Group to examine them constituted] |
| 2. | 29.12.2003 | Expert Group considered the comments   |
| 3. | 9.3.2004   | Final notification put up for approval of DGHS   |
| 4. | 31.3.2004  | Final notification put up for approval of HFM  |
|    |            | [Hon'ble HFM directs that it should be resubmitted after 10 May, 2004, when new Hon'ble Minister assumes the charge]   |
| 5. | 18.10.2004 | Final (draft) notification submitted to new Minister for approval.   |
| 6. | 26.10.2004 | File sent to M/o Law for vetting   |
| 7. | 5.1.2005   | M/o Law approved the file  |
| 8. | 9.2.2005   | Hindi translation from OL Wing received  |
| 9. | 21.3.2005  | Final rules published  |

## **II. The Prevention of Food Adulteration (IIInd Amendment) Rules, 2005 (GSR 185-E of 2005)**

1. 16.6.2003 Draft notification published giving 60 days time for processing objections/suggestions from the public.
- [Large number of comments received which were bulky and technical in nature. Expert Group to examine them constituted]

2. 29.9.2003 Expert Group examined and considered the comments/suggestions
3. 19.11.2003 Minutes of the meeting of the Expert Group circulated to all its members.
4. 12.7.2004 Final draft notifications submitted for approval of Hon'ble HFM after several rounds of discussions, After getting it approval from DGHS (Directorate General of Health Services)
5. 28.7.2004 File sent to M/o Law for vetting
6. 23.9.2004 Law Ministry vetted the notifications
7. 21.3.2005 Final notifications published, Hindi translation was due.

## II. LACUNAE IN THE RECRUITMENT RULES OF ARCHAEOLOGICAL SURVEY OF INDIA.

[illegible]

The following recruitment rules of Archaeological Survey of India were published in the Gazette of India, Part-II, Section 3, Sub-section (i) dated 27 January, 2007:-

- (i) The Archaeological Survey of India, Director (Science), Superintending Archeological Chemist and Deputy Superintending Archeological Chemist, Group ‘A’ Posts Recruitment Rules, 2006 (GSR 16 of 2007).
- (ii) The Archaeological Survey of India, Assistant Superintending Archeological Chemist and Assistant Archeological Chemist, Group ‘B’ Gazetted and Non-gazetted posts Recruitment Rules, 2006 (GSR 17 of 2007)
- (iii) The Archaeological Survey of India, Assistant Superintending Archeological Epigraphists and Assistant Epigraphists (Sanskrit, Dravidian and Arabic and Persian Inscriptions) Group ‘B’ posts Recruitment Rules, 2006 (GSR 18 of 2007)
- (iv) The Archaeological Survey of India, Directors Epigraphy (Sanskrit and Dravidian and Arabic and Persian Inscriptions); Superintending Epigraphists and Deputy Superintending Epigraphists (Sanskrit, Dravidian and Arabic and Persian Inscriptions) Group ‘A’ posts Recruitment Rules, 2006 (GSR 19 of 2007)

On scrutiny of the above rules, it was observed that the year mentioned in the short title of the rules did not tally with year of their publication. Furthermore, in GSR 16 of 2007, in the Schedule to the Rules against the post of Deputy Superintending Archeological Chemist featured at Serial No. 3, the entries in Col. 8 (ii) pertaining to Educational and other Essential and Desirable Qualifications required for direct recruits appeared to be vague as the nature of organization from which the experience was to be considered had not been specified therein. The Ministry of Culture were, therefore, requested to furnish their comments in the matter.

2.2 In this context, the Ministry of Culture vide their replies dated 14<sup>th</sup> November and 26<sup>th</sup> December, 2007 informed the Committee that necessary corrigenda to rectify the errors in the short titles was sent to the Government of India Press for publication in the Gazette of India. Further, regarding the issue of non-specification of the nature of organization from where experience was to be considered for the post of Deputy Superintending Archeological Chemist, the Ministry stated that they would consider candidates having working experience in the field of conservation of cultural heritage as well as those who were directly associated with organisations dealing with analysis of geological/metal-alloys/polymers and similar fields of material science. It was further stated that the Ministry were of the view that organisations like National Research Laboratory for Conservation of Cultural Property, Lucknow; National & State Museums; National Test House; Geological Survey of India, CSIR laboratories were some of the organizations from where experience would be considered for appointment to the aforesaid post.

2.3 The Committee noted that even though the Ministry's reply explained the broad area from where experience would be considered for the particular post under reference, the reply was silent as to whether the said explanation would be incorporated in the rules. It was felt that non-specification in the rules about the nature of organization from where experience was to be gathered could render them prone to varied and wider interpretations by different officials which might result in giving undue advantage to some candidates while putting others at a disadvantage. The Ministry were, therefore, requested to state whether they had any objection in incorporating the above clarification in the rules to make them specific and unambiguous.

2.4 In their replies dated 29<sup>th</sup> February and 4<sup>th</sup> March, 2008, the Ministry of Culture forwarded corrigenda published vide Gazette Notification Nos. GSR 243 to GSR 246 dated 17 October, 2007 wherein the anomaly in the short-titles to the rules was rectified. However, regarding the vague entry in Col. 8 (ii) of

the Schedule to GSR 16 of 2007, the Ministry of Culture simply stated that requisite clarification in the matter have been tendered vide their earlier reply dated 26<sup>th</sup> December, 2007.

**2.5 The Committee have recommended time and again that the year mentioned in the short title of rules, regulations, bye-laws, etc. should tally with the year of publication. With the passage of time, as the number of such orders and subsequent amendments made thereto are increasing, the errors like incorrect year in the short title etc. result in difficulties in referencing and locating the orders. The Committee note that in the instant case, the short title of the four Recruitment Rules notified by the Archeological Survey of India vide GSR Nos. 16 to 19 dated 27<sup>th</sup> January, 2007 did not tally with their year of publication. On being pointed out by the Committee, the Ministry of Culture have promptly issued the desired amendments to rectify the errors in the short title so as to make it in conformity with the year of publication of the notification in the official gazette. The Committee expect the Ministry to be more vigilant in future so that such errors are not repeated.**

**(Recommendation Sl.No.3)**

**2.6 The Committee have recommended time and again that vague expressions should not be used in the rules and the terms and expressions should be clearly specified to avoid any scope for ambiguity and obviate the possibility of being interpreted differently by different officials/persons. Stipulations for experience requirements in the Column pertaining to Essential and Desirable Qualifications for Direct Recruits in Recruitment Rules, being important provisions, have a significant bearing on the fate of the candidates seeking appointment to the post. The Committee, therefore, desire that such provisions should be precise, specific and free from any ambiguity.**

**(Recommendation Sl.No. 4)**

**2.7 The Committee note that the entry under essential qualification for direct recruitment to the post of Deputy Superintending Archaeological Chemist includes ‘three years’ experience in the analysis and application of alloys, silicates, insecticides, fumigants and plastics’ and under the desirable qualification, the entry is ‘One year experience in application of chemistry to Antiques and conservation’. The Committee observe that the entries appeared to be susceptible to the risk of being interpreted variedly by different persons as the nature and type of organization from where experience is to be considered has not been specified. On being pointed out, the Ministry of Culture clarified that they would consider candidates having working experience in the field of conservation of cultural heritage as well as those who are directly associated with organisations dealing with analysis of geological/metal-alloys/polymers and similar field of material science and such experience would be considered from some of the organisations like National Research Laboratory for Conservation of Cultural property, Lucknow; National & State Museums; National Test House; Geological Survey of India, CSIR laboratories, etc.. The Committee desire the Ministry to incorporate the above clarification suitably in the rules itself in order to make the entries more precise and specific, thereby obviating any scope for ambiguity in the recruitment rules.**

**(Recommendation Sl.No.5)**

**III. THE MINISTRY OF AGRICULTURE, DEPARTMENT OF ANIMAL HUSBANDRY, DAIRYING AND FISHERIES, CENTRAL INSTITUTE OF COASTAL ENGINEERING FOR FISHERY JUNIOR ENGINEER RECRUITMENT RULES, 2007 (GSR 37 OF 2007)**

The Ministry of Agriculture, Department of Animal Husbandry, Dairying and Fisheries, Central Institute of Coastal Engineering for Fishery Junior Engineer Recruitment Rules, 2007 (GSR 37 of 2007) were published in Gazette of India, Part-II, Section 3, Sub-section (i) dated 10.3.2007. While scrutinizing these rules, it was observed that under Col. 8 of the Schedule to the rules pertaining to Educational and other qualifications required for direct recruits, the entry reads as:-

- “(i) Diploma in Civil Engineering from recognized board or Institute or equivalent.*
- (ii) Two years experience in survey and design.*

**Note 1:** *Qualifications are relaxable at the discretion of the Staff Selection Commission in case of candidates otherwise well qualified.*

**Note 2:** *The qualification (s) regarding experience is/are relaxable at the discretion of the Staff Selection Commission in the case of candidates belonging to Scheduled Castes/Scheduled Tribes, if at any stage of selection the staff Selection Commission is of the opinion that sufficient number of candidates from these communities possessing the requisite experience are not likely to be available to fill up the vacancy reserved for them.”.*

The Committee found that the prescription of “ Two years experience in survey and designs” in Col. 8(ii) appeared to be vague as it was not specific about the nature and type of organization from where the experience was to be obtained.

3.2 On being pointed out, the Ministry of Agriculture, Department of Animal Husbandry, Dairying and Fisheries vide their reply dated 1 February, 2008 had stated that



they had taken up the matter with the Ministry of Law and Justice to carry out necessary amendment by substituting the entry in Col 8 (ii) by the following:

*“Two years experience in any organization in conduct of topographic survey and designs of building structures.”*

**3.3 The Committee note that the entry under Col. 8 of the Ministry of Agriculture, Department of Animal Husbandry, Dairying and Fisheries, Central Institute of Coastal Engineering for Fishery Junior Engineer Recruitment Rules, 2007 (GSR 37 of 2007) prescribing experience required for direct recruits had not specified the nature and type of organization from where such experience was to be considered. The Committee observe that such unspecific and vague entry, that too pertaining to experience required for direct recruits leaves open scope for arbitrary use of discretionary powers which may result in the misuse of the delegated legislation. On being pointed out by the Committee, the Ministry have initiated the process of rectifying the lacuna in consultation with the Ministry of Law and Justice. The Committee, therefore, stress upon the Ministry to carry out the desired amendments in the Recruitment Rules at the earliest. The Committee would like to be apprised of the progress made in this regard within three months of the presentation of the Report.**

**(Recommendation SL.No.6)**

**IV. INFIRMITIES IN (I) THE DRUGS AND COSMETICS (IST AMENDMENT) RULES, 2005; AND (II) THE DRUGS AND COSMETICS (IIND AMENDMENT) RULES, 2005**

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The Drugs and Cosmetics (Ist Amendment) Rules, 2005 (GSR 35-E of 2005); and the Drugs and Cosmetics (IInd Amendment) Rules, 2005 (GSR 32-E of 2005) were published in the Gazette of India, Extraordinary, Part-II, Section 3(i), dated 20 January, 2005. On scrutiny of the above Rules, it was *inter-alia* observed that (i) the rules were not laid on the Table of the House within the stipulated time; (ii) there was delay in publishing the final rules after its publication in the draft form; and (iii) GSR 35-E was published as the Ist Amendment and GSR 32-E as the IInd Amendment to the rules which was observed to be chronologically incorrect. To avoid confusion and for easy referencing GSR numbers have to be allotted in sequence.

4.2 The above infirmities were referred to the Ministry of Health and Family Welfare for their comments in the matter.

4.3 As regards the delay in laying the rules on the Table of the House, the Ministry vide their replies dated 4<sup>th</sup> and 25<sup>th</sup> July, 2005 stated that:-

*“The aforesaid rules were sent on 24.4.05 for laying in Lok Sabha/Rajya Sabha. The Rajya Sabha Secretariat laid it in the House on 29.4.05. Lok Sabha Secretariat did not accept and informed orally that the required number of copies of notifications was not sent. All 41 copies of notifications were sent to Rajya Sabha Secretariat. Due to lack of time, the same could not be sent to Lok Sabha Secretariat. Now all necessary arrangement has been made to lay on the Table of Lok Sabha in the forthcoming monsoon session”.*

4.4 The Ministry subsequently laid the rules in Lok Sabha on 27 July, 2005.

4.5 As regards the delay in publishing the final rules after its publication in the draft form, the Ministry in their replies dated 4<sup>th</sup> and 25<sup>th</sup> July, 2005 have contended that since the subject matter of the rules were of vital importance in the field of clinical research, a large number of comments were received after its publication in the draft form, which were technical in nature, which entailed a constitution of an Expert Committee to examine them. Moreover, since the rules were voluminous and technical in nature, much time was taken at each stage i.e. intradepartmental deliberations, getting approval of the Hon'ble Minister of Health and Family Welfare, vetting of the Notifications by the Ministry of Law and for getting it translated into Hindi version. The chronology of events responsible for the delays as stated by the Ministry is given in Annexure .

4.6 As regards, the discrepancy in the numbering of amendments made to the Drugs and Cosmetics Rules, 2005 which was not done in a chronological manner, the Ministry vide their reply dated 14 October, 2005 clarified the position as under :-

“The said notifications were sent to Govt. of India Press for publication on 20.1.2005. The Govt. of India Press provides GSR Numbers to the notifications sent to them. Hence, this Ministry have no role in providing GSR Nos. chronologically. This mistake occurred due to the fact that the two notifications were sent to Govt. of India Press on the same day for publication. In view of above position, the following corrigendum is being issued for publication – 1<sup>st</sup> Amendment of Drugs & Cosmetics Rules 2005 bearing GSR No. 35 (E) may be read as 2<sup>nd</sup> Amendment of Drugs & Cosmetics Rules, 2005 and vice-versa.”

**4.7 The Committee note that on scrutiny of the Drugs and Cosmetics (1st Amendment) Rules, 2005 and the Drugs and Cosmetics (IInd Amendment ) Rules, 2005 of the Ministry of Health and Family Welfare, it was *inter-alia* observed that there were inordinate delays in laying the rules in Lok Sabha and also delays in publication of the final rules after they were brought out in the draft form.**

Moreover, it was observed that the numbering of the Ist and IInd amendments to the rules which were given GSR Nos. 35E and 32E respectively, was not done in a chronological manner. On being pointed out, the Ministry stated that a corrigendum was being issued for correcting the discrepancy in numbering the amendments, which had taken place at the Govt. of India Press when the two notifications were sent for publication on the same day. The Committee desire that in such cases priority should have been accorded to GSR No. 32E.

(Recommendation Sl.No. 7)

4.8 As regards, delay in laying the rules in Lok Sabha, Ministry's contention is that the rules were sent for laying in both the Houses of Parliament which were laid in Rajya Sabha on 29<sup>th</sup> April, 2005 but could not be laid in Lok Sabha as the number of copies of the notification were not enough as informed by Lok Sabha Secretariat and later on due to paucity of time, it could not be sent to the Secretariat for laying. Subsequently, the rules were laid in Lok Sabha on 27<sup>th</sup> July, 2005 entailing a delay of about 5 ½ months after the stipulated time of 15 days. The Committee observe that since the Budget Session ended on 13<sup>th</sup> May, 2005, the Ministry's contention of paucity of time is hardly convincing as they had about two weeks time at their disposal to send the requisite number of copies. It appears that the Ministry did not put in sincere efforts to send the same expeditiously. Had the Ministry taken due caution in advance to ensure that the required number of copies of the notification were sent to the Lok Sabha and Rajya Sabha Secretariats for laying in both the Houses of Parliament, the situation could have been easily avoided.

(Recommendation Sl.No.8)

4.9 As regards, the delay in publishing the final rules after bringing out the same in its draft form, the Committee find that the Ministry's plea that since the rules were voluminous, technical and on an important subject matter, considerable time was taken at each stage i.e. for intra-departmental deliberations, for getting approval of the Hon. Minister of Health and Family Welfare, for vetting the notification by the Law Ministry and for getting them translated into Hindi version is not convincing at all. The Committee on Subordinate Legislation, having foreseen such eventualities had stipulated an extended time of upto six months for publication of the final rules after their publication in the draft form in such cases. However, in the instant case, the Committee find that the undue long delay which has taken place in each stage of processing of the notifications reveals that the Ministry have not taken a serious note of the Committee's earlier recommendations in this regard and have dealt with the matter in a casual and complacent manner. A close observation of the chronology of the events reveals that there was a delay of about 11 months after the stipulated time of 6 months in publishing the final rules after their publication in the draft form in the case of the Drugs and Cosmetics (IInd Amendment) Rules, 2005 whereas a delay of about 1 year and 9 months has taken place in the case of the Drugs and Cosmetics (Ist Amendment) Rules, 2005. The Committee are unhappy to note that the Ministry did not pursue the matter with the urgency it required and also did not adhere to the recommendation of the Committee that delays in final publication of rules could be eliminated by having interdepartmental meetings of the concerned Ministry/Department rather than resorting to routine correspondence in a complacent manner. For example, the

**Ministry of Law took an unreasonably long time of 9 months for vetting the Drugs and Cosmetics (1st Amendment) Rules, 2005. The Committee, therefore, desire the Ministry to make sincere efforts and take extra precautions in advance in such cases so that delays in laying the notifications are avoided in future. The Committee also recommend that the Ministry should formulate an internal procedure to process voluminous, technical and important notifications through proper coordination with concerned Ministries/Departments so that undue delay in final publication of rules can be eliminated. The Committee may be apprised of the action taken in this regard at the earliest.**

**(Recommendation Sl.No.9)**

## CHRONOLOGY OF EVENTS RESPONSIBLE FOR DELAY IN LAYING THE RULES AND IN PUBLISHING THE FINAL RULES

1. 28.8.2003 Draft Rules were published specifying 45 days for obtaining comments from the public.
2. 3.2.2004 Expert Committee which was constituted to  
23.2.2004 examine the comments received (209 in number, 24.2.2004 which  
were technical) deliberated upon them in  
their meetings held on these dates.
3. 5.3.2004 Draft of the finalized notification forwarded to the Ministry of Health.
4. Mid April, Secretary (Health) reviewed the notification &  
2004 thereafter, put up to Hon'ble Minister for Health & Family Welfare for approval
5. 17.6.2004 Hon'ble Minister for Health & Family Welfare approved the amendment.

6. 12.7.2004 Notification sent to Ministry of Law for vetting
7. 2.9.2004 Received from the Ministry of Law after vetting  
(Notification bulky – 75 typed pages and technical)
8. 27.12.2004 Hindi version received after being sent to OL Wing  
for Hindi version of the vetted notification
9. 20.1.2005 Notification published in the Gazette of India

Delay of about 11 months over and above the stipulated time of 6 months as prescribed by the Committee on Subordinate Legislation.

**(ii) Drugs and Cosmetics (1st Amendment) Rules, 2005 (GSR 35-E of 2005)**

1. 29.10.2002 Draft rules published for comments
2. 10.4.2003 After examination of the comments received, the matter  
was placed before Drug Technical Advisory Board  
(DTAB) as the draft rules were published without  
consultation of DTAB.
3. 28.7.2003 Revised draft along with recommendations of  
DTAB received in the Ministry
4. 27.12.2003 Notification was approved by the Hon'ble Minister  
of Health & Family Welfare
5. 8.1.2004 Draft notification sent to the Legislative  
Department of the Ministry of Law for vetting
6. 14.10.2004 Final vetted copy of notification received in the  
Ministry
7. 10.1.2005 Hindi version of the vetted notification received  
from the OL Wing
8. 20.1.2005 Notification published in the Gazette of India

Delay of about 1 year & 9 months over and above the stipulated time of 6 months as prescribed by the Committee on Subordinate Legislation.



**V. DELAY IN PUBLICATION AND OTHER LACUNA IN THE DRUGS AND COSMETICS (6<sup>TH</sup> AMENDMENT) RULES, 2005.**

The Drugs and Cosmetics (6<sup>th</sup> Amendment) Rules, 2005 (GSR 733-E of 2005) were published in the Gazette of India, Extraordinary, Part-II, Section 3(i) dated 21 December, 2005. The scrutiny of the above Rules revealed that :-

- (i) The draft of the Drugs & Cosmetics (6<sup>th</sup> Amendment) Rules were published on 13 December, 2004 whereas the final rules were published on 21 December, 2005 after a gap of 11 months; and
- (ii) In rule 2(ii), it was not clear from the 'Explanation' to be inserted as to which amendment of the Drugs & Cosmetics Rules, 2005 was being referred to for the purpose of determining the renewal of license.

5.2 The concerned Ministry of Health and Family Welfare (Department of Health) were requested to furnish their comments on the above points. The Ministry were also requested to furnish the number and nature of objections/suggestions received on the draft rules and also to state the reasons for such a delay in the notification of the final rules. In this connection, the attention of the Ministry was also invited to the oft-repeated recommendation of the Committee on Subordinate Legislation that in cases where no objection/suggestion on the draft rules were forthcoming, the final rules should be published within a period of 3 months and in cases where as large number of objections/suggestions were received, the gap should not be more than 6 months.

5.3 In this connection, the Ministry vide their reply, dated 13 November, 2006, stated as under:-

“HFM Office has taken a time of six months to discuss and sort out the issues relating to finalisation of the notification. The rest of the time has been taken to process the public comments and the completion of interdepartmental procedures. The GSR 733 (E) may kindly be read alongwith the corrigendum issued vide GSR No 65 (E), dated 13.2.06 (copy enclosed) stating that the words”(\_\_\_\_ Amendment)” may be read as “(6<sup>th</sup> Amendment)”

5.4 On scrutiny of the aforesaid reply, the Committee noticed that with regard to the first point, the Ministry simply clarified that the reasons for delay in publication of the final rules occurred since the Hon’ble Minister of the Health & Family Welfare took 6 months time to discuss and finalise the notification and the rest of the time was taken to process the public comments. However, the Ministry did not furnish the number and nature of comments received on the draft notification and also did not indicate its stand on each of the objections/ suggestions received. The Ministry was subsequently asked to furnish the same. As regards the second point pertaining to the lacuna in Rule 2 (ii), the Ministry took out the requisite corrigendum vide G.S.R. No. 65 (E) dated 13.2.2006 stating that the words ( \_\_\_\_ Amendment) may be read as “6<sup>th</sup> Amendment”.

5.5 The Ministry vide their subsequent reply dated 5<sup>th</sup> January, 2007 apprised the Committee as under:-

“The comments on the draft rules were received from the Drugs Control Department, Delhi and Joint Drugs Controller, CDSCO, North Zone, Ghaziabad. The Drugs Controller Department, Delhi agreed to the deletion of the explanation under rule 122F as proposed in the draft rules. They have, however, suggested that the definition of Blood Bank under rule 122 (EA) may be amended. As per the opinion of the Ministry, the draft rules did not envisage amendment of rule 122 (EA), the proposal for its amendment could not be taken up under the finalisation of the notification. Moreover, proposal was for specifying the donor in the definition of Blood Bank whereas donor is already defined in the same rule separately. It was, therefore, not considered necessary to amend the definition of Blood Bank under rule 122 (EA). In regard to amendment of rule 122G, the proposal was for addition of the word ‘Government’ as one of the categories so that the State or Central Government is permitted to open a Blood Bank, if required. It was also suggested that the proviso to the rule should also be

amended to make the provision more explicit. The Joint Drugs Controller (India), CDSCO, North Zone, Ghaziabad in their comments had also pointed out that the word 'Government' may be included in rule 122 G while the proviso may be suitably worded to remove the ambiguity about the interpretation that existing Blood Banks do not require to renew their licenses further. The Ministry accepted the suggestion to include the word 'Government' under rule 122G and reword the entry under sub-rule (ii) of rule 2 of the draft rules making rule 122G as sub-rule (1) and adding sub-rule (2) in place of clause (vi). In place of proviso, an explanation was added to define the word 'renewal' for the purpose of this sub-rule to make it explicit".

**5.6 The Committee note that Drugs and Cosmetics (6<sup>th</sup> Amendment) Rules were notified after a gap of 11 months from its publication in the draft form in deviation to the recommendation of the Committee on Subordinate Legislation that in cases where no objections/ suggestions on the draft rules were forthcoming, the final rules should be published within a period of three months and in case where a large number of objections/ suggestions were received, the gap should not be more than 6 months. The Committee also find that the explanation sought to be inserted by Rule 2(ii) did not indicate as to which amendment of the rules was being referred to. The Committee however note with satisfaction that on being pointed out, the Ministry of Health & Family Welfare (Department of Health) issued the necessary corrigendum vide Gazette of India Notification dated 13<sup>th</sup> February, 2006 (G.S.R. No. 65-E) to rectify the lacunae in Rule 2(ii) by inserting the word "6<sup>th</sup>" to indicate precisely that the Rules referred to is the 6<sup>th</sup> Amendment Rule. As regards delay in publication of final Rules, the Committee are surprised to note that the Ministry received only two comments on the draft rules for which the Ministry took an unduly longer time of 11 months to publish the final rules after its notification in the draft form. The Committee do not find the reasons furnished by the Ministry justifiable as only two comments were received on the draft rules. The Committee,**

therefore, expect the Ministry to take due care in future and strictly adhere to the time limit stipulated by the Committee on Subordinate Legislation in this regard

(Recommendation Sl.No.10)

NEW DELHI;  
20 OCTOBER, 2008  
27 ASVINA, 1930 (SAKA)

N.N. KRISHNADAS,  
*CHAIRMAN,*  
*COMMITTEE ON SUBORDINATE LEGISLATION*

## APPENDIX –I

(Vide Para 4 of the Introduction to the Report)

### STATEMENT OF RECOMMENDATIONS MADE IN THE NINETEENTH REPORT OF THE COMMITTEE ON SUBORDINATE LEGISLATION

(FOURTEENTH LOK SABHA)

Sl. No.	Reference to Para No. in the Report	<u>Recommendations/observations</u>
1	2	3
1.	1.5	<p><b>Inordinate delay in publication of the Prevention of Food Adulteration (Amendment) Rules, 2005 (GSR 184-E of 2005 and GSR 185-E of 2005)</b></p> <p>The Committee regret to note that the Ministry of Health &amp; Family Welfare (Department of Health) have taken as long as over 20 months to publish the final rules after publication of the draft Prevention of Food Adulteration (Amendment) Rules, 2005. The Ministry have stated that more time was taken in examination of the comments received on the draft rules which were bulky and technical in nature. It has further been stated that due to the same reasons, the Ministry of Law also took a long time in vetting the rules and also in getting the same translated in Hindi. A scrutiny of the chronology of events leading to the delay in final publication of the rules (Annexure) reveals that in the case of the Prevention of Food Adulteration (I Amendment) Rules, 2005, the final draft notification was put up for approval of the Directorate General of Health Services after being considered by the Expert Group in about 2 ½ months, in case of the Prevention of Food Adulteration (II Amendment) Rules, 2005, it took more than 9 months for similar action. Further, in the case of the 1<sup>st</sup> Amendment Rules, it took more than 6 months to get final approval leading to considerable delay in the processing of the final rules. Undue long time has also been taken by the Ministry of Law for vetting the notifications and also for translation into Hindi, which have added to the delay in publication of final rules in both the cases.</p>
	1.6	<p>The Committee on Subordinate Legislation have fixed a period of six months for publishing final rules, after taking into consideration all relevant aspects. The Committee feel that there is no reason why the Ministry of Health &amp; Family Welfare (Department of Health) should</p>

		take over 20 months for publishing the final rules. While deploring the delay, the Committee would expect the Ministry, as assured to take necessary steps to streamline their administrative machinery to adhere to the time frame of six months for publication of final rules so that the intended benefits of the rules are available to the public in time. Where it is not possible to adhere to the time limit of six months, the Committee should be approached for extension of time.
2.	<p>2.5</p> <p>2.6</p> <p>2.7</p>	<p><b>Lacunae in the recruitment rules of archaeological survey of India.</b></p> <p>The Committee have recommended time and again that the year mentioned in the short title of rules, regulations, bye-laws, etc. should tally with the year of publication. With the passage of time, as the number of such orders and subsequent amendments made thereto are increasing, the errors like incorrect year in the short title etc. result in difficulties in referencing and locating the orders. The Committee note that in the instant case, the short title of the four Recruitment Rules notified by the Archeological Survey of India <u>vide</u> GSR Nos. 16 to 19 dated 27<sup>th</sup> January, 2007 did not tally with their year of publication. On being pointed out by the Committee, the Ministry of Culture have promptly issued the desired amendments to rectify the errors in the short title so as to make it in conformity with the year of publication of the notification in the official gazette. The Committee expect the Ministry to be more vigilant in future so that such errors are not repeated.</p> <p>The Committee have recommended time and again that vague expressions should not be used in the rules and the terms and expressions should be clearly specified to avoid any scope for ambiguity and obviate the possibility of being interpreted differently by different officials/persons. Stipulations for experience requirements in the Column pertaining to Essential and Desirable Qualifications for Direct Recruits in Recruitment Rules, being important provisions, have a significant bearing on the fate of the candidates seeking appointment to the post. The Committee, therefore, desire that such provisions should be precise, specific and free from any ambiguity.</p> <p>The Committee note that the entry under essential qualification for direct recruitment to the post of Deputy Superintending Archaeological Chemist includes ‘three years’ experience in the analysis and application of alloys, silicates, insecticides, fumigants and plastics’ and under the desirable qualification, the entry is ‘One year experience in application of chemistry to Antiques and conservation’. The Committee observe that the entries appeared to be</p>

3.	3.3	<p>susceptible to the risk of being interpreted variedly by different persons as the nature and type of organization from where experience is to be considered has not been specified. On being pointed out, the Ministry of Culture clarified that they would consider candidates having working experience in the field of conservation of cultural heritage as well as those who are directly associated with organisations dealing with analysis of geological/metal-alloys/polymers and similar field of material science and such experience would be considered from some of the organisations like National Research Laboratory for Conservation of Cultural property, Lucknow; National &amp; State Museums; National Test House; Geological Survey of India, CSIR laboratories, etc.. The Committee desire the Ministry to incorporate the above clarification suitably in the rules itself in order to make the entries more precise and specific, thereby obviating any scope for ambiguity in the recruitment rules.</p> <p><b>The Ministry of Agriculture, Department of Animal Husbandry, Dairying and Fisheries, Central Institute of Coastal Engineering for Fishery Junior Engineer Recruitment Rules, 2007 (GSR 37 of 2007)</b></p> <p>The Committee note that the entry under Col. 8 of the Ministry of Agriculture, Department of Animal Husbandry, Dairying and Fisheries, Central Institute of Coastal Engineering for Fishery Junior Engineer Recruitment Rules, 2007 (GSR 37 of 2007) prescribing experience required for direct recruits had not specified the nature and type of organization from where such experience was to be considered. The Committee observe that such unspecific and vague entry, that too pertaining to experience required for direct recruits leaves open scope for arbitrary use of discretionary powers which may result in the misuse of the delegated legislation. On being pointed out by the Committee, the Ministry have initiated the process of rectifying the lacuna in consultation with the Ministry of Law and Justice. The Committee, therefore, stress upon the Ministry to carry out the desired amendments in the Recruitment Rules at the earliest. The Committee would like to be apprised of the progress made in this regard within three months of the presentation of the Report.</p>
4.	4.7	<p><b>Infirmities in (i) The Drugs and Cosmetics (Ist Amendment) Rules, 2005; and (ii) The Drugs and Cosmetics (IInd Amendment) Rules, 2005</b></p> <p>The Committee note that on scrutiny of the Drugs and Cosmetics (Ist Amendment) Rules, 2005 and the Drugs and Cosmetics (IInd</p>

		<p>Amendment ) Rules, 2005 of the Ministry of Health and Family Welfare, it was <i>inter-alia</i> observed that there were inordinate delays in laying the rules in Lok Sabha and also delays in publication of the final rules after they were brought out in the draft form. Moreover, it was observed that the numbering of the Ist and IInd amendments to the rules which were given GSR Nos. 35E and 32E respectively, was not done in a chronological manner. On being pointed out, the Ministry stated that a corrigendum was being issued for correcting the discrepancy in numbering the amendments, which had taken place at the Govt. of India Press when the two notifications were sent for publication on the same day. The Committee desire that in such cases priority should have been accorded to GSR No. 32E.</p>
	4.8	<p>As regards, delay in laying the rules in Lok Sabha, Ministry's contention is that the rules were sent for laying in both the Houses of Parliament which were laid in Rajya Sabha on 29<sup>th</sup> April, 2005 but could not be laid in Lok Sabha as the number of copies of the notification were not enough as informed by Lok Sabha Secretariat and later on due to paucity of time, it could not be sent to the Secretariat for laying. Subsequently, the rules were laid in Lok Sabha on 27<sup>th</sup> July, 2005 entailing a delay of about 5 ½ months after the stipulated time of 15 days. The Committee observe that since the Budget Session ended on 13<sup>th</sup> May, 2005, the Ministry's contention of paucity of time is hardly convincing as they had about two weeks time at their disposal to send the requisite number of copies. It appears that the Ministry did not put in sincere efforts to send the same expeditiously. Had the Ministry taken due caution in advance to ensure that the required number of copies of the notification were sent to the Lok Sabha and Rajya Sabha Secretariats for laying in both the Houses of Parliament, the situation could have been easily avoided.</p>
	4.9	<p>As regards, the delay in publishing the final rules after bringing out the same in its draft form, the Committee find that the Ministry's plea that since the rules were voluminous, technical and on an important subject matter, considerable time was taken at each stage i.e. for intra-departmental deliberations, for getting approval of the Hon. Minister of Health and Family Welfare, for vetting the notification by the Law Ministry and for getting them translated into Hindi version is not convincing at all. The Committee on Subordinate Legislation, having foreseen such eventualities had stipulated an extended time of upto six months for publication of the final rules after their publication in the draft form in such cases. However, in the instant case, the Committee find that the undue long delay which has taken place in each stage of processing of the notifications reveals that the Ministry have not taken</p>



5	5.6	<p>a serious note of the Committee's earlier recommendations in this regard and have dealt with the matter in a casual and complacent manner. A close observation of the chronology of the events reveals that there was a delay of about 11 months after the stipulated time of 6 months in publishing the final rules after their publication in the draft form in the case of the Drugs and Cosmetics (IInd Amendment) Rules, 2005 whereas a delay of about 1 year and 9 months has taken place in the case of the Drugs and Cosmetics (Ist Amendment) Rules, 2005. The Committee are unhappy to note that the Ministry did not pursue the matter with the urgency it required and also did not adhere to the recommendation of the Committee that delays in final publication of rules could be eliminated by having interdepartmental meetings of the concerned Ministry/Department rather than resorting to routine correspondence in a complacent manner. For example, the Ministry of Law took an unreasonably long time of 9 months for vetting the Drugs and Cosmetics (Ist Amendment) Rules, 2005. The Committee, therefore, desire the Ministry to make sincere efforts and take extra precautions in advance in such cases so that delays in laying the notifications are avoided in future. The Committee also recommend that the Ministry should formulate an internal procedure to process voluminous, technical and important notifications through proper coordination with concerned Ministries/Departments so that undue delay in final publication of rules can be eliminated. The Committee may be apprised of the action taken in this regard at the earliest.</p> <p><b>Delay in publication and other lacuna in the Drugs and Cosmetics (6<sup>th</sup> Amendment) Rules, 2005.</b></p> <p>The Committee note that Drugs and Cosmetics (6<sup>th</sup> Amendment) Rules were notified after a gap of 11 months from its publication in the draft form in deviation to the recommendation of the Committee on Subordinate Legislation that in cases where no objections/suggestions on the draft rules were forthcoming, the final rules should be published within a period of three months and in case where a large number of objections/ suggestions were received, the gap should not be more than 6 months. The Committee also find that the explanation sought to be inserted by Rule 2(ii) did not indicate as to which amendment of the rules was being referred to. The Committee however note with satisfaction that on being pointed out, the Ministry of Health &amp; Family Welfare (Department of Health) issued the necessary corrigendum <u>vide</u> Gazette of India Notification dated 13<sup>th</sup> February, 2006 (G.S.R. No. 65-E) to rectify the lacunae in Rule 2(ii) by inserting the word "6<sup>th</sup>" to indicate precisely that the Rules referred to is the 6<sup>th</sup> Amendment Rule. As regards delay in publication of final Rules, the Committee are surprised to note that the Ministry received only two comments on the draft rules for which the Ministry took an</p>
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		<p>unduly longer time of 11 months to publish the final rules after its notification in the draft form. The Committee do not find the reasons furnished by the Ministry justifiable as only two comments were received on the draft rules. The Committee, therefore, expect the Ministry to take due care in future and strictly adhere to the time limit stipulated by the Committee on Subordinate Legislation in this regard</p>
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**APPENDIX II**  
**(Vide Para 5 of the Introduction to the Report)**

**MINUTES OF NINTH SITTING OF THE COMMITTEE ON SUBORDINATE  
LEGISLATION (2007-2008)**

The Committee met on Monday, 4<sup>th</sup> August, 2008 from 16.00 to 16.45 hours in Committee Room 'E', Parliament House Annexe, New Delhi.

**PRESENT**

**Shri N.N. Krishnadas - Chairman**

**MEMBERS**

2. Shri Anandrao Vithoba Adsul
3. Shri Giridhar Gamang
4. Shri N. Y. Hanumanthappa
5. Shri Faggan Singh Kulaste
6. Shri Jaysingrao Gaikwad Patil
7. Shri Bhupendrasinh Solanki
8. Shri Ramjilal Suman

**SECRETARIAT**

1. Shri Brahm Dutt - Joint Secretary
2. Shri R.K. Bajaj - Director
3. Shri R. D. Silawat - Deputy Secretary-II

2. At the outset, the Chairman welcomed the members to the sitting of the Committee.
3. Thereafter, the Committee took up for consideration the following memoranda:
  1. **Memoranda No. 55** relating to inordinate delay in publication of the Prevention of Food Adulteration (Amendment) Rules, 2005.
  2. **Memoranda No. 56** relating to lacunae in the recruitment rules of Archaeological Survey of India.
  3. **Memoranda No. 57** relating to the Ministry of Agriculture, Department of Animal Husbandry, Dairying and Fisheries, Central Institute of Coastal Engineering for Fishery Junior Engineer Recruitment Rules, 2007.
  4. **Memoranda No. 58** relating to infirmities in (i) the Drugs and Cosmetics (1<sup>st</sup> Amendment) Rules, 2005; and (ii) the Drugs and Cosmetics (2<sup>nd</sup> Amendment) Rules, 2005.
  5. **Memoranda No. 59** relating to delay in publication and other lacuna in the Drugs and Cosmetics (6<sup>th</sup> Amendment) Rules, 2005.
4. After deliberations, the Committee decided to incorporate the points raised in the aforesaid memoranda in their Report to be presented to the House.

The Committee then adjourned.

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## APPENDIX III

(Vide Para 5 of the Introduction to the Report)

**EXTRACTS FROM THE MINUTES OF THE SECOND SITTING OF THE  
COMMITTEE ON SUBORDINATE LEGISLATION (2008-2009)**

The Committee met on Wednesday, 17<sup>th</sup> September, 2008 from 1500 hours to 1545 hours in Committee Room No. 53, Parliament House, New Delhi.

**PRESENT**

**Shri N.N. Krishnadas**

—

**Chairman**

## MEMBERS

2. Shri Anandrao Vithoba Adsul
3. Shri L. Ganesan
4. Shri Ram Singh Kaswan
5. Shri Jaisingrao Gaikwad Patil
6. Shri Lal Mani Prasad
7. Shri Ramji Lal Suman
8. Shri Madhu Goud Yaskhi

**SECRETARIAT**

- |                        |   |                     |
|------------------------|---|---------------------|
| 1. Shri A.K. Singh     | - | Joint Secretary     |
| 2. Shri R.K. Bajaj     | - | Director            |
| 3. Shri Raj Kumar      | - | Deputy Secretary-I  |
| 4. Shri R.D.Silawat    | - | Deputy Secretary-II |
| 5. Shri R.K. Bhatnagar | - | Under Secretary     |

2. At the outset, the Chairman welcomed the members to the sitting of the Committee.

3 The Committee then took up for consideration the draft 21st Report and adopted the same without any modifications/corrections. The Committee also authorized the Chairman to present the same to the House.

4	xx	xx	x x	xx
5	xx	xx	xx	xx

The Committee then adjourned.

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X Omitted portion of the Minutes are not relevant to this Report.

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